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(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) *Salvaging and reprocessing.* Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

(Approved by the Office of Management and Budget under control number 0910–0251)

[55 FR 38023, Sept. 14, 1990, as amended at 64 FR 67763, Dec. 3, 1999]

PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE

Sec.

206.1 Scope.
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206.10 Code imprint required.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 371; 42 U.S.C. 262.

SOURCE: 58 FR 47958, Sept. 13, 1993, unless otherwise noted.

§ 206.1 Scope.

This part applies to all solid oral dosage form human drug products, including prescription drug products, over-the-counter drug products, biological drug products, and homeopathic drug products, unless otherwise exempted under § 206.7.

§ 206.3 Definitions.

The following definitions apply to this part:

The act means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

Debossed means imprinted with a mark below the dosage form surface.

Drug product means a finished dosage form, e.g., a tablet or capsule that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Embossed means imprinted with a mark raised above the dosage form surface.

Engraved means imprinted with a code that is cut into the dosage form surface after it has been completed.

Imprinted means marked with an identification code by means of embossing, debossing, engraving, or printing with ink.

Manufacturer means the manufacturer as described in §§ 201.1 and 600.3(t) of this chapter.

Solid oral dosage form means capsules, tablets, or similar drug products intended for oral use.

§ 206.7 Exemptions.

(a) The following classes of drug products are exempt from requirements of this part:

(1) Drug products intended for use in a clinical investigation under section 505(i) of the act, but not including drugs distributed under a treatment IND under part 312 of this chapter or distributed as part of a nonconcurrently controlled study. Placebos intended for use in a clinical investigation are exempt from the requirements of this part if they are designed to copy the active drug products used in that investigation.

(2) Drugs, other than reference listed drugs, intended for use in bioequivalence studies.

(3) Drugs that are extemporaneously compounded by a licensed pharmacist, upon receipt of a valid prescription for an individual patient from a practitioner licensed by law to prescribe or administer drugs, to be used solely by the patient for whom they are prescribed.

(4) Radiopharmaceutical drug products.

(b) Exemption of drugs because of size or unique physical characteristics:

(1) For a drug subject to premarket approval, FDA may provide an exemption from the requirements of § 206.10 upon a showing that the product's size, shape, texture, or other physical characteristics make imprinting technologically infeasible or impossible.

(i) Exemption requests for products with approved applications shall be made in writing to the appropriate review division in the Center for Drug

Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. If FDA denies the request, the holder of the approved application will have 1 year after the date of an agency denial to imprint the drug product.

(ii) Exemption requests for products that have not yet received approval shall be made in writing to the appropriate review division in CDER or CBER.

(2) Any product not subject to premarket approval is exempt from the requirement of §206.10 if, based on the product's size, shape, texture, or other physical characteristics, the manufacturer or distributor of the product is prepared to demonstrate that imprinting the dosage form is technologically infeasible or impossible.

(c) For drugs that are administered solely in controlled health care settings and not provided to patients for self-administration, sponsors may submit requests for exemptions from the requirements of this rule. Controlled settings include physicians' offices and other health care facilities. Exemption requests should be submitted in writing to the appropriate review division in CDER or CBER.

[58 FR 47958, Sept. 13, 1993, as amended at 70 FR 14981, Mar. 24, 2005]

§206.10 Code imprint required.

(a) Unless exempted under §206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. Identification of the drug product requires identification of its active ingredients and its dosage strength. Inclusion of a letter or number in the imprint, while not required, is encouraged as a more effective means of identification than a symbol or logo by itself. Homeopathic drug products are required only to bear an imprint that identifies the manufacturer and their homeopathic nature.

(b) A holder of an approved application who has, under §314.70 (b) of this chapter, supplemented its application to provide for a new imprint is not required to bring its product into compliance with this section during the pendency of the agency's review. Once the review is complete, the drug product is subject to the requirements of the rule.

(c) A solid oral dosage form drug product that does not meet the requirement for imprinting in paragraph (a) of this section and is not exempt from the requirement may be considered adulterated and misbranded and may be an unapproved new drug.

(d) For purposes of this section, *code imprint* means any single letter or number or any combination of letters and numbers, including, e.g., words, company name, and National Drug Code, or a mark, symbol, logo, or monogram, or a combination of letters, numbers, and marks or symbols, assigned by a drug firm to a specific drug product.

[58 FR 47958, Sept. 13, 1993, as amended at 60 FR 19846, Apr. 21, 1995; 69 FR 18763, Apr. 8, 2004]

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

Subpart A—General

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207.3 Definitions.
207.7 Establishment registration and product listing for human blood and blood products and for medical devices.

Subpart B—Exemptions

207.10 Exemptions for establishments.

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207.20 Who must register and submit a drug list.
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