§ 6811-a. Certain drugs to be clearly marked or labeled. 1. Except as otherwise authorized in the Federal Food, Drug and Cosmetic Act, no drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health may be manufactured or commercially distributed within this state in tablet or capsule form unless it has clearly marked or imprinted on each such tablet or capsule in conformance with the applicable plan required by subdivision three of this section:

(a) an individual symbol, number, company name, words, letters, marking or National Drug Code (hereinafter referred to as N. D. C.) number identifying the manufacturer or distributor of the drug; and

(b) an N. D. C. number, symbol, number, letters, words or marking identifying such drug or combination of drugs.

2. Except as otherwise authorized in the Federal Food, Drug and Cosmetic Act, no drug for which any prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health contained within a bottle, vial, carton or other container, or in any way affixed or appended to or enclosed within a package of any kind, and designed or intended for delivery in such container or package to an ultimate consumer, shall be manufactured or distributed within this state unless such container or package has clearly and permanently marked or imprinted upon it in conformance with the applicable plan required by subdivision three of this section:

(a) an individual symbol, N. D. C. number, company name, number, letters, words or marking identifying the manufacturer or distributor of the drug;

(b) an N. D. C. number, symbol, number, letters, words or marking identifying such drug or combination of drugs; and

(c) whenever the distributor of the prescription drug product does not also manufacture the product the names and places of business of both shall appear on the label in words clearly distinguishing each.

3. (a) Each manufacturer and distributor shall prepare and submit to the commissioner of health a proposed plan of the manufacturer or distributor, as the case may be, to have its products comply with the marking and labeling requirements of this section.

(b) Such plan shall be in writing and shall give the respective dates by which the various products manufactured or distributed will each contain the required mark or label. The plan shall state the reasons why the projected date of compliance has been proposed and such other information deemed relevant or that the commissioner of health shall require.

(c) The commissioner may either approve the plan as proposed or, after consultation with the manufacturer or distributor, require an amendment or the commissioner may promulgate a plan for the manufacturer or distributor. No plan or amendment to the plan shall be effective until approved or promulgated by the commissioner of health upon a finding by him that the time limitations provided for therein are reasonable and will best carry out the intendment of this section.

4. Each manufacturer and/or distributor shall publish and make available, upon request, to the department of education, to each physician, dentist, pharmacy, hospital or other institution wherein such drugs may be used, a printed material which will identify each imprint used by the manufacturer or distributor. Updated materials shall be provided as changes occur, upon the filing of an annual request. The provisions of this subdivision shall be deemed to be complied with when a prescription drug product is included in the Physician's Desk Reference.

5. Every person, firm or corporation violating the provisions of this section for any prescription drug product shall be guilty of an offense punishable by a fine of not less than twenty-five hundred dollars nor more than ten thousand dollars. Any prescription drug product prepared or manufactured in violation of this section shall be contraband and subject to seizure either by the state board of pharmacy or by any law enforcement officer of the state.

6. The provisions of this section shall not apply to any tablet or capsule which contains a controlled substance as that term is defined by article thirty-three of the public health law or which is prepared or manufactured by a pharmacist duly licensed by the state which is made by him for the purpose of retail sale from his principal place of business

and not intended for resale.

7. The commissioner of health may exempt a particular tablet or capsule from the requirements of this section, upon application by a manufacturer, on the grounds that labeling such a tablet or capsule is unfeasible because of size or texture or other unique characteristics.

8. (a) As used in this section, the term "distributor" means the person, firm, corporation or other entity which is not the actual manufacturer of a prescription drug product but which distributes such product for resale under the label of such person, firm, corporation or entity.

(b) For purposes of subdivision four "drug product" means the entire supply of the finished dosage form of the drug.