

The State Department of Health of the State of New Jersey, pursuant to authority vested in it by statute, hereby establishes the following rules and regulations governing the keeping of records by drug manufacturing businesses and wholesale drug businesses.

N.J. (STATE) DEPARTMENT OF HEALTH (OF THE STATE OF NEW JERSEY)

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Roscoe P. Kandle
Roscoe P. Kandle, M. D.
State Commissioner of Health

REGULATIONS GOVERNING THE KEEPING OF RECORDS
BY DRUG MANUFACTURING BUSINESSES
AND WHOLESALE DRUG BUSINESSES

1. Drug manufacturing businesses shall maintain records identifying the source of each ingredient used in the manufacture or processing of a drug. Records identifying the source of each ingredient shall include the date of receipt of the ingredient, vendor's name and address, the name of the ingredient and the vendor's batch number, lot number, control number or other identifying symbol if any, used by the vendor to identify the ingredient as well as the grade (U.S.P., N.F., reagent, technical, crude, etc.) and the quantity of said ingredient.

2. Drug manufacturing businesses shall maintain a system of record keeping that will permit the identification for purposes of recall of any lot or batch of a drug from the market when such is found to be unsafe for use. As part of this system, the manufacturer shall insure that the container of any drug at any stage in the process of manufacture and distribution bears an identifying name and number, commonly known as "lot" or "control" number, to make it possible to determine the complete manufacturing history of the package of the drug.

This Regulation shall not require that the manufacturer keep a record of the control number of any given shipment of drugs if the manufacturer's overall records are such as to enable the manufacturer to recall an unsafe drug.

3. Wholesale drug businesses shall maintain records identifying each drug received. Records of receipt shall include the date the drug was received, the vendor's name and address, the drug name and the quantity of the drug received. Such records in the form of vendors' invoices shall suffice for compliance with this regulation.

4. Wholesale drug businesses shall maintain records of shipments which identify the recipient of the drug by name, street address, city and state, date of shipment, the drug name and the quantity of the drug shipped. Such records in the form of customers' invoices shall suffice for compliance with this regulation.

5. Records required by these regulations shall be maintained for not less than 24 consecutive months.

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6. The provisions of these regulations shall not apply to "commercial feeding stuff" as these articles are defined and administered under the provisions of R.S. 4:4-1 et seq.

S T A T E M E N T

Recent supplements to New Jersey Food and Drug laws require registration and other regulations of drug manufacturing and wholesale drug businesses. These supplements were enacted when Department investigations revealed evidence of counterfeiting of drugs of legitimate manufacturers. It was further found that some marginal businesses were manufacturing drugs under unsanitary conditions without quality controls. Not infrequently, drug products of such businesses carried sub-standard qualities and quantities of essential drugs. The above regulations are promulgated to implement New Jersey Food and Drug laws to meet these specific problems and to permit the identification for recall of any drug found to be unsafe for use.

Amendments to the Federal Food, Drug and Cosmetic Act, which became law October 10, 1962, require registration and periodical inspection of all drug manufacturing establishments. The primary purpose of these amendments is to oblige all drug producers to meet standards of good manufacturing practice. It is anticipated that regulations promulgated by the Department of Health, Education and Welfare under authority of these amendments will establish standards for drug quality controls adequate for preservation of public health in this State. Several months may elapse before those regulations are promulgated.

Effective and efficient administration at both federal and state levels, as well as protection of the public and industry of this State, demands that standards governing good manufacturing practice and quality control of drugs be uniform throughout the state and nation. Accordingly, the regulations of this State promulgated hereinabove will be reviewed and revised when the aforementioned federal regulations have been promulgated.