

§ 200.7

21 CFR Ch. I (4-1-03 Edition)

IMPORTANT
CORRECTION
OF DRUG
INFORMATION

The statement shall be in four lines, all capitals, and centered. "Important" shall be in 36 point Gothic Bold type. "Correction," "Of Drug," and "Information" shall be in 36 point Gothic Condensed type. The rectangle's border and the statement therein shall be brown.

§ 200.7 Supplying pharmacists with indications and dosage information.

There are presently no regulations under the Federal Food, Drug, and Cosmetic Act that prevent a manufacturer of prescription drugs from sending the pharmacist data he needs on indications and dosage in exercising his important professional function of checking against possible mistakes in a prescription. The Food and Drug Administration believes manufacturers should be encouraged to supply such printed matter to the pharmacist for his professional information. Obviously, such printed matter should not be displayed to prospective purchasers to promote over-the-counter sale of prescription drugs.

§ 200.10 Contract facilities (including consulting laboratories) utilized as extramural facilities by pharmaceutical manufacturers.

(a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act specifically authorizes inspection of consulting laboratories as well as any factory, warehouse, or establishment in which prescription drugs are manufactured, processed, packed, or held.

(b) The Food and Drug Administration is aware that many manufacturers of pharmaceutical products utilize extramural independent contract facilities, such as testing laboratories, contract packers or labelers, and custom grinders, and regards extramural facilities as an extension of the manufacturer's own facility.

(c) The Food and Drug Administration reserves the right to disclose to the pharmaceutical manufacturer, or to the applicant of a new drug applica-

tion (NDA) or to the sponsor of an Investigational New Drug (IND) Application, any information obtained during the inspection of an extramural facility having a specific bearing on the compliance of the manufacturer's, applicant's, or sponsor's product with the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration's position is that by the acceptance of such contract work, the extramural facility authorizes such disclosures.

(d) The Food and Drug Administration does not consider results of validation studies of analytical and assay methods and control procedures to be trade secrets that may be withheld from the drug manufacturer by the contracted extramural facility.

[40 FR 13996, Mar. 27, 1975, as amended at 55 FR 11576, Mar. 29, 1990]

§ 200.11 Use of octadecylamine in steam lines of drug establishments.

The Food and Drug Administration will not object to the use of octadecylamine in steam lines where the steam may be used for autoclaving surgical instruments and gauze if the octadecylamine in the steam is not more than 2.4 parts per million.

§ 200.15 Definition of term "insulin."

For purposes of sections 801 and 802 of the act and this title, the term *insulin* means the active principle of the pancreas that affects the metabolism of carbohydrates in the animal body and which is of value in the treatment of diabetes mellitus. The term includes synthetic and biotechnologically derived products that are the same as, or similar to, naturally occurring insulins in structure, use, and intended effect and are of value in the treatment of diabetes mellitus.

[63 FR 26698, May 13, 1998]

Subpart B [Reserved]

Subpart C—Requirements for Specific Classes of Drugs

§ 200.50 Ophthalmic preparations and dispensers.

(a)(1) Informed medical opinion is in agreement that all preparations offered