DIVISION OF NARCOTIC
AND DRUG ABUSE CONTROL
New Jersey State
Department of Health
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CONTROLLED DANGEROUS SUBSTANCE REGULATIONS

New Jersey Administrative Code
(Title 8 — Chapter 65 — Subchapter 1 through 9)

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SUBCHAPTER 1.
GENERAL PROVISIONS, REGISTRATION

8:65-1.1 Registration fees

(a) Manufacturers of controlled dangerous substances shall pay an annual fee of $100.00 at the time of application for registration or for renewal of registration.

(b) Distributors of controlled dangerous substances shall pay an annual fee of $50.00 at the time of application for registration or for renewal of registration.

(c) Dispensers of controlled dangerous substances or practitioners registered to conduct research with controlled dangerous substances shall pay an annual fee of $10.00 at the time of application for registration or for renewal of registration.

(d) A separate fee shall be paid for each separate place of business or professional practice for which registration is required.

(e) The following persons shall be exempt from payment of a fee for registration or renewal of registration:

1. Any hospital, clinic, institution, or other facility operated by any department of the State of New Jersey;
2. Any other agency, excluding individual State employees, for which the State of New Jersey would be responsible for payment of the fee, provided that such exemption is approved by the Commissioner;
3. Hospitals and other facilities operated by any department of the United States of America.

(f) Exemption from payment of a fee for registration or renewal of registration does not relieve the person of the requirement to obtain a registration or of any other requirements or duties prescribed by law.

8:65-1.2 Registration requirements

(a) Every person who manufactures or proposes to manufacture a controlled dangerous substance or substances, unless specifically exempted by Statute or specifically waived by the Commission of Health, shall obtain a registration within 30 days of the adoption of these regulations, and shall obtain a renewal of the registration on or before July 1 of every year thereafter.

(b) Every person who distributes or proposes to distribute a controlled dangerous substance or substances, unless specifically exempted by Statute or specifically waived by the Commissioner of Health, shall obtain a registration within 30 days of the adoption of these regulations, and shall obtain a renewal of the registration on or before July 1 of every year thereafter.

(c) Every person who dispenses (including prescribing, administering, compounding, or delivering), or proposes to dispense a controlled dangerous substance or substances, unless specifically exempted by Statute or specifically waived by the Commissioner of Health, shall obtain a registration within 30 days of the adoption of these regulations, and shall obtain a renewal of the registration on or before July 1 of every year thereafter.

(d) Every person who conducts research or proposes to conduct research with a controlled dangerous substance or substances, unless specifically exempted by Statute or specifically waived by the Commissioner of Health, shall obtain a registration within 30 days of the adoption of these regulations, and shall obtain a renewal of the registration on or before July 1 of every year thereafter.

(e) A person desiring to obtain a registration or a renewal of registration as provided in Sections (a) through (d) above shall prepare and file an application in accordance with the procedure set forth in Section 4 of this Chapter, accompanied by the annual registration fee as set forth in Section 1 of this Chapter.

(f) A separate application shall be made and a separate registration obtained for each place of business or professional practice, where the applicant manufactures, distributes, or dispenses controlled dangerous substances. A separate application shall be made and a separate registration obtained for each separate and distinct business entity, affiliated corporation, or subsidiary corporation that engages in such activities, but a single entity doing business at one location under more than one business name or trade name may obtain a single registration provided that all such business names or trade names are stated in the application.

8:65-1.3 Activities requiring registration

(a) Registration under N.J.A.C. 8:65-1.2 (a) or (b) shall be issued to authorize the registrant to manufacture or distribute respectively specific controlled dangerous substances included in Schedule I or Schedule II, or to authorize the registrant to manufacture or distribute respectively the controlled dangerous substances included in Schedules III, IV, or V. Any registrant authorized to manufacture or distribute substances in Schedules III, IV, or V may manufacture or distribute respectively any controlled dangerous substance listed in the Schedule or Schedules for which he is registered.

(b) A person desiring to obtain a registration under N.J.A.C. 8:65-1.2 (a) or (b) shall specify the controlled dangerous substances or the schedules for which he wishes to obtain a registration in his application and may manufacture or distribute only those controlled dangerous substances authorized in his registration.

(c) Registration under N.J.A.C. 8:65-1.2 (c) shall be issued to authorize the registrant to dispense controlled dangerous substances in Schedules II, III, IV, or V by Schedules. Any person desiring to obtain a registration to dispense shall specify the Schedules for which he wishes to be registered in his application and may dispense only those controlled dangerous substances in the Schedules included in his registration.

(d) Every practitioner registered to dispense controlled dangerous substances who desires to conduct research with substances included in Schedule I or with narcotic substances included in Schedules II through V shall make a separate application and be issued a separate registration to conduct such research. Such practitioner shall, in addition to the general requirements of these regulations, furnish the Commissioner of Health with a copy or photocopy of his Federal registration or Federal authorization to conduct

research with such substances and, where required by Federal regulations, a copy of the research protocol.

(e) A practitioner registered to dispense controlled dangerous substances may conduct research with non-narcotic substances in Schedules II through V which are included in his registration without applying for a separate registration to conduct research.

(f) A practitioner not registered to dispense may be registered to conduct research only for the purpose of making a laboratory analysis of substances to determine the presence of controlled dangerous substances. Such registrant may not possess or have under his control any controlled dangerous substance except such amounts as are reasonably necessary to make such analysis on the premises of the registered location.

(g) A person registered to manufacture controlled dangerous substances may distribute those substances which he is authorized to manufacture without obtaining a separate registration, provided that distribution is from the registered location. A person desiring to distribute controlled dangerous substances other than those he is registered to manufacture or from a different location shall obtain a separate registration as a distributor.

(h) For purposes of registration, the following activities by a registrant will not be deemed to require an additional registration for a separate location:

1. An office used by a registered manufacturer or distributor or his agents or employees to solicit or make sales of controlled dangerous substances, provided that no such substances are contained in or distributed from such office.
2. An office used by a registered dispenser where controlled dangerous substances are prescribed, provided that no such substances are administered, delivered, or otherwise dispensed, and no such substances are contained in such office.

8:65-1.4 Registration application

(a) All applications for registration shall be made on forms provided by the Commissioner of Health and shall be filed with the Division of Narcotic and Drug Abuse Control, State Department of Health, P.O. Box 1540, Trenton, New Jersey 08625.

(b) Applications shall contain all information called for on the forms provided, except where such information is not applicable in which case this fact shall be stated.

(c) The Commissioner may require an applicant to submit documents and statements pertinent to the application or may require the applicant to amend the application to make it more definite and certain.

(d) Each application and each additional document or statement required by the Commissioner shall be signed by the applicant, if an individual; by a general partner of the applicant, if a partnership; or by an officer of the applicant if a corporation or other entity.

(e) Any application may be amended or withdrawn by the applicant as a matter of right prior to the date of service of any order to show cause pursuant to N.J.S.A. 24:21-12. An application may be amended or withdrawn by the applicant after the date of service of such an order to show cause only upon the written consent of the Commissioner.

(f) A duplicate copy of each application and of each additional document or statement required pursuant to subsection (c) of this Section shall be kept by the applicant at the location to be registered.

8:65-1.5 Action upon application

(a) After an application for registration has been filed, the Commissioner or his authorized agent or representative shall make such inspection of the place of business or professional practice described in the application and such investigation of the applicant as may be necessary to determine that the applicant meets the requirements of the applicable statutes and regulations.

(b) A person lawfully engaged in the manufacture, distribution, or dispensing of any controlled dangerous substance prior to January 17, 1971, who was registered or licensed by the State to engage in such activity, may in the discretion of the Commissioner, after making proper application for registration, be issued a registration as to such controlled dangerous substances prior to the making of an inspection or investigation by the Commissioner or his authorized agent or representative.

(c) Any application for renewal of a registration issued pursuant to the New Jersey Controlled Dangerous Substances Act and these regulations may in the discretion of the Commissioner be granted and a renewal of registration issued prior to the making of an inspection or investigation by the Commissioner or his authorized agent or representative.

(d) The issuance of a registration pursuant to paragraphs 5b or c shall not be deemed to vest any right to continue the registration or to obtain a renewal thereof, if upon subsequent inspection or investigation the Commissioner determines that the registrant does not meet the requirements of the applicable statutes or regulations.

(e) The registration certificate issued hereunder shall be displayed conspicuously in the registered location.

8:65-1.6 Assignment or transfer of registration

(a) No registration nor any right granted thereunder shall be assigned or otherwise transferred to any person not named as the registrant therein nor to any place of business of professional practice not stated therein, except as provided by statute or regulations.

(b) A registrant who changes his place of business or professional practice from the location which is stated in the registration to a new location within the State of New Jersey, without any change in the ownership of the business or professional practice, may obtain an endorsement validating his registration for the remainder of the registration period at the new location by notifying the Commissioner in writing, which notice shall set forth the name and registration number of the registrant, the address of the registered location, the address of the new location, and the effective date of the change of location.

(c) A registration shall terminate and become void if and when the registrant dies, ceases legal existence, or discontinues business or professional practice in the State of New Jersey. A registrant who ceases legal existence or discontinues business or professional practice in the State of New Jersey or who changes ownership of the business or professional practice shall notify the Commissioner in writing and surrender his current registration. In the event that the business or professional practice will be continued or resumed after a change in ownership a new application for registration shall be made pursuant to Sections 1 and 2 of this Chapter.

(d) For purposes of this Section it shall be deemed to be a change of ownership of a business or professional practice in the case of a partnership, if any partners are added or deleted from the partnership and in the case of a corporation if there is a change in the president or chief executive officer of the corporation, or in the ownership of ten percent or more of the outstanding shares in the corporation.

8:65-1.7 Changes in schedule

Consistent with the provisions set forth in N.J.S.A. 24:21-3, regulations promulgated pursuant to the United States Comprehensive Drug Abuse Prevention and Control Act of 1970, which designate, reschedule or delete a substance as a controlled substance under Federal Law, shall be deemed to be effective under the New Jersey Controlled Dangerous Substances Act (N.J.S.A. 24:21-1 et seq.) 30 days after the effective date of the Federal regulation, unless the Commissioner, within that 30 day period, shall object to inclusion, rescheduling or deletion, which objection shall thereafter be published in the New Jersey Register.

SUBCHAPTER 2. SECURITY REQUIREMENTS

8:65-2.1 Security requirements generally

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department shall use the security requirements set forth in Sections 2 through 6 of this Subchapter as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in Sections 2, 3 and 5 of this Subchapter may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in Sections 2 through 6 of this Subchapter may be deemed sufficient by the Department after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Department may consider any of the following factors as may deem relevant to the need for strict compliance with security requirements:

1. The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying and so forth);
2. The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
3. The quantity of controlled substances handled;
4. The location of the premises and the relationship such location bears on security needs;
5. The type of building construction comprising the facility and the general characteristics of the building or buildings;
6. The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
7. The type of closures on vaults, safes, and secure enclosures;
8. The adequacy of key control systems and/or combination lock control systems;
9. The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
10. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
11. The adequacy of supervision over employees having access to manufacturing and storage areas;
12. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
13. The availability of local police protection or of the registrant's or applicant's security personnel, and;
14. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in Sections 2 through 6 of this Subchapter when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in Sections 2 through 6 of this Subchapter may submit any plans, blueprints, sketches or other materials regarding the proposed security system to the New Jersey State Department of Health, Division of Narcotic and Drug Abuse Control, Drug Control Program, P.O. Box 1540, Health John Fitch Plaza, Trenton, New Jersey 08625.

(e) Physical security controls of locations licensed under the New Jersey Uniform Narcotic Drug Act (N.J.S.A.

24:18-1 et seq.) on January 17, 1971, shall be deemed to comply substantially with the standards set forth in Sections 2, 3 and 5 of this Subchapter. Any new facilities or work or storage area constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Department, shall not necessarily be deemed to comply substantially with the standards set forth in Sections 2, 3 and 5 of this Subchapter, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Department.

8:65-2.2 Physical security controls for nonpractitioners: storage areas

(a) Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in schedule I or II shall be stored in one of the following secure storage areas:

1. Where small quantities permit, a safe:
   i. Which safe has an Underwriters' Laboratories Burglary Rating of T-20, E or better, or the equivalent of such a safe;
   ii. Which safe, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and
   iii. Which safe, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Department may approve.
2. A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or
3. A vault constructed after September 1, 1971:
   i. The walls, floors and ceilings of which vault are constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½-inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings;
   ii. The door of which vault contains a multiple-position combination lock or the equivalent, a relocking device or the equivalent, and steel plate with a thickness of at least ½-inch or with a two-hour fire rating or the equivalent;
   iii. Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;
   iv. The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Department may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;
   v. The door of which vault is equipped with contact switches; and
   vi. Which vault has one of the following: complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Department.

(b) Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in schedules III, IV, and V shall be stored in one of the following secure storage areas:

1. Where small quantities permit, a safe which complies with the requirements set forth in subsection (a) (1) of this Section;
2. A vault which complies with the requirements set forth in either subsection (a) (2) or (3) of this Section; or
3. A building or area located within a building, which building or area:
   i. Has walls or perimeter fences of sufficient height and construction to provide security from burglary;
   ii. Has substantial doors which may be securely locked during nonworking hours by a multiple-position combination or key lock;
   iii. Is equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Department may approve; and
   iv. In which all controlled substances are segregated from all other merchandise and kept under constant surveillance during normal business hours.

(c) Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

8:65-2.3 Physical security controls for nonpractitioners; manufacturing areas

(a) All manufacturing activities (including processing, packaging, and labeling) involving controlled sub-

stances listed in any schedule shall be conducted in accordance with the following:

1. All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If the security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.
2. Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacutirng operation being conducted: Provided, that he is to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.
3. During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

8:65-2.4 Other security controls for nonpractitioners

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Bureau of Narcotic and Dangerous Drugs, Department of Justice, or with the New Jersey State Department of Health, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Regional Office of the Bureau of Narcotics and Dangerous Drugs or the New Jersey State Department of Health, Drug Control Program, of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Regional Office of the Bureau of Narcotics and Dangerous Drugs or the New Jersey State Department of Health, Drug Control Program, of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The registrant shall also complete BND Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in schedules II through V as a complimentary sample to any potential or current customer without the prior written request of the customer, to be used only for satisfying the legitimate medical needs of patients of the customer, and only in reasonable quantities. Such request must contain the name, address and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of Subchapter 6 shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term 'customer' includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in Section 2 of this Subchapter. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

8:65-2.5 Physical security controls for practitioners

(a) Controlled substances listed in schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

8:65-2.6 Other security controls for practitioners

(a) The registrant shall not employ as an agent or em-

ployee who has access to controlled substances any person who has had an application for registration denied, or has had his registration revoked, at any time.

(b) The registrant shall notify the Regional Office of the Bureau of Narcotics and Dangerous Drugs, Department of Justice or the New Jersey State Department of Health, Drug Control Program, of the theft or significant loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete BND Form 106 regarding such loss or theft.

SUBCHAPTER 3. LABELING AND PACKAGING REQUIREMENTS

8:65-3.1 Scope

Requirements governing the labeling and packaging of controlled substances pursuant to sections 305 and 1008 (d) of the Act [21 U.S.C. 825 and 958 (d)] are set forth generally by those sections and specifically by the sections of this part.

8:65-3.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Commercial container" means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "commercial container" does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

"Label" means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

"Labeling" means all labels and other written, printed, or graphic matter upon any controlled substance or any of its commercial containers or wrappers, or accompanying such controlled substance.

"Manufacture" means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his administration or dispensing such substance in the course of his professional practice, prepares, compounds, packages or labels such substance. The term "manufacturer" means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

Any term not defined in this Section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or 301.02 of 21 CFR.

8:65-3.3 Symbol required; exceptions

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Department pursuant to N.J.S.A. 24:21-8d) shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this part.

(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto:

Schedule	*Symbol*
1. Schedule I	I or C-I.
2. Schedule II	II or C-II.
3. Schedule III	III or C-III.
4. Schedule IV	IV or C-IV.
5. Schedule V	V or C-V.

6. The word "schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances.

(d) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

(e) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

(f) The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

8:65-3.4 Location and size of symbol on label

(a) The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commerical container normally displayed to dispensers of any controlled substance listed in schedules I through V. The symbol must be at least two times as large as the largest type otherwise printed on the label.

(b) In lieu of locating the symbol in the corner of the label, as prescribed in subsection (a) of this Section, the symbol may be overprinted on the label, in which case the symbol must be printed at least one-half the height of the label and in a contrasting color providing clear visibility against the background color of the label.

(c) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

8:65-3.5 Location and size of symbol on labeling

(a) The symbol shall be prominently located on all labeling other than labels covered by Section 4 of this Subchapter.

(b) In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

8:65-3.6 Effective dates of labeling requirements

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on May 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of Section 3 of this Subchapter.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule of May 1, 1971, and thereafter transferred to another schedule or is added to any schedule after May 1, 1971 and which is packaged more than 180 days following the date on which the transfer or addition becomes effective, shall comply with the requirements of Section 3 of this Subchapter.

(c) The Department may, in the case of any controlled substance, require compliance with the requirements of Section 3 of this Subchapter within a period of time shorter than required by this section if he finds that public health or safety necessitate an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under Federal and State law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

8:65-3.7 Sealing of controlled substances

(a) On each bottle, multiple dose vial or other commercial container of any controlled substance listed in schedules I or II or of any narcotic controlled substance listed in schedule III or IV, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

(b) Any seal accepted for use under Federal law prior to May 1, 1971, shall be deemed acceptable for use under this section.

8:65-3.8 Labeling and packaging requirements for imported and exported substances

(a) The symbol requirements of Sections 3 through 6 of this Subchapter apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of the United States, as defined to be the several States, the District of Columbia, and Puerto Rico.

(b) The symbol requirements of Sections 3 through 6 of this Subchapter do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from the jurisdiction of the United States, as defined to be the several States, the District of Columiba, and Puerto Rico.

(c) The sealing requirements of Section 7 of this Subchapter apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedule I or II, or of any narcotic controlled substance listed in schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of and/or the customs territory of the United States, as defined to be the several States, the District of Columbia, and Puerto Rico.

SUBCHAPTER 4. QUOTAS

8:65-4.1 Scope

Procedures governing the establishment of production and manufacturing quotas on basic classes of controlled substances listed in schedules I and II pursuant to section 306 of the Act (21 U.S.C. 826) are governed generally by that section and specifically by the sections of this part.

8:65-4.2 Definition

The following words and terms, when used in this chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Hearing" means any hearing held pursuant to this part regarding the determination of aggregate production quota or the issuance, adjustment, suspension, or denial of a procurement quota or an individual manufacturing quota.

"Inventory" means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

"Net disposal" means the quantity of a basic class of controlled substance sold, exchanged, given away, used in the production of another substance (whether a controlled substance or not), contained in or combined with other substances, or otherwise consumed by or transferred to another person by the registrant during a stated period, less the quantity returned to the registrant by any purchaser and the quantity sold or transferred by the registrant to another registered manufacturer of the same basic class of controlled substance.

"Net disposal" means the quantity of a basic class of controlled substance sold, exchanged, given away, used in the production of another substance (whether a controlled substance or not), contained in or combined with other substances, or otherwise consumed by or transferred to another person by the registrant by any purchaser and the quantity sold or transferred by the registrant to another registered manufacturer of the same basic class of controlled substance.

"Registrant" means any person registered pursuant to section 303 of the Act (21 U.S.C. 823) and N.J.S.A. 24:21-1 et seq. Any term not defined in this Section shall have the definition set forth in N.J.S.A. 24:21-2 or Section 102 of the Act (21 U.S.C. 802) and 301.02 of 21 CFR.

8:65-4.3 Aggregate production quotas

(a) The Director, Bureau of Narcotics and Dangerous Drugs, shall, on or before May 1 of each year, determine the total quantity of each basic class of controlled substance listed in schedule I or II necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful

export requirements, and for the establishment and maintenance of reserve stocks.

(b) In making his determinations, the Director, Bureau of Narcotics and Dangerous Drugs, shall consider the following factors:

1. Total net disposal of the class by all manufacturers during the current and 2 preceding years;
2. Trends in the national rate of net disposal of the class;
3. Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;
4. Project demand for such class as indicated by procurement quotas requested pursuant to Section 4 of this Subchapter; and
5. Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Director finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (Including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) The Director, Bureau of Narcotics and Dangerous Drugs, shall, on or before May 1 of each year, publish in the Federal Register general notice of an aggregate production quota by filing with the Director a written request for a hearing in accordance with Section 15 of Subchapter. If a hearing is requested and reasonable grounds are shown, the Director shall hold a public hearing on the aggregate production quota for the basic class. Notice of the hearing shall be published in the Federal Register at least 30 days prior to the hearing and mailed simultaneously to all persons to whom the notice of the determination of the aggregate production quota was mailed.

Any interested person may participate in the hearing by filing a notice of appearance in accordance with Section 15 of this Subchapter.

8:65-4.4 Procurement quotas

(a) In order to determine the estimated needs for, and to insure an adequate and uninterrupted supply of, basic classes of controlled substances listed in schedules I and II (except raw opium) the Director, Bureau of Narcotics and Dangerous Drugs, shall issue procurement quotas authorizing persons to procure and use quantities of each basic class of such substances for the purpose of manufacturing such class into dosage forms or into other substances.

(b) Any person who is registered to manufacture controlled substances listed in any schedule and who desires to use during the next calendar year any basic class of controlled substances listed in schedule I or II (except raw opium) for purposes of manufacturing, shall apply on BND Form 250 for a procurement quota for such basic class. A separate application must be made for each basic class desired to be procured or used. The applicant shall state whether he intends to manufacture the basic class himself or purchase it from another manufacturer. The applicant shall state separately each purpose for which the basic class is desired, the quantity desired for that purpose during the next calendar year, and the quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years. If the purpose is to manufacture the basic class into dosage form, the applicant shall state the official name, common or usual name, chemical name, or brand name of that form. If the purpose is to manufacture another substance, the applicant shall state the official name, common or usual name, chemical name, or brand name of the substance, and, if a controlled substance listed in any schedule, the schedule number and the Department of Justice, Bureau of Narcotics and Dangerous Drugs Control Code Number assigned to the substance. If the purpose is to manufacture another basic class of controlled substance listed in schedule I or II, the applicant shall also state the quantity of the other basic class which the applicant has applied to manufacture pursuant to Section 6 of this Subchapter and the quantity of the first basic class necessary to manufacture a specified unit of the second basic class. BND Form 250 shall be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of BND Form 250 may be obtained from, and shall be filed with, the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(c) The Director shall, on or before July 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing him to procure and use:

1. All quantities of such class necessary to manufacture all quantities of other basic classes of controlled substances listed in schedules I and II which the applicant is authorized to manufacture pursuant to Section 7 of this Subchapter.
2. Such other quantities of such class as the applicant has applied to procure and use and are consistent with his past use, his estimated needs, and the total quantity of such class that will be produced.

(d) Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Director with a statement showing the need for the adjustment. Such application shall be filed with the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. The Director shall increase or decrease the procurement quota of such person if and to the extent that he finds, after considering the factors enumerated in subsection (c) of this Section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

(e) The following persons need not obtain a procurement quota:

1. Any person who is registered to manufacture a basic class of controlled substance listed in schedule I or II and who uses all of the quantity he man-

ufactures in the manufacture of a substance not controlled under the Act.

2. Any person who is registered or authorized to conduct chemical analysis with controlled substances (for controlled substances to be used in such analysis only); and
3. Any person who is registered to conduct research with a basic class of controlled substance listed in schedule I or II and who is authorized to manufacture a quantity of such class pursuant to 301.22 (b) of 21 CFR.

8:65-4.5 Individual manufacturing quotas

(a) The Director shall, on or before July 1 of each year, fix for and issue to each person who is registered to manufacture a basic class of controlled substance listed in schedule I or II, and who applies for a manufacturing quota, an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that basic class. Any manufacturing quota fixed and issued by the Director shall be subject to his authority to reduce or limit it at a later date pursuant to Section 10 of this Subchapter and to his authority to revoke or suspend it at any time pursuant to 301.45 and 301.46 of 21 CFR.

(b) No individual manufacturing quota shall be required for registrants listed in N.J.A.C. 8:65-4.4 (e).

8:65-4.6 Procedure for applying for individual manufacturing quotas

(a) Any person who is registered to manufacture any basic class of controlled substance listed in schedule I or II and who desires to manufacture a quantity of such class shall apply on BND Form 189 for a manufacturing quota for such quantity of such class. Copies of BND Form 189 may be obtained from, and shall be filed (on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with, the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. A separate application must be made for each class desired to be manufactured. The applicant shall state:

1. The name the Department of Justice, Bureau of Narcotics and Dangerous Drugs Control Code Number assigned to the substance of the basic class.
2. For the basic class in each of the current and preceding two calendar years,
   i. The authorized individual manufacturing quota, if any;
   ii. The actual or estimated net disposal;
   iii. The actual or estimated inventory allowance pursuant to Section 8 of this Subchapter and
   iv. The actual or estimated inventory as of December 31;
3. For the basic class in the next calendar year,
   i. The desired individual manufacturing quota; and
   ii. Any additional factors which the applicant finds relevant to the fixing of his individual manufacturing quota, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods and fires.

8:65-4.7 Procedures for fixing individual manufacturing quotas

(a) In fixing individual manufacturing quotas for a basic class of controlled substance listed in schedule I or II, the Director shall allocate to each applicant who is currently manufacturing such class a quota equal to 100 per cent of the estimated net disposal of that applicant for the next calendar year, adjusted by the amount necessary to increase or reduce the estimated inventory of the applicant on December 31 of the current year to his estimated inventory allowance for the next calendar year, pursuant to Section 8 of this Subchapter and by any other factors which the Director deems relevant to the fixing of the individual manufacturing quota of the applicant, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(b) In fixing individual manufacturing quotas for a basic class of controlled substance listed in schedule I or II, the Director shall allocate to each applicant who is not currently manufacturing such class a quota equal to 100 per cent of the reasonable estimated net disposal of that applicant for the next calendar year, as determined by the Director, adjusted by the amount necessary to provide the applicant his estimated inventory allowance for the next calendar year, pursuant to Section 8 of this Subchapter and by any other factors which the Director deems relevant to the fixing of the individual manufacturing quota of the applicant including the trend of (and recent changes in) the national rate of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes); and recent unforeseen emergencies such as floods and fires.

(c) The Director shall, on or before January 31 of each year, adjust the individual manufacturing quota allocated for that year to each applicant in subsection (a) of this Section by the amount necessary to increase or reduce the actual inventory of the applicant to December 31 of the preceding year to his estimated inventory allowance for the current calendar year, pursuant to Section 8 of this Subchapter.

8:65-4.8 Inventory allowance

(a) For the purpose of determining individual manufac-

turing quotas pursuant to Section 7 of this Subchapter, each registered manufacturer shall be allowed as a part of such quota an amount sufficient to maintain an inventory equal to:

1. For current manufacturers, 50 per cent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or
2. For new manufacturers, 50 per cent of his reasonably estimated net disposal for the next calendar year as determined by the Director.

(b) During each calendar year each registered manufacturer shall be allowed to maintain an inventory of a basic class not exceeding 65 per cent of his estimated net disposal of that class for that year, as determined at the time of his quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 65 per cent of his estimated net disposal, his quota for that class is automatically suspended and shall remain suspended until his inventory is less than 60 per cent of his estimated net disposal. The Director may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this subsection to continue manufacturing and to accumulate an inventory in excess of 65 per cent of his estimated net disposal, upon such conditions and within such limitations as the Director may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a basic class allocated to him under an individual manufacturing quota, and his inventory of that class is less than 40 per cent of his estimated net disposal of that class for that year, the Director may, upon application pursuant to Section 9 of this Subchapter, increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 per cent of the estimated net disposal for that year.

8:65-4.9 Increase in individual manufacturing quotas

(a) Any registrant who holds an individual manufacturing quota for a basic class of controlled substance listed in schedule I or II may file with the Director an application on Bureau Form 189 for an increase in such quota in order for him to meet his estimated net disposal, inventory and other requirements during the remainder of such calendar year.

(b) The Director, in passing upon a registrant's application for an increase in his individual manufacturing quota, shall take into consideration any occurrences since the filing of such registrant's initial quota application that may require an increased manufacturing rate by such registrant during the balance of the calendar year . In passing upon such application the Director may also take into consideration the amount, if any, by which his determination of the total quantity for the basic class of controlled substance to be manufactured under Section 3 of this Subchapter exceeds the aggregate of all the individual manufacturing quotas for the basic class of controlled substance, and the equitable distribution of such excess among other registrants.

8:65-4.10 Reduction in individual manufacturing quotas

(a) The Director may at any time reduce an individual manufacturing quota for a basic class of controlled substance listed in schedule I or II which he has previously fixed in order to prevent the aggregate of the individual manufacturing quotas outstanding or to be granted from exceeding the aggregate production quota which has been established for that class pursuant to Section 3 of this Subchapter.

(b) If a quota assigned to a new manufacturer pursuant to N.J.A.C. 8:65-4.7 (b) or if a quota assigned to any manufacturer is increased pursuant to N.J.A.C. 8:65-4.8 (c) or if an import permit issued to an importer pursuant to Part 312 of the Federal Act, causes the total quantity of a basic class to be manufactured and imported during the year to exceed the aggregate production quota which has been established for that class pursuant to Section 3 of this Subchapter, the Director may proportionately reduce the individual manufacturing quotas of all other registrants to keep the aggregate production quota within the limits originally established, or, alternatively, the Director may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to 303.24 (b) or 301.45 or 301.46 of 21 C.F.R., or is abandoned pursuant to Section 11 of this Subchapter.

8:65-4.11 Abandonment of quota

(a) Any manufacturing assigned an individual manufacturing quota for any basic class pursuant to Section 7 of this Subchapter may at any time abandon his right to manufacture all or any part of such quota by filing with the Distribution Audit Branch a written notice of such abandonment, stating the name and the Department of Justice, Bureau of Narcotics and Dangerous Drugs Control Code Number of the substance and the amount which he has chosen not to manufacture.

(b) The Director may, in his discretion, allocate such amount among the other manufacturers in proportion to their respective quotas.

8:65-4.12 Hearings generally

(a) In any case where the Director shall hold a hearing regarding the determination of an aggregate production quota pursuant to N.J.A.C. 8:65-4.3 (c), the procedures for such hearing shall be governed generally by the rule making procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by section 306 of the Act (21 U.S.C. 826), by Sections 13 through 18 of this Subchapter, and by the procedures for administrative hearings under the Act set forth in N.J.A.C. 8:65-9.20 to 8:65-9.46.

(b) In any case where the Director shall hold a hearing regarding the issuance, adjustment, suspension, or denial of a procurement quota pursuant to Section 4 of this Subchapter, or the issuance, adjustment, suspension, or denial of an individual manufacturing quota pursuant to Sections 5 through 11 of this Subchapter, procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedures Act (5 U.S.C. 551-559)

and specifically by section 306 of the Act (21 U.S.C. 826), by Sections 13 through 18 of this Subchapter, and by the procedures for administrative hearings under the Act set forth in N.J.A.C. 8:65-9.20 to 8:65-9.46.

8:65-4.13 Purpose of hearing

(a) If requested by an interested person who shows reasonable grounds therefore, the Director shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the issuance, adjustment, suspension, or denial of such quota to such person, but the Director need not hold a hearing on the suspension of a quota pursuant to 301.45 or 301.46 of 21 C.F.R. separate from a hearing on the suspension of registration pursuant to those sections.

(b) Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

8:65-4.14 Waiver or modification of rules

(a) The Director or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served.

(b) Such notice of modification or waiver shall be made a part of the record of the hearing.

8:65-4.15 Request for hearing or appearance; waiver

(a) Any applicant or registrant who desires a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota, shall, within 30 days after the date of receipt of the issuance, adjustment, suspension, or denial of such quota, file with the Director a written request for a hearing in the form prescribed in N.J.A.C. 8:65-9.25. Any interested person who desires a hearing on the determination of an aggregate production quota shall, within the time prescribed in N.J.A.C. 8:65-4.3 (c), file with the Director a written request for a hearing in the form prescribed in N.J.A.C. 8:65-9.25, including in the request a statement of the grounds for a hearing.

(b) Any interested person who desires to participate in a hearing on the determination of an aggregate production quota, which hearing is requested pursuant to N.J.A.C. 8:65-4.3 (c) shall, within 30 days of the date of publication of notice of the hearing in the Federal Register, file with the Director a written notice of his intention to participate in such hearing in the form prescribed in N.J.A.C. 8:65-9.26. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to N.J.A.C. 8:65-4.3 (c) may, within the period permitted for filing a request or a notice of appearance, file with the Director a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to N.J.A.C. 8:65-4.3 (c), fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Director may cancel the hearing, if scheduled, and issue his final order pursuant to Section 18 of this Subchapter without a hearing.

8:65-4.16 Burden of proof

(a) At any hearing regarding the determination of an aggregate production quota, each interested person participating in the hearing shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing regarding the issuance, adjustment, suspension or denial of a procurement or individual manufacturing quota, the Bureau shall have the burden of proving that the requirements of this part for such issuance, adjustment, suspension, or denial are satisfied.

8:65-4.17 Time and place of hearing

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota pursuant to Section 15 of this Subchapter, the Director shall hold such hearing. Notice of the hearing shall be given to the applicant or registrant of the time and place at least 30 days prior to the hearing, unless the applicant or registrant waives such notice and requests the hearing to be held at an earlier time, in which case the Director shall fix a date for such hearing as early as reasonably possible.

(b) The hearing will commence at the place and time designated in the notice given pursuant to subsection (a) of this Section or in the notice of hearing published in the Federal Register pursuant to N.J.A.C. 8:65-4.3 (c), but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

8:65-4.18 Final order

(a) As soon as practicable after the presiding officer has certified the record to the Director, the Director shall issue his order on the determination of the aggregate production quota or on the issuance, adjustment, suspension, or denial of the procurement quota or individual manufacturing quota, as the case may be.

(b) The order shall include the findings of fact and conclusions of law upon which the order is based.

(c) The order shall specify the date on which it shall take effect.

(d) The director shall serve one copy of his order upon each party in the hearing.

8:65-4.19 Quota system for 1971

For purposes of fixing aggregate production and individual manufacturing quotas for basic classes of controlled substances listed in schedules I and II pursuant to section 306 of the Act (21 U.S.C. 326) for the calendar year 1971 only, procedures for fixing quotas on narcotic drugs prescribed in regulations in effect prior to the effective date of this part (i.e., 307.121-307.126 of 21 U.S.C.) shall be utilized.

8:65-4.20 Quota system for 1972

For purposes of fixing aggregate production and individual manufacturing quotas for basic classes of controlled substances listed in schedules I and II pursuant to section 306 of the Act (21 U.S.C. 326) for the calendar year 1972 only, applications required pursuant to N.J.A.C. 8:65-4.4 (b) and Section 6 of this Subchapter shall be filed no later than September 1, 1971.

SUBCHAPTER 5.
RECORDS AND REPORTS OF REGISTRATION

8:65-5.1 Scope

Inventory and other records and reports required under section 307 or section 1008 (d) of the Act [21 U.S.C. 827 and 958 (d)] shall be in accordance with, and contain the information required by, those sections and by the sections of this part.

8:65-5.2 Definitions

The following words and terms, when used in this Chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

"Commercial container" means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "commercial container" does not include any package liner, package insert of other material kept with or within a commercial container, nor any carton, crate, drum or other package in which commercial containers are stored or are used for shipment of controlled substances.

"Dispenser" means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

"Individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

"Institutional practitioner" means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

"Name" means the official name, common or usual name, chemical name, or brand name of a substance.

"Pharmacist" means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

"Readily retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records. Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and N.J.S.A. 24:21-1 et seq.

8:65-5.3 Persons required to keep records and file reports

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to N.J.S.A. 24:21-10 or pursuant to N.J.A.C. 8:65-8.4 to 8.8, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities (e.g., when a registered manufacturer conducts chemical analysis, he shall maintain the records and inventories required of chemical analysis).

(b) A registered individual practitioner is not required to keep records with respect to narcotic controlled substances listed in schedules II through V which he prescribes or administers in the lawful course of his professional practice; he shall keep records, however, with respect to such substances that he dispenses other than by prescribing or administering.

(c) A registered individual practitioner is not required to keep records with respect to nonnarcotic controlled substances listed in schedules II through V which he dispenses in any manner unless he regularly charges his patients, either separately or together with charges for other professional services, for such substances so dispensed (e.g., when he substitutes his services for those of a pharmacist).

(d) A registered person using any controlled substance in research conducted in conformity with an exemption granted under section 505 (i) or 512 (j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355 (i) or 360b (j)] at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if he notifies the Bureau of the name, address, and registration number

of the establishment maintaining such records.

(e) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records if he notifies the Bureau of the name, address, and registration number of the establishment maintaining such records.

(f) Notice required by subsections (d) and (e) of this Section shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

8:65-5.4 Maintenance of records and inventories

(a) Every inventory and other record required to be kept under Subchapter 5 shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspecting and copying by authorized employees of the Bureau, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to N.J.A.C. 8:65-6.13) may be kept at a central location, rather than at the registered location, if the registrant obtains from the Bureau approval of his central record keeping system and a permit to keep central records. The central record keeping system of any person whose system was approved by the Bureau prior to May 1, 1971, shall continue to be approved under this paragraph if such person satisfies the Bureau by July 1, 1971, of such approval and applies for a permit to keep central records. The permit to keep central records shall be issued by the Bureau to a registrant upon application if the Bureau approves his central record keeping system and shall be subject to the following conditions:

1. The permit shall specify the nature of the records to be kept centrally and the exact location where the records will be kept;
2. The registrant agrees to deliver all or any part of such records to the registered location within 48 hours of receipt of a written request from the Bureau for such records, and, if the Bureau chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Bureau to inspect such records at the central location upon request by such employees without a warrant of any kind; and
3. The failure of the registrant to perform his agreements under the permit shall revoke without further action by the Bureau such permit and all other such permits held by the registrant under other registrations. In the event of a revocation of other permits under this subparagraph, the registrant shall, within 30 days after such revocation, comply with the requirements of this section that all records be kept at the registered location.

(b) Each registered manufacturer, distributor, importer, and exporter shall maintain inventories and records of controlled substances as follows:

1. Inventories and records of controlled substances listed in schedules I and II shall be maintained separately from all of the records of the registrant; and
2. Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(c) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in subsection (b) of this Section.

(d) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

1. Inventories and records of all controlled substances listed in schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and
2. Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed either in the prescription file for controlled substances listed in schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

8:65-5.5 General requirements for inventories

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered,

except as provided in Section 12 of this subchapter.

(d) A registrant may take an inventory on a date that is within 4 days of his biennial inventory date pursuant to Section 7 of this subchapter if he notifies in advance the Regional Director of the Bureau in his region of the date on which he will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

8:65-5.6 Initial inventory date

(a) Every person required to keep records who is provisionally registered on May 1, 1971, shall take an inventory of all stocks of controlled substances on hand on that date in accordance with Sections 9 through 13 of this subchapter as applicable.

(b) Every person required to keep records who is registered after May 1, 1971, and who was not provisionally registered on that date, shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with Sections 9 through 13 of this subchapter as applicable.

8:65-5.7 Biennial inventory date

Every two years following the date on which the initial inventory is taken by a registrant pursuant to Section 6 of this subchapter, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken on the day of the year on which the initial inventory was taken or on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply or on any other fixed date which does not vary by more than six months from the biennial date that would otherwise apply. If the registrant elects to take the biennial inventory on his regular general physical inventory date or another fixed date, he shall notify the Bureau of this election and of the date on which the biennial inventory will be taken.

8:65-5.8 Inventory date for newly controlled substances

On the effective date of a rule by the Director pursuant to 308.48, 308.49, or 308.50 of the Act adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substance shall be included in each inventory made by the registrant pursuant to Section 7 of this subchapter.

8:65-5.9 Inventories of manufacturers

Each person registered or authorized (by 301.22 (b), 307.12, or 307.15 of the Act) to manufacture controlled substances shall include the following information to his inventory:

1. For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form:
   i. The name of the substance; and
   ii. The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, avoirdupois weights may be utilized where metric weights are not readily available).
2. For each controlled substance in the process of manufacture on the inventory date:
   i. The name of the substance;
   ii. The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number;
   iii. The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., ten milligram tablet or ten milligram concentration per fluid ounce or milliliter) and the number or volume thereof; and
3. For each controlled substance in finished form:
   i. The name of the substance;
   ii. Each finished form of the substance (e.g., ten milligram tablet or ten milligram concentration per fluid ounce or milliliter);
   iii. The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or three milliliter vial); and
   iv. The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six three milliliter vials).
4. For each controlled substance not included in paragraphs 1, 2 or 3 of this subsection (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings):
   i. The name of the substance;
   ii. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and
   iii. The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

8:65-5.10 Inventories of distributors

Each person registered or authorized (by 301.22 (b) or 307.11-307.14 of this Chapter) to distribute controlled substances shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9 (c) and (d).

8:65-5.11 Inventories of dispensers and researchers

(a) Each person registered or authorized (by 301.22 (b)

of the Act) to dispense or conduct research with controlled substances and required to keep records pursuant to Section 5.3 of this subchapter shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9 (c) and (d). In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

1. If the substance is listed in schedule I or II, he shall make an exact count or measure of the contents; and
2. If the substance is listed in schedule III, IV, or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he must make an exact count of the contents.

8:65-5.12 Inventories of importers and exporters

(a) Each person registered or authorized (by 301.22 (b) of the Act) to import or export controlled substances shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9 (a) (c) and (d). Each such person who is also registered as a manufacturer or as a distributor shall include in his inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

8:65-5.13 Inventories for chemical analysts

(a) Each person registered or authorized (by 301.22 (b) of the Act) to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9 (a), (c) and (d) as to substances which have been manufactured, imported, or received by such person.

(b) If less than one kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in schedule I), or less than 20 grams of a hallucinogenic substance listed in schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory.

(c) Laboratories of the Bureau may possess up to 150 grams of any hallucinogenic substance in schedule I without regard to a need for an inventory of those substances.

(d) No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

8:65-5.14 General requirements for continuing records

(a) On and after May 1, 1971, every registrant required to keep records pursuant to Section 3 of this subchapter shall maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in Section 4 (a) of this subchapter. In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he is registered, except as provided in Sections 18 and 19 of this subchapter.

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

8:65-5.15 Records of manufacturers

(a) Each person registered or authorized (by 301.22 (b) or 307.15 of the Act) to manufacture controlled substances shall maintain records with the following information:

1. For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,
   i. The name of the substance;
   ii. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;
   iii. The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;
   iv. The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him, including the date, quantity, and import permit or declaration number for each importation;
   v. The quantity used to manufacture the same substance in finished form, including:
      1. The date and batch or other identifying number of each manufacture;
      2. The quantity used in the manufacture;
      3. The finished form (e.g., ten milligram tablets or ten milligram concentration per fluid ounce or milliliter);
      4. The number of units of finished form manufactured;
      5. The quantity used in quality control;
      6. The quantity lost during manufacturing and the cause therefor, if known;
      7. The total quantity of the substance contained in the finished form;
      8. The theoretical and actual yields; and
      9. Such other information as is necessary to account for all controlled substances used

in the manufacturing process;

vi. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in subparagraph v. of this Section;

vii. The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

viii. The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

ix. The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed.

2. For each controlled substance in finished form,

i. The name of the substance;

ii. Each finished form (e.g., ten milligram tablet or ten milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or three milliliter vial);

iii. The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph 1. v. of subsection (a) of this Section;

iv. The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

v. The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

vi. The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

1. The date and batch or other identifying number of each manufacture;
2. The operation performed (e.g., repackaging or relabeling);
3. The number of units of finished form used in the manufacture, the number manufactured and the number lost during manfacture, with the causes for such losses, if known; and
4. Such other information as is necessary to account for all controlled substances used in the manufacturing process;

vii. The number of commercial containers distributed to other persons, including the date of and number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

viii. The number of commercial containers exported directly by the registrant (under a registration as an exporter,) including the date, number of containers and export permit or declaration number for each exportation; and

ix. The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

8:65-5.16 Records for distributors

(a) Each person registered or authorized (by 301.22 (b) or 307.11-307.14 of the Act) to distribute controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. Each finished form (e.g., ten milligram tablet or ten milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or three milliliter vial);
3. The number of commercial containers of each such finished form received from other persons, including the date of an number of containers in each receipt and the name, address, and registration number of the persons from whom the containers were received;
4. The number of commercial containers or each such finished form imported directly by the person (under a registration or authorization to import), including the date of, the number of commercial containers in, and the import permit or declaration number for, each importation;
5. The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address, and registration number of the person to whom the containers were distributed;
6. The number of commercial containers of each such finished form exported directly by the person (under a registration or authorization to export), including the date of, the number of commercial containers in, and the export permit or declaration number for, each exportation; and
7. The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the person (e.g., by distribution as complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address, and

registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed.

8:65-5.17 Records for dispensers and researchers

(a) Each person registered or authorized (by 301.22(b) of the Act) to dispense or conduct research with controlled substances and required to keep records pursuant to Section 3 of this subchapter shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. Each finished form (e.g., ten milligram tablet or ten milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or three milliliter vial);
3. The number of commercial containers of each such finished form received from other persons, including the date and number of containers in each receipt and the name, address, and registration number of the persons from whom the containers were received;
4. The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser; and
5. The number of units or volume of such finished forms and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

8:65-5.18 Records for importers

(a) Each person registered or authorized (by 301.22(b) of the Act) to import controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume), and import permit or declaration number for each importation;
3. The quantity (or number of units or volume in finished form) distributed to other persons, including the date and quantity (or number of units or volume) of each distribution and the name, address, and registration number of each person to whom a distribution was made; and
4. The quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer, which quantities are to be recorded pursuant to N.J.A.C. 8:65-5.15 (a) 4. or (b) 5., including the date and manner of disposal and the quantity disposed.

8:65-5.19 Records for exporters

(a) Each person registered or authorized (by 301.22(b) of the Act) to export controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. The quantity (or number of units or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address, and registration number of each person from whom the substance was received;
3. The quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to subsection (a) 1. or (a) 2. of Section 15 of this subchapter; and
4. The quantity disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity disposed.

8:65-5.20 Records for chemical analysts

(a) Each person registered or authorized (by 301.22(b) of the Act) to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

1. The name of the substance;
2. The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., ten milligram tablet or ten milligram concentration per milliliter);
3. The total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty one milliliter vials, or ten grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and registration number, if any, of the person from whom the substance was received;
4. The quantity distributed, exported, or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and registration number, if any, of each person to whom the substance was distributed or exported.

(b) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(c) Records relating to known, or suspected, controlled substances received as evidentiary material for analysis are not required under paragraph (a) of this section.

8:65-5.21 Reports from manufacturers and importers

(a) Each registered manufacturer and registered importer

shall submit a quarterly report (BND Form 234) accounting for all stocks of narcotic controlled substances listed in schedules I, II, and III on hand at the beginning and at the end of the quarter, and for all receipts (BND Form 234a), dispositions (BND Form 234b), manufacturing (BND Form 234c) and packaging (BND Form 234d), of such substances. The returns shall be submitted to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month succeeding the period for which it is submitted.

(b) All narcotic controlled substances listed in schedules I, II, and II received by a manufacturer or importer, shall be recorded on Form 234a in order and at the time of receipt. Where record on Form 234a cannot, for any good and sufficient reason, be made immediately, the manufacturer or importer shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or receipt.

(c) All dispositions of narcotic controlled substances listed in schedules I, II, and III by a manufacturer or importer, including exports, distributions, and losses, shall be reported on BND Form 234b. A separate sheet, properly headed in the space provided, shall be used for each different type of transaction. On each sheet separate entries shall be used to report dispositions of each substance and of each different type and size of container or unit involved. All losses reported shall be fully explained. The details of all exports and all domestic distributions of narcotic controlled substances shall be reported in full on BND Form 234b, except that the details of distributions of narcotic controlled substances listed in schedule III sold to dispensers shall be included in summarized entries on BND Form 234b. For all such distributions not reported in detail the manufacturer shall have available for inspection original sales orders, delivery slips, or other papers or records sufficient to fully evidence and explain the dispositions.

(d) All narcotic controlled substances listed in schedules I, II, and III used in the production of other drugs or preparations, with the exception of transactions involving original manufacture from raw opium or coca leaves, shall be entered on BND Form 234c in the order and at the time they are placed into the process of manufacture. All narcotic controlled substances listed in schedules I, II, and III and preparations produced therefrom shall be entered on the same form, at the time of production, which entry shall be clearly identified with the entry of substances used in their production. Where record of "Used for Production" or "Production" cannot be made immediately the manufacturer shall have available such batch tags, production orders, or other papers as may be required to evidence any unrecorded quantity used or produced. Any loss in manufacture, and any recoverable wastes salvaged from the manufacture shall be reported. All such wastes shall be returned to raw stock and included in the report of raw materials on hand at the end of the month. Any narcotic controlled substances listed in schedules I, II, and III actively in process of manufacture at the end of the month shall be so reported. Where substances are placed in process during one quarter and a portion of the production is removed from process as finished goods during the same quarter, the portion thus removed from process shall be reported "Produced" and the remainder reported as "In process" at the close of the period. Narcotic controlled substances listed in schedules I, II, and III placed in process for the manufacture of narcotic controlled substances listed in schedule V shall be reported on a separate BND Form 234c, on which the kind and quantity of narcotic used and the name of the substance to be produced therefrom shall be stated.

(e) All narcotic controlled substances listed in schedules I, II, and III, either bulk finished goods or goods already packaged, which are used during the quarter for packaging or repackaging into commercial containers shall be reported as credit entries in BND Form 234d, and in each instance clearly identified with the entry of substance used in such packaging. A separate entry shall be made for each different size of commercial container produced, but all entries representing a single packaging lot shall be grouped together. The number of commercial containers of a given size produced, the size of the commercial container (indicating the number of pills, tablets, ounces, etc.) the narcotic controlled substance contained in each unit in the commercial container, the total narcotic controlled substance content of each commercial container, and the aggregate narcotic controlled substance content of all commerical containers, represented by the entry shall be indicated. The recoverable wastes salvaged from the packaging operation and the losses in packaging shall be shown as credit entries on the form. All recoverable wastes reported during the quarter shall be returned to raw stock and further accounted for as raw materials. Any goods actively in process of packaging at the close of the quarter shall be so reported. Where substances are placed in process for packaging during one quarter and a portion thereof are removed as commercial containers produced and the remainder reported as in process at the end of the quarter.

(f) Each manufacturer and importer shall submit as a part of his fourth quarterly report (BND Form 234) an inventory (BND Form 234e) of narcotic controlled substances listed in schedules I, II, and III which are in his possession on December 31 of each year. The substances shall be classified as follows:

1. Raw materials;
2. Goods in process;
3. Finished bulk stock;
4. Finished goods in marketable commercial containers;
5. Miscellaneous stock.

8:65-5.22 Reports of distributors and exporters

(a) Every registered distributor except any officer or agency of the Veterans Administration or who or which is exempted from registration pursuant to 301.25 of the Act and registered exporter shall submit a monthly report on BND Form 235 and its supplements 235a and 235b accounting for all transactions involving narcotic controlled substances listed in

schedules I and II, including all receipts (BND Form 235a) and dispositions (BND Form 235b). The report shall be submitted to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month succeeding that for which the return is submitted.

(b) All narcotic controlled substances listed in schedules I and II received by a distributor or exporter shall be recorded on BND Form 235a in order and at the time of receipt. Where a record on BND Form 235a cannot, for any good and sufficient reason, be made immediately, the distributor or exporter shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or other receipt.

(c) All dispositions of narcotic controlled substances listed in schedules I and II, including distributions, exports, and losses, shall be reported on BND Form 235b. A separate sheet, properly headed in the space provided, shall be used for each different type of transaction. On each sheet separate entries shall be made of dispositions of each substance and of each different type and size of container or unit involved. All losses reported shall be fully explained.

(d) Each distributor and exporter shall submit, as part of his December 31 monthly report on BND Form 235 and its supplements, an inventory on BND Form 235c of narcotic controlled substances listed in schedules I and II which are in his possession on December 31 of each year. A separate entry shall be made for each narcotic substances as follows:

1. The name, quantity, and narcotic content of the drug or preparation;
2. The size of each commercial container; and
3. The number of commercial containers.

(e) The distributor and exporter shall report on BND Form 235 a complete summary of transactions for the month.

8:65-5.23 Reports from manufacturers importing opium

(a) Every manufacturer importing crude opium shall submit, in addition to the report on BND Form 234 and its supplements, BND Form 247 and its supplements, 247a and 247b, accounting for the importation and for all manufacturing operations performed between importation and the production in bulk of finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary, or other recognized medical standards. Subsequent manufacture from such products, including bottling or packaging operations, shall be accounted for in the quarterly returns on BND Form 234 and its supplements, BND Form 247 and its supplements shall be submitted quarterly to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537 on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from crude opium shall consist of summaries (BND Forms 247 and 247a) with supporting detail sheets (on BND Form 247b) accounting for original manufacture from crude opium, production from morphine for further manufacture and production from manufacturing opium, and also accounting for stocks and crude opium, manufacturing opium, morphine for further manufacture and other crude alkaloids.

(c) The detail sheets (BND Form 247b) supporting the summary of original manufacture from crude opium shall show separately the crude opium used for the manufacture of opium tinctures and extracts, crude opium used for the extraction of alkaloids, crude opium used for the manufacture of controlled substances listed in schedule V, and crude opium used for the production of manufacturing opium; and shall show separately the medicinal opium, alkaloids and salts, opium tinctures and extracts, controlled substances listed in schedule V, and manufacturing opium produced.

(d) Importation of opium shall be reported in summarized entries in the debit summary of the quarterly report (BND Form 234) and shall be immediately reported by similar summarized entries in the credit summary of the quarterly report (BND 234) as transferred to importing manufacturer's report. Such importations shall further be reported in summary (BND Form 247) and supporting detail sheets (BND Form 247) and supporting detail sheets (BND Form 247b). Products manufactured therefrom shall be reported as produced in accordance with subsection (b) and (c) of this Section and, with the exception of manufacturing opium, morphine for further manufacture, and other crude or unfinished alkaloids, shall be transferred to the quarterly report (BND Form 234) when reported produced.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. These assays shall be accounted for in terms of its anhydrous morphine alkaloid content. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Upon withdrawal of crude opium from customs custody, the importing manufacturer shall assign to each container an identification mark or number by which the opium will be associated with the lot assay and identified in reports.

(g) Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(h) Opium products and derivatives which are produced for exclusive use in further manufacturing purposes shall be reported produced when they come into existence in that form in which they are to be used. Medicinal opium, morphine and its salts, or other alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has

actually been completed and the finished marketable product ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Medicinal opium, tinctures, extracts, or other products manufactured partly for distribution and partly for use in further manufacture will be reported produced as soon as manufacture is complete and they are ready either for use in further manufacture or for packaging for distribution.

(i) Subject to N.J.A.C. 8:65-4.8 (c), no accumulations of morphine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process for an unreasonable time in light of efficient industrial practices. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks, and reported as produced.

(j) In making conversions of opium alkaloids and their salts to anhydrous morphine the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multiplied by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the respective molecular weight of such alkaloid or salt and the molecular weight of anhydrous morphine (285.16), such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopoeia.

8:65-5.24 Reports of manufacturers importing medicinal coca leaves

(a) Every manufacturer importing raw coca leaves for the manufacture of medicinal products shall submit, in addition to the report on BND Form 234 and its supplements, BND Form 168 and its supplements, 168a and 168b, accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopeia, National Formulary, or other recognized standards. Subsequent manufacture from such products, including bottling or packaging operations, shall be accounted for in quarterly reports on BND Form 234 and its supplements. Reports on Form 168 and its supplements shall be submitted quarterly to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from medicinal coca leaves shall consist of summaries (BND Forms 168 and 168a) with supporting detail sheets (BND Form 168b) accounting for original manufacture from such leaves, conversions or production from manufacturing coca extracts, and also accounting for stocks of raw coca leaves, manufacturing coca extracts, and other crude coca alkaloids.

(c) The detail sheets (BND Form 168b) supporting the summary of original manufacture from medicinal coca leaves, shall show separately the coca leaves used for the manufacture of manufacturing coca extracts, coca leaves used for the direct manufacture of marketable coca tinctures and extracts, and coca leaves used for the extraction of alkaloids, and shall show separately the coca alkaloids and salts, coca tinctures and extracts, and manufacturing coca extracts produced.

(d) Importations of medicinal coca leaves shall be reported in summarized entries in the debit summary of the quarterly report (BND Form 234) and shall be immediately reported by similar summarized entries in the credit summary of the quarterly report (BND Form 234) as transferred to importing manufacturer's report. Such importations shall further be reported in summary (BND Form 168) and supporting detail sheets (BND Form 168b). Products manufactured therefrom shall be reported as produced in accordance with subsection (h) of this Section and, with the exception of manufacturing coca extracts, residues or bases for further manufacture, and other crude or unfinished alkaloids, shall be transferred to the quarterly report (BND Form 234) when reported produced.

(e) Upon importation of medicinal coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submitting the report, the report shall be made on the basis of the best data available, subject adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Upon withdrawal of medicinal coca leaves from customs custody, the importing manufacturer shall assign to each bale or container an identification mark or number by which the coca leaves will be associated with the lot assay and identified in reports.

(g) Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

(h) Manufacturing coca extracts shall be reported as produced when they come into existence in that form in which they are intended for exclusive use in further manufacture. Cocaine and its salts, ecgonine and its salts, or other alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product is ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Tinctures, extracts, or other products manufactured partly for distribution and partly for use in further manufacture shall be reported produced as soon as manufacture is complete and they are ready

either for use in further manufacture or for packaging for distribution.

(i) No accumulations of cocaine or ecgonine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks and reported as produced.

(j) In making conversions of coca alkaloids and their salts to cocaine alkaloid and to anhydrous ecgonine alkaloid, the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multipled by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the molecular weight of such alkaloid or salt and the molecular weight of cocaine alkaloid (303.172) or anhydrous ecgonine alkaloid (185.125), as the case may be, such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopeia.

8:65-5.25 Reports from manufacturers importing special coca leaves

(a) Every manufacturer using special coca leaves imported into the United States shall submit a quarterly report (BND Form 249) accounting for all transactions involving such leaves or substances derived therefrom which contain cocaine or ecgonine, or any salts, derivatives, or preparations from which cocaine or ecgonine may be synthesized or made. This report shall be submitted to the Distribution Audit Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month following the period for which the report is made. Such report shall include a report of all importations of special coca leaves (BND Form 249a), a report of all materials entered into the processes of manufacture (BND Form 249b), a report of the various substances produced therefrom (BND Forms 249c, 249d, and 249e), a report of all such substances destroyed (BND Form 249f), and a summary of operations (BND Form 249g).

(b) The report of importations shall provide in appropriate columns the following data as to each importation:

1. The date of the import permit;
2. The serial number of the import permit;
3. The name of the foreign consignor;
4. The address of the foreign consignor;
5. The foreign port of export;
6. The number of bales imported;
7. The serial numbers of the bales imported; and
8. The quantity imported in avoirdupois pounds.

(c) The report of materials entered into the process of manufacture shall provide in appropriate columns the following information as to each lot of leaves dumped:

1. The lot number of specification, a specification to be assigned to each dump for identification purposes in order to avoid repeating the serial numbers of the bales when the lot is subsequently referred to;
2. The date the leaves entered into the process of manufacture;
3. The number of bales dumped;
4. The serial numbers of the bales;
5. The quantity of leaves entered into the process of manufacture, stated in avoirdupois pounds;
6. The quantity of alcohol used for each extraction or wash of the leaves;
7. The quantity of water used for each water extraction or dilution;
8. The quantity of any other or additional substance introduced at any stage into the process of manufacture; and
9. The dry weight of any filter cloth or other absorbent material to be later removed from the process after saturation.

(d) The reports of substances produced from special coca leaves shall provide in columns the following information as to each production lot or dump:

1. The lot number;
2. The quantity of ground leaves entered into process, in terms of avoirdurois ounces and the quantity, in ounces and grains, of alkaloid contained therein as determined by analysis;
3. The quantity of substance in process after each distinct step in the manufacturing process and the total alkaloid contained in each, stated in ounces and grains;
4. The quantity of exhausted or spent leaves and the quantity of each residue removed from process, and the total alkaloid contained in each, stated in ounces and grains;
5. The weight of the used filter cloth or other absorbent material removed, after saturations; and
6. The quantity, in gallons, of finished extract produced.

(e) The report of substances destroyed, shall provide in appropriate columns the following data as to each lot destroyed:

1. The lot numbers;
2. The quantity of spent leaves, residues, and saturated materials destroyed, stated separately for each; and
3. The name of the Government officer witnessing the destruction.

(f) The summary shall include a complete accounting for all transactions in raw leaves, leaves in process, and residues removed from production processes.

1. The summary of raw coca leaves shall include:
   i. The quantity of special coca leaves on hand at the beginning of the quarter;
   ii. The quantity of special coca leaves imported during the quarter;
   iii. The quantity of special coca leaves entered into the process of manufacture during the quarter;
   iv. The quantity of special coca leaves on hand at the end of the quarter; and
   v. Any other transaction during the quarter which increased or decreased the quantity of raw coca leaves on hand.

2. The summary of coca leaves in process shall include:
   i. The quantity of special coca leaves in process at the beginning of the quarter;
   ii. The quantity of such leaves placed in the process during the quarter;
   iii. The quantity of such leaves represented by lots completed during the quarter;
   iv. The quantity of such leaves represented by lots in process at the end of the quarter; and
   v. Any other transaction during the quarter which increased or decreased the quantity of leaves in process.
3. The summary of residues removed from production processes shall provide in appropriate columns, separately as to spent leaves, each residue and saturated material, the following information:
   i. The quantity of each, on hand at the beginning of the quarter, awaiting destruction;
   ii. The quantity of each removed from process during the quarter;
   iii. The quantity of each destroyed during the quarter;
   iv. The quantity of each on hand at the end of the quarter; and
   v. Any other transaction during the quarter affecting the quantity of such residues on hand.

SUBCHAPTER 6. ORDER FORMS

8:65-6.1 Scope

Procedures governing the issuance, use and preservation of order forms pursuant to section 308 of the Act (21 U.S.C. 828 are set forth generally by that section and specifically by the sections of this part.

8:65-6.2 Definitions

The following words and terms, when used in this Chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

"Purchaser" means any registered person entitled to obtain and execute order forms pursuant to Sections 4 and 6 of this Subchapter.

"Supplier" means any registered person entitled to fill order forms pursuant to Sections 8 of this Subchapter.

Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) and 301.02 and 302.02 of the Act, or N.J.S.A. 24:21-1 et seq.

8:65-6.3 Distribution requiring order forms

(a) An order form (BND Form 222c) is required for each distribution of a controlled substanced listed in schedule I or II, except for the following:
   1. The exportation of such substances from the United States in conformity with the Act;
   2. The delivery of such substances to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business (but excluding such carriage or storage by the owner of the substance in connection with the distribution to a third person);
   3. The procurement of a sample of such substances by an exempt law enforcement official pursuant to 316.04 (d) of the Act, provided that the receipt required by that section is used and is preserved in the manner prescribed in this part for order forms;
   4. The procurement of such substances by a civil defense or disaster relief organization, pursuant to 301.27 of the Act, provided that the civil defense emergency order form required by that section is used and is preserved with other records of the registrant; and
   5. The purchase of such substances by the master of a vessel pursuant to 301.28 (a) (3) of the Act; provided, that the special order form provided by the U.S. Public Health Service as required by that section is used and preserved in the manner prescribed on this order form.

8:65-6.4 Persons entitled to obtain and execute order forms

(a) Order forms may be obtained only by persons who are registered under section 303 of the Act (21 U.S.C. 823) to handle controlled substances listed in schedules I and II, and by persons who are registered under section 1008 of the Act (21 U.S.C. 958) to export such substances. Persons not registered to handle controlled substances listed in schedules I or II and persons registered only to import controlled substances listed in any schedule are not entitled to obtain order forms.

(b) An order form may be executed only on behalf of the registrant named thereon and only if his registration as to the substances being purchased has not expired or been revoked or suspended.

8:65-6.5 Procedure for obtaining order forms

(a) Order forms are issued in books of six forms, each form containing an original, duplicate and triplicate copy (respectively, Copy 1, Copy 2 and Copy 3). A limit of three books of forms will be furnished on any requisition, unless additional books are specifically requested and a reasonable need for such additional books is shown.

(b) Any person applying for a registration which would entitle him to obtain order forms may requisition such forms by so indicating on the application form; order forms will be supplied upon the registration of the applicant. Any person holding a registration entitling him to obtain order forms may requisition such forms for the first time on BND Form 222d, which may be obtained from the Registration Branch of the Bureau. Any person already holding order forms may requisition additional forms only on BND Form 222b, which is contained in each book of order forms. All requisitions shall be submitted to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005.

(c) Each requisition shall show the name, address, and registration number of the registrant and the number of books of order forms desired. Each requisition shall be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to Section 7 of this Subsection.

(d) Order forms will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Branch of the Bureau by returning the forms with notification of the error.

8:65-6.6 Procedure for executing order forms

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the BND Form 222c. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. There are five lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. The total number of items ordered shall be noted on that form in the space provided.

(c) An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item shall be made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item the form shall show the name of the article ordered, the finished or bulk form of the article (e.g., ten milligram tablet, ten-milligram concentration per fluid ounce or milliliter, or U.S.P.), the number of units or volume in each commercial or bulk container (e.g., 100-tablet bottle of three-milliliter vial) or the quantity or volume of each bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the article if not in pure form. The catalogue number of the article may be included at the discretion of the purchaser.

(d) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any one form.

(e) Each order form shall be signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to Section 5 (c) of this Subchapter. The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspections, or to enforce, any Federal, State or local law regarding controlled substances.

8:65-6.7 Power of attorney

(a) Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his behalf by filing a power of attorney on BND Form 231 for each such individual with the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005.

(b) The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and shall contain the signature of the individual being authorized to obtain and execute order forms, which individual shall affirm his signature.

(c) Any power of attorney may be revoked at any time by filing a notice of revocation, signed by the person who signed the power of attorney, with the Registration Branch at the foregoing address.

(d) It shall be necessary to submit a new power of attorney upon the reregistration of a purchaser only if the application for reregistration was signed by a person different from the person who signed the existing power of attorney.

8:65-6.8 Persons entitled to fill order forms

(a) An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in schedules I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

1. A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he is discontinuing business or if his registration is expiring without reregistration may dispose of any controlled substances listed in schedule I or II in his possession pursuant to order forms in accordance with N.J.A.C. 8:65-8.7;
2. A person who has obtained any controlled substance in schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance pursuant to the order form of the latter person; and
3. A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, N.J.A.C. 8:65-8.4.

8:65-6.9 Procedure for filling order forms

(a) The purchaser shall submit copy 1 and copy 2 of the order form to the supplier, and retain copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he desires to do so, and record on copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60

days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in Subsection (f) of this Section.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Bureau on the order form, except as specified in Subsection (f) of this Section.

(d) The supplier shall retain copy 1 of the order form for his own files and forward copy 2 to the regional director of the bureau in the region in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense Supply Agency for delivery to armed services established within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

8:65-6.10 Procedure for endorsing order forms

(a) An order form made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in N.J.A.C. 8:65-6.9 may be endorsed to another supplier for filling. The endorsement shall be made only by the supplier to whom the order form was first made, shall state (in the spaces provided on the reverse sides of Copies 1 and 2 of the order form) the name and address of the second supplier, and shall be signed by a person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The first supplier may not fill any part of an order on an endorsed form. The second supplier shall fill the order, if possible and if he desires to do so, in accordance with N.J.A.C. 8:65-6.9 (b), (c) and (d), including shipping all substances directly to the purchaser.

(b) Distribution made on endorsed order forms shall be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier shall record the name, address and registration number of the first supplier.

8:65-6.11 Unaccepted and defective order forms

(a) No order form shall be filled if it:
1. Is not complete, legible, or properly prepared, executed or endorsed; or
2. Shows any alteration, erasure, or change of any description.

(b) If an order form cannot be filled for any reason under this Section, the supplier shall return copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, copies 1 and 2 of the order form and the statement shall be attached to copy 3 and retained in the files of the purchaser in accordance with Section 13 of this Subchapter. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

8:65-6.12 Lost and stolen order forms

(a) If a purchaser ascertains that an unfilled order form has been lost, he shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with copy 3 of the order form first executed. A copy of the statement shall be attached to copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof "Not accepted" and return copies 1 and 2 to the purchaser, who shall attach it to copy 3 and the statement.

(b) Whenever any used or unused order forms are stolen from or lost (otherwise than in the course of transmission) by any purchaser or supplier, he shall immediately upon discovery of such theft or loss, report the same to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers.

(c) If an entire book of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the registration branch of the bureau shall immediately be notified.

8:65-6.13 Preservation of order forms

(a) The purchaser shall retain copy 3 of each order form which has been filled. He shall also retain in his files all copies of each unaccepted or defective order form and each statement attached thereto.

(b) The supplier shall retain copy 1 of each order form which he has filled.

(c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period

of two years. If a purchaser has several registered locations, he must retain copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to Section 6 (e) of this Subchapter at the registered location printed on the order form).

8:65-6.14 Return of unused order forms

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked pursuant to 301.45 or 301.46 of the Act as to all controlled substances listed in schedules I and II for which he is registered, he shall return all unused order forms for such substance to the nearest office of the Bureau.

8:65-6.15 Cancellation and voiding of order forms

(a) A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

(b) A supplier may void part or all of an order on an order form by notifying the purchaser in writing of such voiding. The supplier shall indicate the voiding in the manner prescribed for cancellation in Subsection (a) of this Section.

(c) No cancellation or voiding permitted by this section shall affect in any way contract rights of either the purchaser or the supplier.

8:65-6.16 Interim use of IRS order forms and requisitions

(a) Existing order forms (IRS Form 2513) will be valid until April 30, 1972, for transactions of controlled substances listed in schedule I and II. Purchasers using existing IRS Forms 2513 after April 30, 1972, must place the registration number assigned by the Bureau on the form in the block which contains the name, address, old IRS registration, and class of registration. Registrants who obtain BND Form 222c, but still possess IRS order forms, should not discard the IRS Forms, but instead draw a line thru the unused forms and print "Void" across the line. Voided forms must be maintained for at least two years in the manner prescribed in Section 13 of this Subchapter.

(b) Effective May 1, 1971, only the Bureau will issue order forms. A purchaser desiring order forms (BND Form 222c) may obtain them by using IRS Form 679 found in the back of his current IRS order form book. In utilizing IRS Form 679, the registration number assigned by the Bureau must be placed in section 8 of the requisition form and the requisition forwarded to Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005. IRS Form 679 will not be valid after April 30, 1972.

(c) An existing power of attorney filed for Internal Revenue Service order forms will be valid until the provisional registration of the registrant expires.

SUBCHAPTER 7. PRESCRIPTIONS

8:65-7.1 Scope

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

8:65-7.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801).

"Individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

"Institutional practitioner" means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

"Pharmacist" means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., a pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

"Prescription" means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

"Register" and "registered" refer to registration required and permitted by section 303 of the Act (21 U.S.C. 823).

Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or 301.02 of the Act.

8:65-7.2 Persons entitled to issue prescriptions

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession; and
2. Either registered or exempted from registration pursuant to 301.24(c) and 301.25 of the Act.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

8:65-7.3 Purpose of issue of prescription

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

8:65-7.4 Manner of issuance of prescription

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address, and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

(b) An intern, resident, or foreign-trained physician, or physician on the staff of a Veterans Administration facility, exempted from registration under 301.24 (c) shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in 301.24 (c) in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(c) An official exempted from registration under 301.25 shall include on all prescriptions issued by him his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

8:65-7.5 Persons entitled to fill prescriptions

A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

8:65-7.6 Dispensing of narcotic drugs for maintenance purposes

The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his professional practice or research" in section 308 (e) of the Act [21 U.S.C. 828 (e)]; provided, that approval is obtained prior to the initiation of such a program by submission of a notice of claimed investigational exemption for a New Drug to the Food and Drug Administration which will be reviewed concurrently by the Food and Drug Administration for scientific merit and by the Bureau for drug control requirements, and that the clinical investigation thereafter accords with such approval, as required in 130.44 of 21 U.S.C.

8:65-7.7 Requirement of prescription; schedule II

(a) A pharmacist may dispense directly a controlled substance listed in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in subsection (d) of this Section.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule II in the course of his professional practice without a prescription, subject to Section 6 of this Subchapter.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in 1.110 of 21 U.S.C., a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

1. The quantity prescribed and dispensed is limited

to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Section 4 of this Subchapter, except for the signature of the prescribing individual practitioner;
3. If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and
4. Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Section 4 of this Subchapter, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 72 hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Bureau if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

8:65-7.8 Refilling prescriptions; schedule II

The refilling of a prescription for a controlled substance listed in schedule II is prohibited.

8:65-7.9 Partial filling of prescription; schedule II

(a) The partial filling of a prescription for a controlled substance listed in schedule II is permissable, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription).

(b) The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within 72-hour period, the pharmacist shall so notify the prescribing individual practitioner.

(c) No further quantity may be supplied beyond 72 hours without a new prescription.

8:65-7.10 Labeling of substances; schedule II

The pharmacist filling a written or emergency oral prescription for a controlled substance listed in schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

8:65-7.11 Filing of prescriptions; schedule II

All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of N.J.A.C. 8:65-5.4.

8:65-7.12 Requirement of prescription; schedules III and IV

(a) A pharmacist may dispense directly a controlled substance listed in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required N.J.A.C. 8:65-7.4, except for the signature of the prescribing practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule III or IV in the course of his professional practice without a prescription, subject to Section 6 of this Subchapter.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule III or IV pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in N.J.A.C. 8:65-7.4 except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to Section 6 of this Subchapter.

8:65-7.13 Refilling of prescriptions; schedules III and IV

(a) No prescription for a controlled substance listed in schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times.

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate uniformly maintained, readily retrievable record, such as medication records, which indicates by the number of the prescription of the following information:

1. The name and dosage form of the controlled substance;
2. The date of each refilling;
3. The quantity dispensed;
4. The identity or initials of the dispensing pharmacist in each refilling; and

5. The total number of refills for that prescription, initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed.

(c) If the pharmacist merely initials and dates the back of the prescription he shall be deemed to have dispensed a refill for the full face amount of the prescription.

(d) Additional quantities of controlled substances listed in schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in Section 12 of this Subchapter which shall be a new and separate prescription.

8:65-7.14 Partial filling of prescriptions; schedules III and IV

(a) The partial filling of a prescription for a controlled substance listed in schedule III, IV, or V is permissible, provided that:

1. Each partial filling is recorded in the same manner as refilling;
2. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
3. No dispensing occurs after six months after the date on which the prescription was issued.

8:65-7.15 Labeling of substances; schedules III and IV

The pharmacist filling a prescription for a controlled substance listed in schedule III or IV shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

8:65-7.16 Filing prescriptions; schedule III and IV

All prescriptions for controlled substances listed in schedules III and IV shall be kept in accordance with 304.04 (d) of the Act.

8:65-7.17 Requirement of prescriptions; schedule V

(a) A pharmacist may dispense directly a controlled substance listed in schedule V pursuant to a prescription as required for controlled substances listed in schedules III and IV in Section 12 of this Subchapter. A prescription for a controlled substance listed in schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with Section 14 of this Subchapter and file the prescription in accordance with Section 15 of this Subchapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule V in the course of his professional practice without a prescription, subject to Section 6 of this Subchapter.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule V only pursuant to a written prescription signed by the prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in N.J.A.C. 8:65-7.4 except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to Section 6 of this Subchapter.

8:65-7.18 Dispensing without prescription

(a) A controlled substance listed in schedule V, and a controlled substance listed in schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

1. Such dispensing is made only by a pharmacist (as defined in Section 1 of this Subchapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);
2. Not more than 240 cc. (eight ounces) of any such controlled substance containing opium, nor more than 120 cc. (four ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;
3. The purchaser is at least 18 years of age;
4. The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);
5. A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record keeping requirement of N.J.A.C. 8:65-5.4); and
6. A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

SUBCHAPTER 8. MISCELLANEOUS

8:65-8.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

Any terms not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in 301.02 of 21 C.F.R.

8:65-8.2 Application of State law and other Federal law

Nothing in Parts 301-308, 311, 312, or 316 of Federal Regulations shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he desires to do such act nor shall compliance with such Parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

8:65-8.3 Exceptions to regulations

(a) Any person may apply for an exception to the application of any provision of Parts 301-308, 311, 312, or 316 of Federal Regulations by filing a written request stating the reasons for such exception.

(b) Requests shall be filed with the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(c) The Director may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

8:65-8.4 Distribution by dispenser to another practitioner

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his or its patients; provided that:

1. The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;
2. The distribution is recorded by the distributing practitioner in accordance with N.J.A.C. 8:65-5.17 (a) 5 and by the receiving practitioner in accordance with N.J.A.C. 8:65-5.17 (a) 3;
3. If the substance is listed in schedule I or II, an order form is used as required in Subchapter 6;
4. The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section during the 12-month period in which the practitioner is registered to dispense does not exceed 5 per cent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the 12-month period.

(b) If, at any time during the 12-month period during which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to this section will exceed five per cent of the total number of dosage units of all controlled substances distributed and dispensed by him during the 12-month period, the practitioner shall obtain a registration to distribute controlled substances.

8:65-8.5 Manufacture and distribution of narcotic solutions and compounds by a pharmacist

As an incident to a distribution under Section 4 of this Subchapter, a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 per cent of the complete solution, compound, or mixture.

8:65-8.6 Distribution to supplier

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer.

(b) In the case of returning a controlled substance listed in schedule I or II, an order form shall be used in the manner prescribed in Part 305 of the Act and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302 (c) or 1007 (b) (1) of the Act (21 U.S.C. 823 (c) or 957 (b) (1) shall be exempt from maintaining the records required by this section.

8:65-8.7 Distribution upon discontinuance or transfer of business

(a) Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall return his Certificate of Registration, and any unexecuted order forms in his possession, to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D. C. 20005 for cancellation. Any controlled substances in his possession may be disposed of either in accordance with Section 9 of this Subchapter or by transfer to another registrant. If the registrant desires to transfer the substance of another registrant, he shall take an inventory of all controlled substances which he desires to transfer and submit this inventory, together with his name, address, and registration number, and the name, address, and registration number of the proposed transferee, to the Regional Director of the Bureau in the region in which he is doing business at least 15 days in advance of the date of the proposed transfer. If the Regional Director does not notify the registrant that the transfer should be postponed or canceled, the registrant may transfer the substances to the named transferee without being registered as a distributor. All controlled substances listed in schedule I or II must be transferred pursuant to order forms in accordance to Part 305 of the Act. Schedule III, IV, and V substances will be transferred in

accordance to the inventory prepared by the registrant and submitted to the Regional Director. If the Regional Director denies the registrant authority to make the proposed transfer, the registrant shall either dispose of the substance in accordance with Section 9 of this Subchapter or transfer the substances to another registrant in accordance with this section and/or the instructions of the Regional Director.

(b) In the case of registrants required to make reports pursuant to Part 304 of the Act, a report marked "Final" will be prepared and submitted by the transferor registrant showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him, provided that no further transactions involving controlled substances are consummated by him. The initial report of the transferee registrant shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor registrant, and the substances transferred to him shall be reported as receipts of his initial report.

8:65-8.8 Incidental manufacture of controlled substances

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to Part 303 of the Act (if such substance or class is listed in schedule I or II) shall be exempt from the requirement of registration pursuant to Part 301 of the Act and, if such incidentally manufactured substance is listed in schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to Part 303 of the Act, if such substances are disposed of in accordance with 307.21, C.F.R.

8:65-8.9 Procedure for disposing of controlled substances

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Regional Director of the Bureau in the region in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

1. If the person is a registrant required to make reports pursuant to Part 304 of the Act, he shall list the controlled substance or substances which he desires to dispose of on the "b" subpart of the report normally filed by him, and submit three copies of that subpart to the Regional Director of the Bureau in his region;
2. If the person is a registrant not required to make reports pursuant to Part 304 of the Act, he shall list the controlled substance or substances which he desires to dispose of on BND Form 41, and submit three copies of that form to the Regional Director in his region; and
3. If the person is not a registrant he shall submit to the Regional Director a letter stating:
   i. The name and address of the person;
   ii. The name and quantity of each controlled substance to be disposed of;
   iii. How the applicant obtained the substance, if known; and
   iv. The name, address, and registration number, if known of the person who possessed the controlled substance prior to the applicant, if known.

(b) The Regional Director shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

1. By transfer to person registered under the Act and authorized to possess the substance;
2. By delivery to an agent of the Bureau or to the nearest office of the Bureau;
3. By destruction in the presence of an agent of the Bureau or other authorized person; or
4. By such other means as the Regional Director may determine to assure that the substance does not become available to unauthorized persons.

(c) This Section shall not be constructed as affecting or alerting in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

8:65-8.10 Disposal of controlled substances by the Bureau

(a) Any controlled substance delivered to the Bureau under Section 9 of this Subchapter or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(b) The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended.

(c) The delivery of such controlled drugs shall be ordered by the Director, if, in his opinion, there exists a medical or scientific need therefor.

8:65-8.11 Native American Church

The listing of peyote as a controlled substance in schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.

SUBCHAPTER 9. ADMINISTRATIVE FUNCTIONS, PRACTICES AND PROCEDURES

8:65-9.1 Scope, administrative inspections

Procedures regarding administrative inspections and warrants pursuant to sections 302(f), 510, 1008(d), and 1015 of the Act (21 U.S.C. 822(f), 880, 958(d), and 965)

are governed generally by those sections and specifically by the Sections of this Subchapter.

8:65-9.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

"Bureau" means the Bureau of Narcotics and Dangerous Drugs.

"Controlled premises" means—

1. Places where original or other records or documents required under the Act are kept or required to be kept, and
2. Places, including factories, warehouses, or other establishments, and conveyances, where persons registered under the Act or exempted from registration under the Act may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances.

"Director" means the Director of the Bureau. The Director has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

"Inspector" means an officer or employee of the Bureau authorized by the Director to make inspections under the Act.

"Register" and "registration" refer to registration required and permitted by sections 303 and 1008 of the Act (21 U.S.C. 823 and 958). Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951).

8:65-9.3 Authority to make inspections

(a) In carrying out his functions under the Act, the Director, through his inspectors, is authorized in accordance with Sections 510 and 1015 of the Act (21 U.S.C. 880 and 965) to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

1. Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and the regulations promulgated under the Act, including but not limited to inventory and other records required to be kept pursuant to Part 304 of the Act, order form records required to be kept pursuant to Part 305 of the Act, prescription and distribution records required to be kept pursuant to Part 306 of the Act, shipping records identifying the name of each carrier used and the date and quantity of each shipment and storage records identifying the name of each warehouseman used and the date and quantity of each storage;
2. Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;
3. Making a physical inventory of all controlled substances on-hand at the premises;
4. Collecting samples of controlled substances or precursors (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on BND Form 84 to the owner, operator, or agent in charge of the premises);
5. Checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased within the past year, and if so why); and
6. Except as provided in Section 4 of this Subchapter, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder.

8:65-9.4 Exclusion from inspection

(a) Unless the owner, operator or agent in charge of the controlled premises so consents in writing, no inspection authorized by these regulations shall extend to:

1. Financial data;
2. Sales data other than shipping data; or
3. Pricing data.

8:65-9.5 Entry

An inspection shall be carried out by an inspector. Any such inspector, upon stating his purpose and presenting to the owner, operator or agent in charge of the premises to be inspected, appropriate credentials, and written notice of his inspection authority under 314.06 of the Act, and receiving informed consent under Section 8 of this Subchapter or through the use of administrative warrant issued under Sections 9 through 14 of this Subchapter, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

8:65-9.6 Notice of inspection

(a) The notice of inspection (BND Form 82) shall contain:

1. The name and title of the owner, operator, or agent in charge of the controlled premises;
2. The controlled premises name;
3. The address of the controlled premises to be inspected;
4. The date and time of the inspection;
5. A statement that a notice of inspection is given pursuant to section 510 of the Act (21 U.S.C. 880);
6. A reproduction of the pertinent parts of section 510 of the Act; and
7. The signature of the inspector.

8:65-9.7 Requirement for administrative inspection warrant; exceptions

(a) In all cases where an inspection is contemplated, an administrative inspection warrant is required pursuant to section 510 of the Act (21 U.S.C. 880), except that such warrant shall not be required for establish-

ments applying for initial registration under the Act, for the inspection of books and records pursuant to an administrative subpoena issued in accordance with section 506 of the Act (21 U.S.C. 876) nor for entries in administrative inspections (including seizures of property):

1. With the consent of the owner, operator, or agent in charge of the controlled premises as set forth in Section 8 of this Subchapter;
2. In situations presenting imminent danger to health or safety;
3. In situations involving inspection of conveyances where there is reasonable cause to obtain a warrant;
4. In any other exceptional or emergency circumstances or time or opportunity to apply for a warrant is lacking; or
5. In any other situations where a warrant is not constitutionally required.

8:65-9.8 Consent to inspection

(a) An administrative inspection warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected.

(b) Wherever possible, informed consent shall consist of a written statement signed by the owner, operator, or agent in charge of the premises to be inspected and witnessed by two persons. The written consent shall contain the following information:

1. That he (the owner, operator, or agent in charge of the premises) has been informed of his constitutional right not to have an administrative inspection made without an administrative inspection warrant;
2. Of his right to refuse to consent to such an inspection;
3. Of the possibility that anything of an incriminating nature which may be found may be seized and used against him in a criminal prosecution;
4. That he has been presented with a notice of inspection as set forth in Section 6 of this Subchapter.
5. That the consent is given by him is voluntary and without threats of any kind; and
6. That he may withdrawn his consent at any time during the course of inspection.

(c) The written consent shall be produced in duplicate and be distributed as follows:

1. The original will be retained by the inspector; and
2. The duplicate will be given to the person inspected.

8:65-9.9 Application for administrative inspection warrant

(a) An administrative inspection warrant application shall be submitted to any judge of the United States or of a State court of record, or any United States magistrate and shall contain the following information:

1. The name and address of the controlled premises to be inspected;
2. A statement of statutory authority for the administrative inspection warrant, and that the fact that the particular inspection in question is designed to insure compliance with the Act and the regulations promulgated thereunder;
3. A statement relating to the nature and extent of the administrative inspection, including, where necessary, a request to seize specified items and/or to collect samples of finished or unfinished controlled substances;
4. A statement that the establishment either:
   i. Has not been previously inspected, or
   ii. Was last inspected on a particular date.

(b) The application shall be submitted under oath to an appropriate judge or magistrate.

8:65-9.10 Administrative probable cause

(a) If the judge or magistrate is satisfied that "administrative probable cause," as defined in section 510(d) (1) of the Act (21 U.S.C. 880 (d) (1)) exists, he shall issue an administrative warrant.

(b) Administrative probable cause shall not mean criminal probable cause as defined by Federal statute or case law.

8:65-9.11 Execution of warrants

(a) An administrative inspection warrant shall be executed and returned as required by, and any inventory or seizure made shall comply with the requirements of, section 510(d) (3) of the Act (21 U.S.C. 880(d) (3)).

(b) The inspection shall begin as soon as is practicable after the issuance of the administrative inspection warrant and shall be completed with reasonable promptness.

(c) The inspection shall be conducted during regular business hours and shall be completed in a reasonable manner.

8:65-9.12 Refusal to allow inspection with an administrative warrant

If a registrant or any person subject to the Act refuses to permit execution of an administrative warrant or impedes the inspector in the execution of that warrant, he shall be advised that such refusal or action constitutes a violation of section 402(a) (6) of the Act (21 U.S.C. (a) (6)). If her persists and the circumstances warrant, he shall be arrested and the inspection shall commence or continue.

8:65-9.13 Frequency of administrative inspections

Except where circumstances otherwise dictate, it is the intent of the Bureau to inspect all manufacturers of controlled substances listed in schedules I and II and distributors of controlled substances listed in schedule I once each year; and to inspect all distributors of controlled substances listed in schedules II through V and manufacturers of controlled substances listed in schedules III through V once every three years.

8:65-9.14 Confidentiality of research subjects

(a) Any person registered to conduct research in controlled substances under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801), who intends to

maintain the confidentiality of those persons who are the subjects of such research, shall, upon registration or within a reasonable time thereafter, submit to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537, a separate request for each research project involving controlled substances, which shall contain the following:

1. The researcher's registration number for that project;
2. The location of the research project;
3. A general description of the research or a copy of the research protocol;
4. A specific request to withhold the names and/or any other identifying characteristics of the research subjects; and
5. The reasons supporting the request.

(b) Within 30 days from the date of receipt of the request, the Director shall issue a letter, either granting confidentiality, requesting additional information, or denying confidentiality, in which case the reasons for the denial shall be limited solely to the specific research project indicated in the request.

(c) Within 30 days after the date of completion of the research project, the researcher shall so notify the Director.

8:65-9.15 Exemption from prosecution for researcher

(a) Upon registration of a practitioner to engage in research in controlled substances under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801), the Director of the Bureau of Narcotics and Dangerous Drugs, on his own motion or upon request in writing from the Secretary or from the practitioner, shall exempt the registrant when acting within the scope of his registration from prosecution under Federal, State, or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his exemption. However, this exemption does not diminish any requirement of compliance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301).

(b) The exemption shall consist of a letter issued by the Director, which shall include:

1. The researcher's name and address;
2. The researcher's registration number from the research project;
3. The location of the research project;
4. A concise statement of the scope of the researcher's registration; and
5. The limits of the exemption.

(c) The exemption shall apply to all acts done in the scope of the exemption while the exemption is in effect. The exemption shall remain in effect until completion of the research project or until the registration of the research is either revoked or suspended or his renewal of registration is denied. Within 30 days of the date of completion of the research project, the researcher shall so notify the Director. The Director shall issue another letter including the information required in Subsection (b) of this Section and stating the date on which the period of exemption concluded; upon receipt of this letter, the researcher shall return the original letter of exemption.

8:65-9.16 Authority for enforcement proceeding

A hearing may be ordered or granted by any Regional Director of the Bureau of Narcotics and Dangerous Drugs, at his discretion, to permit any person against whom criminal and/or civil action is contemplated under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951) an opportunity to present his views and his proposals for bringing his alleged violations into compliance with the law. Such hearing will also permit him to show cause why prosecution should not be instituted, or to present his views on the comtemplated proceeding.

8:65-9.17 Notice of proceeding; time and place

Appropriate notice designating the time and place for the hearing shall be given to the person. Upon request, timely and properly made, by the person to whom notice has been given, the time or place of the hearing, or both, may be changed if the request states reasonable grounds for such change. Such request shall be addressed to the Regional Director who issued the notice.

8:65-9.18 Conduct of proceeding

(a) Presentation of views at a hearing under this Subchapter shall be private and informal.

(b) The views presented shall be confined to matters relevant to bringing violations into compliance with the Act or to other contemplated proceedings under the Act. These views may be presented orally or in writing by the person to whom the notice was given, or by his authorized representative.

8:65-9.19 Records of proceeding

(a) A formal record, either verbatim or summarized, of the hearing may be made at the request of either the Regional Director or the person for whom the hearing is being conducted.

(b) If such record is to be made at the request of the Regional Director, the person attending the hearing will be so advised prior to the start of the hearing.

8:65-9.20 Scope; administrative hearings

Procedures in any administrative hearing held under the Act are governed generally by the rule making and/or adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by the procedures set forth in this Subchapter, except where more specific regulations (set forth in 301.51-301.57, 303.41-303.47, or 308.41-308.51 of the Act) apply.

8:65-9.21 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

"Director" means the Director of the Bureau. The Direc-

tor has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

"Hearing" means any hearing held pursuant to the Act.

"Hearing clerk" means the hearing clerk of the Bureau.

"Person" includes an individual, corporation, government or governmental subdivision or agency, business trust, partnership, association or other legal entity.

"Presiding officer" means a hearing examiner qualified and appointed as provided in the Administrative Procedure Act, (5 U.S.C. 556).

"Proceeding" means all actions involving a hearing, commencing with the publication by the Director of the notice of proposed rule making or the issuance of an order to show cause.

Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) and in 301.02 of CFR.

8:65-9.22 Information; special instructions

Information regarding procedure under these rules and instructions supplementing these rules in special instances will be furnished by the hearing clerk upon request.

8:65-9.23 Waiver or modification of rules

(a) The Director or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this Subchapter by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served.

(b) Such notice of modification or waiver shall be made a part of the record of the hearing.

8:65-9.24 Filings; address; hours

(a) Documents required or permitted to be filed in, and correspondence relating to, hearings governed by the regulations in this chapter shall be filed with the Hearing Clerk, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(b) This office is open Monday through Friday from 9 a.m. to 5:30 p.m. eastern standard or daylight saving time, whichever is effective in the District of Columbia at the time, except on national legal holidays.

(c) Documents shall be dated and deemed filed upon receipt by the Hearing Clerk.

8:65-9.25 Inspection of record

(a) The record bearing on any proceeding, except for material described in subsection (b) of this Section, shall be available for inspection and copying by any person entitled to participate in such proceeding, during office hours in the office of the Hearing Clerk, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537.

(b) The following material shall not be available for inspection as part of the record:

1. A research protocol filed with an application for registration to conduct research with controlled substances listed in schedule I, pursuant to 301.32 (a) (3) of the Act, if the applicant requests that the protocol be kept confidential;
2. An outline of a production or manufacturing process filed with an application for registration to manufacture a new narcotic controlled substance, pursuant to 301.33 of the Act, if the applicant requests that the outline be kept confidential;
3. Any confidential or trade secret information disclosed in conjunction with an application for registration, or in reports filed while registered, or acquired in the course of an investigation, entitled to protection under subsection 402(a) (8) of the Act (21 U.S.C. 842 (a) (8)) or any other law restricting public disclosure of information; and
4. Any material contained in any investigatory report, memorandum, or file, or case report compiled by the Bureau.

8:65-9.26 Request for hearing

Any person entitled to a hearing and desiring a hearing shall, within the period permitted for filing, file a request for a hearing in the following form:

(Date)

DIRECTOR, BUREAU OF NARCOTICS
AND DANGEROUS DRUGS,
Department of Justice,
Washington, D. C. 20537

Attention: Hearing Clerk, Office of Chief Counsel.

Dear Sir: The undersigned ..... hereby requests a hearing in the matter of: .....

.....

(Identification of the proceeding) (person)

(A) (State with particularity the interest of the person in the proceeding.)

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.)

(C) (State briefly the position of the person with regard to the particular objections or issues.)

All notices to be sent pursuant to the proceeding should be addressed to:

(Name) _____

(Street address) _____

(City and State) _____

Respectfully yours,

(Signature of person) _____

8:65-9.27 Notice of appearance

Any person entitled to a hearing and desiring to appear in any hearing, shall, if he has not filed a request for hearing, file within the time specified in the notice of proposed

rule making, a written notice of appearance in the following form:

(Date)

DIRECTOR, BUREAU OF NARCOTICS
AND DANGEROUS DRUGS,
Department of Justice,
Washington, D. C. 20537

Attention: Hearing Clerk, Office of Chief Counsel.
DEAR SIR: Please take notice that ..... will appear in the matter of: .....
.....
(Identification of the proceeding)
(Name)

(A) (State with particularity the interest of the person in the proceeding.)
(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.)
(C) (State briefly the position of the person with regard to the particular objections or issues.)

All notices to be sent pursuant to this appearance should be addressed to:

(Name)_____

(Street address)_____

(City and State)_____

Respectfully yours,

(Signature of person)_____

8:65-9.28 Waiver of hearing

Any person entitled to a hearing may, within the period permitted for filing a request for hearing or notice of appearance, waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

8:65-9.29 Appearance; representation; authorization

(a) Any person entitled to appear in a hearing may appear in person or by a representative in any proceeding or hearing and may be heard with respect to matters relevant to the issues under consideration.

(b) A representative must either be an employee of the person or an attorney at law who is a member of the bar, in good standing, of any State, territory, or the District of Columbia, and admitted to practice before the highest court of that jurisdiction.

(c) Any representative may be required by the Director or the presiding officer to present a notarized power of attorney showing his authority to act in such representative capacity and/or an affidavit or certificate of admission to practice.

8:65-9.30 Conduct of hearing and parties; ex parte communications

(a) Hearings shall be conducted in an informal but orderly manner in accordance with law and the directions of the presiding officer.

(b) Participants in any hearing and their representatives, whether or not members of the bar, shall conduct themselves in accordance with judicial standards of practice and ethics and the directions of the presiding officer. Refusal to comply with this Section shall constitute grounds for immediate exclusion from any hearing.

(c) If any official of the Bureau is contacted by any individual in private or public life concerning any substantive matter which is the subject of any hearing, at any time after the date on which the proceedings commence, the official who is contacted shall prepare a memorandum setting forth the substance of the conversation and shall file this memorandum in the appropriate public docket file. The presiding officer and employees of the Bureau shall comply with the requirements of 5 U.S.C. 554 (d) regarding ex parte communications and participation in any hearing.

8:65-9.31 Presiding officer

(a) A presiding officer, designated by the Director, shall preside over all hearings.

(b) The functions of the presiding officer shall commence upon his designation and terminate upon the certification of the record to the Director.

(c) The presiding officer shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He shall have all powers necessary to these ends, including (but not limited to) the power to:

1. Arrange and change the date, time and place of hearings (other than the time and place prescribed in 301.60) and prehearing conferences and issue notice thereof.
2. Hold conferences to settle, simplify, or determine the issues in a hearing, or to consider other matters that may aid in the expeditious disposition of the hearing.
3. Require parties to state their position in writing with respect to the various issues in the hearing and to exchange such statements with all other parties.
4. Examine witnesses and direct witnesses to testify.
5. Receive, rule on, exclude, or limit evidence.
6. Rule on procedural items pending before him.
7. Take any action permitted to the presiding officer as authorized by this chapter or by the provisions of the Administrative Procedure Act (5 U.S.C. 551-559).

8:65-9.32 Time and place of hearing

The hearing will commence at the place and time designated in the notice of hearing published in the Federal Register but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

8:65-9.33 Prehearing conference

(a) The presiding officer on his own motion, or on the motion of any party for good cause shown, may direct all parties to appear at a specified time and place for a conference for:

1. The simplification of the issues.
2. The possibility of obtaining stipulations, admission of facts, and documents.
3. The possibility of limiting the number of expert witnesses.
4. The identification and, if practicable, the scheduling of all witnesses to be called.
5. The advance submission at the prehearing conference of all documentary evidence and affidavits to be marked for identification.
6. Such other matters as may aid in the expeditious disposition of the hearing.

8:65-9.34 Prehearing ruling

(a) The presiding officer may have the prehearing conference reported verbatim and shall make a ruling reciting the action taken at the conference, the agreements made by the parties, the schedule of witnesses, and a statement of the issues for hearing.

(b) Such ruling shall control the subsequent course of the hearing unless modified by a subsequent ruling.

8:65-9.35 Burden of proof

At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.

8:65-9.36 Submission of documentary evidence and affidavits and identification of witnesses subsequent to prehearing conference

(a) All documentary evidence and affidavits not submitted and all witnesses not identified at the prehearing conference shall be submitted or identified to the presiding officer as soon as possible, with a showing that the offering party had good cuase for failing to so submit or identify at the prehearing conference.

(b) If the presiding officer determines that good cause does exist, the documents or affidavits shall be submitted or witnesses identified to all parties sufficiently in advance of the offer of such documents or affidavits or witnesses at the hearing to avoid prejudice or surprise to other parties.

(c) If the presiding officer determines that good cause does not exist, he may refuse to admit as evidence such documents or affidavits or the testimony of such witnesses.

8:65-9.37 Summary of testimony; affidavits

(a) The presiding officer may direct that summaries of the direct testimony of witnesses be prepared in writing and served on all parties in advance of the hearing. Witnesses will not be permitted to read summaries of their testimony into the record and all witnesses shall be available for cross-examination. Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) Affidavits submitted at the prehearing conference or pursuant to Section 36 of this Subchapter with good cause may be examined by all parties and opposing affidavits may be submitted to the presiding officer within a period of time fixed by him. Affidavits admitted into evidence shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to statements made therein.

8:65-9.38 Submission and receipt of evidence

(a) The presiding officer shall admit only evidence that is competent, relevant, material and not unduly repetitious.

(b) Opinion testimony shall be admitted when the presiding officer is satisfieid that the witness is properly qualified.

(c) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the presiding officer, except that a party will be permitted to challenge such authenticity at a later time upon showing of good cause for failure to have filed such written objection.

(d) Samples, if otherwise admissible into evidence, may be displayed at the hearing and may be described for purposes of the record, or may be admitted in evidence as exhibits.

(e) Where official notice is taken or is to be taken of a material fact not appearing in the evidence of record, any party, on timely request, shall be afforded opportunity to controvert such fact.

(f) The presiding officer shall file as exhibits copies of the following documents:

1. The order to show cause or notice of hearing;
2. Any notice of waiver or modification of rules made pursuant to 316.44 or otherwise;
3. Any waiver of hearing (together with any statement filed therewith) filed pursuant to Section 28 of this Subchapter or otherwise;
4. The prehearing ruling, if any, made pursuant to Section 34 of this Subchapter;
5. Any other document necessary to show the basis for the hearing.

8:65-9.39 Objections; offer of proof

(a) If any party in the hearing objects to the admission or rejection of any evidence or to other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection without extended argument or debate thereon except as permitted by the presiding officer.

(b) A ruling of the presiding officer on any such objection shall be a part of the transcript, together with such offer of proof as has been made if a proper foundation has been laid for its admission.

(c) An offer made in connection with an objection taken to any ruling of the presiding officer rejecting or excluding proffered oral testimony shall consist of a statement of the substance of the evidence which the party contends would be adduced by such testimony; and, if the excluded evidence consists of evidence in

documentary or written form a copy of such evidence shall be marked for identification and shall accompany the records as the offer of proof.

8:65-9.40 Exceptions to rulings

(a) Exceptions to rulings of the presiding officer are unnecessary.

(b) It is sufficient that a party, at the time the ruling of the presiding officer is sought, makes known the action that he desires the presiding officer to take, or his objection to an action taken, and his grounds therefor.

8:65-9.41 Appeal from ruling of presiding officer

(a) Rulings of the presiding officer may not be appealed to the Director prior to his consideration of the entire hearing, except with the consent of the presiding officer and where he certifies on the record or in writing that the allowance of an interlocutory appeal is clearly necessary to prevent exceptional delay, expense, or prejudice to any party or substantial detriment to the public interest.

(b) If an appeal is allowed, any party in the hearing may file a brief in quintuplicate with the Director within such period that the presiding officer directs.

(c) No oral argument will be heard unless the Director directs otherwise.

8:65-9.42 Official transcript; index; corrections

(a) Testimony given at a hearing shall be reported verbatim. The Bureau will make provision for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purpose. Any person desiring a copy of the transcript of the testimony and exhibits taken at the hearing or of any part thereof (except such materials as are described in 316.46(b)) shall be entitled to the same upon application to the Hearing Clerk of the Bureau and upon payment of the cost thereof.

(b) At the close of the hearing, the presiding officer shall afford the parties and witnesses time (not longer than 30 days, except in unusual cases) in which to submit written proposed corrections of the transcript, pointing out errors that may have been made in transcribing the testimony. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony.

8:65-9.43 Proposed findings of fact and conclusions of law

(a) Any party in the hearing may file in quantuplicate proposed findings of fact and conclusions of law within the time fixed by the presiding officer.

(b) Any party so filing shall also serve one copy of his proposed findings and conclusion upon each other party in the hearing.

(c) The party shall include a statement of supporting reasons for the proposed findings and conclusions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of authorities relied upon.

8:65-9.44 Report and record

(a) As soon as practicable after the time for the parties to file proposed findings of fact and conclusion of law has expired, the presiding officer shall prepare a report containing the following:

1. His recommended rulings on the proposed findings of fact and conclusions of law;
2. His recommended findings of fact and conclusions of law, with the reasons therefor; and
3. His recommended decision.

(b) The presiding officer shall certify to the Director the record, which shall contain the transcript of testimony, exhibits, the findings of fact and conclusions of law proposed by the parties, and his report. Upon receipt of the certified record, the Director shall serve one copy of the report of the presiding officer upon each party in the hearing.

8:65-9.45 Final order

(a) As soon as practicable after the presiding officer has certified the record to the Director, the Director shall cause to be published in the Federal Register his order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based.

(b) This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the Federal Register unless the Director finds that emergency conditions exist necessitating an earlier effective date, in which event the Director shall specify in the order his findings as to such conditions.

8:65-9.46 Copies of petitions for judicial review

(a) Copies of petitions for judicial review, filed pursuant to section 507 of the Act (21 U.S.C. 877) shall be delivered to and served upon the Director in quintuplicate.

(b) The Director shall certify the record of the hearing and shall file the certified record in the appropriate U.S. Court of Appeals.

8:65-9.47 Definitions; seizure, forfeiture and disposition of property

The following words and terms, when used in this Chapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

"Custodian" means the officer required under 316.72 C.F.R. to take custody of particular property which has been seized pursuant to the Act.

"Property" means a controlled substance, raw material, product, container, equipment, vessel, vehicle, or aircraft within the scope of the Act.

"Seizing officer," "officer seizing," etc., means any officer, authorized and designated by 316.72 C.F.R. to carry out the provisions of the Act, who initially seizes

property or adopts a seizure initially made by any other officer or by a private person.

"Regional Director" means the Regional Director of the Bureau. Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in 301.02 of C.F.R.

8:65-9.48 Officers who will make seizures

For the purpose of carrying out the provisions of the Act, all special agents of the Bureau are authorized and designated to seize such property as may be subject to seizure.

8:65-9.49 Custody and other duties

(a) An officer seizing property under the Act shall store the property in a location designated by the custodian, generally in the judicial district of seizure.

(b) The Regional Directors are designated as custodians to receive and maintain in storage all property seized pursuant to the Act.

(c) The Regional Directors are also authorized to dispose of any property pursuant to the Act and any other applicable statutes or regulations relative to disposal, and to perform such other duties regarding such seized property as are imposed on the District Directors of the U.S. Bureau of Customs with respect to seizures under the customs laws.

8:65-9.50 Appraisement

(a) The custodian shall appraise the property to determine the domestic value at the time and place of seizure.

(b) The domestic value shall be considered the retail price at which such or similar property is freely offered for sale.

(c) If there is no market for the property at the place of seizure, the domestic value shall be considered the value in the principal market nearest the place of seizure.

8:65-9.50 Advertisement

(a) If the appraised values does not exceed $2,500.00, the custodian shall cause a notice of the seizure and of the intention to forefeit and sell or otherwise dispose of the property to be published once a week for at least 3 successive weeks in a newspaper of general circulation in the judicial district in which the seizure occurred.

(b) The notice shall:

1. Describe the property seized and show the motor and serial numbers, if any;
2. State the time, cause, and place of seizure; and
3. State that any person desiring to claim the property may, within 20 days from the date of first publication of the notice, file with the custodian a claim to the property and a bond with satisfactory sureties in the sum of $250,00.

8:65-9.51 Requirements as to claim and bond

(a) The bond shall be rendered to the United States, with sureties to be approved by the custodian, conditioned that in the case of condemnation of the property the obligor shall pay all costs and expenses of the proceedings to obtain such condemnation. When the claim and bond are received by the custodian, he shall, after finding the documents in proper form and the sureties satisfactory, transmit the documents, together with a description of the property and a complete statement of the facts and circumstances surrounding the seizure, to the United States Attorney for the judicial district in which the seizure was made for the purpose of proceeding to a condemnation of the property in the manner prescribed by law. If the documents are not in satisfactory condition when first received, a reasonable time for correction may be allowed. If correction is not made within a reasonable time the documents may be treated as nugatory, and the case shall proceed as though they had not been tendered.

(b) The filing of the claim and the posting of the bond does not entitle the claimant to possession of the property, however, it does stop the summary forfeiture proceedings. The bond posted to cover costs may be in cash, certified check, or on Treasury Department Form 171 with satisfactory sureties. The costs and expenses secured by the bond are such as are incurred after the filing of the bond including storage cost, safeguarding, court fees, marshal's costs, and so forth.

8:65-9.52 Summary forfeiture

(a) If the appraised value does not exceed $2,500.00, and a claim and bond are not filed within the 20 days hereinbefore mentioned, the custodian shall declare the property forfeited.

(b) The custodian shall prepare the declaration of forfeiture and forward it to the Director of the Bureau as notification of the action he has taken.

(c) Thereafter, the property shall be retained in the custodian's district or delivered elsewhere for official use, or otherwise disposed of, in accordance with official instructions received by the custodian.

8:65-9.53 Judicial forfeiture

If the appraised value is greater than $2,500.00 or a claim and satisfactory bond have been received for property appraised at $2,500.00 or less, the custodian shall transmit a description of the property and a complete statement of the facts and circumstances surrounding the seizure to the U.S. Attorney for the judicial district in which the seizure was made for the purpose of instituting condemnation proceedings. The U.S. Attorney shall also be furnished the newspaper advertisements required by Section 50 of this Subchapter.

8:65-9.54 Petitions for remission or mitigation of forfeiture

(a) Any person interested in any property which has been seized, or forfeited either summarily or by court proceedings, may file a petition for remission or mitigation of the forfeiture. Such petition shall be filed in triplicate with the Regional Director for the judicial district in which the seizure occurred. It shall be addressed to the Director if the property is subject to summary forfeiture pursuant to Section 52 of this Subchapter, and addressed to the Attorney General

if the property is subject to judicial forfeiture pursuant to Section 53 of this Subchapter. The petition must be executed and sworn to by the person alleging interest in the property.

(b) The petition shall include the following:

1. A complete description of the property, including motor serial numbers, if any, and the date and place of seizure;
2. The petitioner's interest in the property, which shall be supported by bills of sale, contracts, mortgages, or other satisfactory documentary evidence; and
3. The facts and circumstances, to be established by satisfactory proof, relied upon by the petitioner to justify remission or mitigation.

(c) Where the petition is for restoration of the proceeds of sale, or for value of the property placed in official use, it must be supported by satisfactory proof that the petitioner did not know of the seizure prior to the declaration of condemnation of forfeiture and was in such circumstances as prevented him from knowing of the same.

8:65-9.55 Time for filing petitions

(a) In order to be considered as seasonably filed, a petition for remission or mitigation of forfeiture should be filed within 30 days of the receipt of the notice of seizure. If a petition for remission or mitigation of forfeiture has not been received within 30 days of the notice of seizure, the property will either be placed in official government service or sold as soon as it is forfeited. Once property is placed in official use, or is sold, a petition for remission or mitigation of forfeiture can no longer be accepted.

(b) A petition for restoration of proceeds of sale, or for the value of property placed in official use, must be filed within 90 days of the sale of property, or within 90 days of the date the property is placed in official use.

8:65-9.56 Handling of petitions

Upon receipt of a petition, the custodian shall request an appropriate investigation. The petition and the report of investigation shall be forwarded to the Director. If the petition involves a case which has been referred to the U.S. Attorney for the institution of court proceedings, the custodian shall transmit the petition to the U.S. Attorney for the judicial district in which the seizure occurred. He shall notify the petitioner of this action.