

## § 206.10

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 pre-market 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.

### § 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)(2)(xi) or (b)(2)(xii) 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 re-

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view. 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]

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

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