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.

(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.

§ 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...
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to provide for a new imprint is not re-
quired to bring its product into compli-
ance with this section during the pend-
ency 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 require-
ment for imprinting in paragraph (a) of
this section and is not exempt from the
requirement may be considered adul-
terated and misbranded and may be an
unapproved new drug.

(d) For purposes of this section, code
imprint means any single letter or num-
ber or any combination of letters and
numbers, including, e.g., words, com-
pany 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 PRO-
DUCERS OF DRUGS AND LISTING
OF DRUGS IN COMMERCIAL DIS-
TRIBUTION

Subpart A—General

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Subpart D—Procedure for Foreign Drug
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207.40 Establishment registration and drug
listing requirements for foreign estab-
lishments.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355,
360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264,
271.

SOURCE: 45 FR 38043, June 6, 1980, unless
otherwise noted.

Subpart A—General

§ 207.3 Definitions.

(a) The following definitions apply to
this part:

(1) Act means the Federal Food, Drug,
and Cosmetic Act approved June 25,
1938 (52 Stat. 1040 et seq., as amended
(21 U.S.C. 301–392)), except as otherwise
provided.

(2) Advertising and labeling include the
promotional material described in
§ 202.1(l)(1) and (2) respectively.

(3) Any material change includes but is
not limited to any change in the name
of the drug, any change in the identity
or quantity of the active ingredient(s),
any change in the identity or quantity
of the inactive ingredient(s) where
quantitative listing of all ingredients
is required by § 207.31(a)(2), any signifi-
cant change in the labeling of a pre-
scription drug, and any significant
change in the label or package insert of
an over-the-counter drug. Changes that
are not significant include changes in
arrangement or printing or changes of
an editorial nature.

(4) Bulk drug substance means any
substance that is represented for use in
a drug and that, when used in the manu-
facturing, processing, or packaging of
a drug, becomes an active ingredient or a
finished dosage form of the drug, but
the term does not include intermedi-
ates used in the synthesis of such sub-
stances.

(5) Commercial distribution means any
distribution of a human drug except for
investigational use under part 312 of
this chapter, and any distribution of an
animal drug or animal feed bearing or
containing an animal drug for non-
investigational uses, but the term does
not include internal or interplant