CHAPTER 21A

GOOD DRUG MANUFACTURING PRACTICES

Authority

N.J.S.A. 24:5-1 et seq.

Source and Effective Date

R.1997 d.312, effective August 4, 1997. See: 29 N.J.R. 2260(a), 29 N.J.R. 3450(a).

Executive Order No. 66(1978) Expiration Date

Chapter 21A, Good Drug Manufacturing Practices, expires on August 4, 2002.

Chapter Historical Note

Chapter 21A, Good Drug Manufacturing Practices, was adopted as R.1979 d.453, effective November 13, 1979.

Pursuant to Executive Order No. 66(1978), Chapter 21A was readopted as R.1985 d.141, effective April 1, 1985. See: 16 N.J.R. 3248(a), 17 N.J.R. 815(a). Pursuant to Executive Order No. 66(1978), Chapter 21A, Good Drug Manufacturing Practices, expired on April 1, 1990.

Chapter 21A, Good Drug Manufacturing Practices, was adopted as R.1992 d.316, effective August 3, 1992. See: 24 N.J.R. 2003(c), 24 N.J.R. 2729(a).

Chapter 21A, Good Drug Manufacturing Practices, was repealed and a new Chapter 21A, Good Drug Manufacturing Practices, was adopted by R.1997 d.312, effective August 4, 1997. See: Source and Effective Date.

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SUBCHAPTER 1. GENERAL REQUIREMENTS

8:21A-1.1 Manufacturing, processing, packing or holding of drugs, general

The "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs, General" at 21 C.F.R. 210, as amended and supplemented, are incorporated herein by reference.

8:21A-1.2 Finished pharmaceuticals

The "Current Good Manufacturing Practice for Finished Pharmaceuticals" at 21 C.F.R. 211, as amended and supplemented, are incorporated herein by reference.