§ 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]
Subpart D—Procedure for Foreign Drug Establishments

207.40 Establishment registration and drug listing requirements for foreign establishments.


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

Subpart A—General

§ 207.3 Definitions.

(a) The following definitions apply to this part:


(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 significant change in the labeling of a prescription 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 manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(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 transfer of a bulk drug substance between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term “commercial distribution” shall have the same meaning except that the term shall not include distribution of any drug that is neither imported nor offered for import into the United States.

(6) Drug product salvaging means the act of segregating drug products that may have been subjected to improper storage conditions, such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation, for the purpose of returning some or all of the products to the marketplace.

(7) Establishment means a place of business under one management at one general physical location. The term includes, among others, independent laboratories that engage in control activities for a registered drug establishment (e.g., consulting laboratories), manufacturers of medicated feeds and of vitamin products that are drugs in accordance with section 201(g) of the act, human blood donor centers, and animal facilities used for the production or control testing of licensed biologicals, and establishments engaged in drug product salvaging.

(8) Manufacturing or processing means the manufacture, preparation, propagation, compounding, or processing of a drug or drugs as used in section 510 of the act and is the making by chemical, physical, biological, or other procedures of any articles that meet the definition of drugs in section 201(g) of the act. The term includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process. The term also includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package to further the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(9) Representative sampling of advertisements means typical advertising material (excluding labeling as determined in §202.1(1) (1) and (2)) that gives a balanced picture of the promotional claims used for the drug, e.g., if more
than one medical journal advertisement is used but the promotional content is essentially identical, only one need be submitted.

(10) Representative sampling of any other labeling means typical labeling material (excluding labels and package inserts) that gives a balanced picture of the promotional claims used for the drug, e.g., if more than one brochure is used but the promotional content is essentially identical, only one need be submitted.

(11) United States agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment’s agent is not physically present.

(b) The definitions and interpretations of terms in sections 201, 502(e), and 510 of the act apply to the use of terms in this part.

§ 207.10 Exemptions for establishments.

The following classes of persons are exempt from registration and drug listing in accordance with this part under section 510(g)(1), (g)(2), and (g)(3) of the act, or because FDA has found, under section 510(g)(5) of the act, that their registration is not necessary for the protection of the public health. The exemptions in paragraphs (a) and (b) of this section are limited to pharmacies, hospitals, clinics, and public health agencies located in any State as defined in section 201(a)(1) of the act.

(a) Pharmacies that operate under applicable local laws regulating dispensing of prescription drugs and that do not manufacture or process drugs for sale other than in the regular course of the practice of the profession of pharmacy, including dispensing and selling drugs at retail. The supplying of prescription drugs by these pharmacies to a practitioner licensed to administer these drugs for his or her use in the course of professional practice or to other pharmacies to meet temporary inventory shortages are not acts that require pharmacies to register.

(b) Hospitals, clinics, and public health agencies that maintain establishments in conformance with any applicable local laws regulating the practices of pharmacy or medicine and that regularly engage in dispensing prescription drugs, other than human
food or blood products, upon prescription of practitioners licensed by law to administer these drugs to patients under their professional care.

(c) Practitioners who are licensed by law to prescribe or administer drugs and who manufacture or process drugs solely for use in their professional practice.

(d) Persons who manufacture or process drugs not for sale but solely for use in research, teaching, or chemical analysis.

(e) Manufacturers of harmless inactive ingredients that are excipients, colorings, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs, and who otherwise would not be required to register under this part.

(f) Persons who only manufacture the following:

1. Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds, and/or;

2. Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

3. Persons who manufacture free-choice feeds, as defined in §510.455 of this chapter, or medicated liquid feeds, as defined in §558.5 of this chapter, where a medicated feed mill license is required are not exempt.

(g) Any manufacturer of a virus, serum, toxin, or analogous product intended for treatment of domestic animals who holds an unsuspended and unrevoked license issued by the Secretary of Agriculture under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832 (21 U.S.C. 151 et seq.)), provided that this exemption from registration applies only to the manufacture or processing of that animal virus, serum, toxin, or analogous product.

(h) Carriers, in their receipt, carriage, holding, or delivery of drugs in the usual course of business as carriers.

§ 207.21 Times for registration and drug listing.

(a) The owner or operator of an establishment entering into the manufacture or processing of a drug or drugs shall register the establishment within 5 days after the beginning of the operation and shall submit a list of every drug in commercial distribution at that time. If the owner or operator of the establishment has not previously entered into such an operation, the owner or operator shall register within 5 days after submitting a new drug application, abbreviated new drug application, new animal drug application, abbreviated new animal drug application, a medicated feed mill license application, or a biologics license application. Owners or operators shall renew their registration information annually.

The schedule is as follows:

<table>
<thead>
<tr>
<th>First letter of company name</th>
<th>Date FDA will mail forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>A or B</td>
<td>January</td>
</tr>
<tr>
<td>C, D, or E</td>
<td>February</td>
</tr>
<tr>
<td>F, G, or H</td>
<td>March</td>
</tr>
<tr>
<td>I, J, K, L, or M</td>
<td>April</td>
</tr>
<tr>
<td>N, O, P, Q, or R</td>
<td>May</td>
</tr>
<tr>
<td>S or T</td>
<td>June</td>
</tr>
<tr>
<td>U, V, W, X, Y, or Z</td>
<td>July</td>
</tr>
</tbody>
</table>

(b) Owners and operators of all registered establishments shall update their drug listing information every June and December.

§ 207.22 How and where to register and list drugs.

(a) An establishment shall register the first time on Form FDA–2656 (Registration of Drug Establishment), obtainable on request from the Records Repository Team (HFD–143), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or from FDA district offices. An establishment whose drug registration for that year was validated under § 207.35 shall make subsequent annual registration on Form FDA–2656 as described in § 207.21(a) by mailing the completed form to the above address within 30 days after receipt from FDA.

(b) The first list of drugs and later June and December updatings shall be on Form FDA–2657 (Drug Product Listing), obtainable upon request as described in paragraph (a) of this section. An establishment may submit, in lieu of Form FDA–2657, tapes for computer inputs containing the information specified in Form FDA–2657 if formats proposed for this use were reviewed and approved by the Records Repository Team (HFD–143), Center for Drug Evaluation and Research, FDA.


§ 207.25 Information required in registration and drug listing.

(a) Form FDA–2656 (Registration of Drug Establishment) provides for furnishing or confirming information required by the act. This information includes, for each establishment, the name and full address of the drug establishment; all trade names used by the establishment; the kind of ownership or operation (that is, individually owned, partnership or corporation); and the name of the owner or operator of the establishment. The term name of the owner or operator includes in the case of a partnership the name of each partner; in the case of a corporation the name and title of each corporate officer and director and the name of the State of incorporation.

(b) Form FDA–2657 (Drug Product Listing) provides that information required by the act be furnished as follows:

(1) A list of drugs, including bulk drug substances and Type A articles for use in the manufacture of animal feeds as well as finished dosage forms, by established name and by proprietary name, that are being manufactured or processed for commercial distribution and that have not been included in any list previously submitted to FDA on Form FDA–2657 or in conjunction with the FDA voluntary inventory on Form FDA–2422 (Survey Report of Marketed Drugs), or Form FDA–2250 (National Drug Code Directory Input).

(2) For each drug listed that the registrant regards as subject to section 505 or 512 of the act, the new drug application number, abbreviated new drug application number, new animal drug application number, new animal drug application number, or abbreviated new animal drug application number and a copy of all current labeling, except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement.

(3) For each drug listed that the registrant regards as subject to section 351 of the Public Health Service Act, the license number of the manufacturer.

(4) For each human prescription drug listed that the registrant regards as not subject to section 505 of the act or 351 of the Public Health Service Act, and that is not manufactured by a registered blood bank, a copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement) and a representative sampling of advertisements.

(5) For each human over-the-counter drug listed, or each animal drug listed, that the registrant regards as not subject to section 505 or 512 of the act or 351 of the Public Health Service Act, a copy of the label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), the package insert, and a representative sampling of any other labeling.

(6) For each prescription or over-the-counter drug so listed that the registrant regards as not subject to section 505 or 512 of the act or 351 of the Public Health Service Act, and that is
§ 207.26 Amendments to registration.

Changes in individual ownership, corporate or partnership structure location or drug-handling activity, shall be submitted by Form FDA–2656 (Registration of Drug Establishment) as amendment to registration within 5 days of such changes. A change in a registered establishment’s firm name within 6 months of the registration of the establishment is required to be supported by a signed statement of the establishment’s owner or operator that the change is not made for the purpose of changing the name of the manufacturer of a drug product under §201.1 of this chapter. Changes in the names of officers and directors of the corporations do not require such amendment but must be shown at time of annual registration.


§ 207.30 Updating drug listing information.

(a) After submitting the initial drug listing information, every person who is required to list drugs under §207.20 shall submit on Form FDA–2657 (Drug Product Listing) during each subsequent June and December, or at the discretion of the registrant when the change occurs, the following information:

(1) A list of each drug introduced by the registrant for commercial distribution which has not been included in any list previously submitted. The registrant shall provide all of the information required by §207.25(b) for each such drug.

(2) A list of each drug formerly listed in accordance with §207.25(b) for which commercial distribution has been discontinued, including for each drug so listed the National Drug Code (NDC) number, the identity by established name and by proprietary name, and date of discontinuance. It is requested but not required that the reason for discontinuance of distribution be included with this information.

(3) A list of each drug for which a notice of discontinuance was submitted under paragraph (a)(2) of this section and for which commercial distribution has been resumed, including for each drug so listed the NDC number, the identity by established name and by proprietary name, the date of resumption, and any other information required by §207.25(b) not previously submitted.

(4) Any material change in any information previously submitted.
§ 207.35 Notification of registrant; drug establishment registration number and drug listing number.

(a) FDA will provide to the registrant a validated copy of Form FDA–2656 (Registration of Drug Establishment) as evidence of registration. This validated copy will be sent to the mailing address shown on the form. FDA will assign a permanent registration number to each drug establishment registered in accordance with these regulations.

(b) Using the National Drug Code (NDC) numbering system, FDA assigns a drug listing number to each drug or class of drugs listed as follows:

1. If a drug is already listed in the National Drug Code System or in the National Health Related Items Code System, the number is the same as that assigned under those codes. FDA adds a lead zero to the first three characters of the code, which identifies the manufacturer or distributor, to expand the ‘‘Labeler Code’’ segment to four characters. The National Drug Code, Product Code, and Package Code configurations used to describe these drugs, or any drugs added to the product line, remain the same, i.e., a four-character Product Code and a two-character Package Code. A manufacturer or distributor may either retain alphanumeric characters that are already used in the Product Code and Package Code segments of the National Drug Code or convert these alphanumeric characters to all numeric digits. The manufacturer or distributor shall inform FDA of a decision to convert the alphanumeric characters to all numeric digits.

2. If a registered establishment or distributor has not previously participated in the National Drug Code System or in the National Health Related Items Code System, FDA uses the National Drug Code numbering system in assigning a number, as follows (only numerals are used):

(i) The first 5 numeric characters of the 10-character code identify the manufacturer or distributor and are known as the Labeler Code. FDA will expand the Labeler Code from five to six numeric characters when the available five-character code combinations are exhausted. FDA will assign Labeler Code numbers and provide them to the registrant along with the validated copy of Form FDA–2656. Any registered firm that does not have an assigned Labeler Code will be assigned one when registration and listing information are submitted.

(ii) The last 5 numeric characters of the 10-character code identify the drug and the trade package size and type. The segment that identifies the drug...
formulation is known as the Product Code and the segment that identifies the trade package size and type is known as the Package Code. The manufacturer or distributor will assign the Product Code and the Package Code before drug listing and include these codes in Form FDA–2657 (Drug Product Listing). The manufacturer or distributor may use either of two methods in assigning the Product and Package Codes: a 3–2 Product-Package Code configuration (e.g., 542–12) or a 4–1 Product-Package Code configuration (e.g., 5421–2). A manufacturer or distributor with a given Labeler Code shall use only one such Product-Package Code configuration and shall use this same configuration in assigning the Product-Package Codes for all drugs included in the drug listing. The manufacturer or distributor shall report to FDA the Product-Package Code configuration used in assigning these codes.

(iii) If the drug formulation is a Type A medicated article intended for use in the manufacture of an animal feed, FDA assigns a separate Product Code only for each variation of level of active drug ingredient.

(3) FDA requests but does not require that the NDC number appear on all drug labels and in other drug labeling, including the label of any prescription drug container furnished to a consumer. If the NDC number is shown on a drug label, it shall be placed as follows:

(i) The NDC number shall appear prominently in the top third of the principal display panel of the label on the immediate container and of any outside container or wrapper. Instead of appearing in the top third of the label, the NDC number may appear as part of and contiguous to any bar-code symbol for any drug product if two conditions are met. First, the symbol appears prominently on the immediate container and on any outside container or wrapper and in a conspicuous location; this condition is not satisfied by the appearance of the symbol only on the natural bottom of a container or wrapper. Second, the bar-code symbol is compatible with the NDC, i.e., the symbol provides a format capable of encoding the numeric characters of an NDC Number. The term principal display panel, as used in this paragraph, means that part of a label most likely to be displayed, presented, shown, or examined under customary conditions of display to the consumer (for over-the-counter drug products) or to the dispenser (for prescription drug products).

(ii) The NDC number shall be preceded by the prefix “NDC” or “N” when it is used on a label or in labeling. The prefix used for a drug product shall be used consistently on the label of the immediate container, outside container, or wrapper, if any, and on other labeling for that drug product.

(iii) The Product-Package Code configuration shall be indicated and the segments of the number shall be separated by a dash, e.g., NDC 15643–542–12 or N 15643–542–12.

(iv) All 10 characters shall appear and the leading zeros in any segment of the NDC number shall be shown, except that leading zeros may be omitted from any segment of the NDC number when the NDC number is used for product identification by direct imprinting on dosage forms or in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear both required and optional labeling information.

(v) The placing of the assigned NDC number on a label or in other labeling does not require the submission of a supplemental new drug application, supplemental new animal drug application, or a modification to an index listing.

(4)(i) If any change occurs in those product characteristics that clearly distinguish one drug product version from another, the registrant shall assign a new NDC number to the new product version and submit that information to FDA. Such a change includes, but is not limited to, a change in active ingredient(s); strength or concentration of active ingredient(s); dosage form; route of administration, if it also includes a change in product formulation; product name; and a change in marketing status from prescription to over-the-counter or over-the-counter to prescription. If, by notice in the Federal Register, FDA requires a change in drug product characteristics and determines the change will require...
assignment of a new product code to the reformulated product, FDA will announce its determination in the Federal Register publication that requires the change, setting forth its reasoning and justification for its determination. If a change only in the trade package is involved, the registrant may revise the trade package code without the assignment of a new product code segment, but shall inform FDA of the new code for the trade package and the characteristics of the new trade package.

(ii) When a registrant has discontinued a drug product, its product code may be reassigned to another drug product 5 years after the expiration date of the discontinued product, or, if there is no expiration date, 5 years after the last shipment of the discontinued product into commercial distribution. Reuse of product codes may occur, under the specified conditions, regardless of the NDC, Product Code, and Package Code configuration used.

(c) Although registration and drug listing are required to engage in the drug activities described in §207.20, validation of registration and the assignment of a drug listing number do not, in themselves, establish that the holder of the registration is legally qualified to deal in such drugs.

§ 207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FDA–2656 (Registration of Drug Establishment) filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Records Repository Team (HFD–143), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. In addition, copies of these forms for establishments located within a particular geographic area are available for inspection at FDA district offices responsible for that geographical area. Copies of forms submitted by foreign drug establishments are available for inspection at the Division of Manufacturing and Product Quality, Foreign Inspection Team (HFD–325), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(1) The following types of information submitted under the drug listing requirements will be available for public disclosure when compiled:

(i) A list of all drug products.

(ii) A list of all drug products arranged by labeled indications or pharmacological category.

(iii) A list of all drug products arranged by manufacturer.

(iv) A list of a drug product’s active ingredients.

(v) A list of drug products newly marketed or for which marketing is resumed.

(vi) A list of drug products discontinued.

(vii) Labeling.

(viii) Advertising.

(ix) Information that has become a matter of public knowledge.

(x) A list of drug products containing a particular active ingredient.

(xi) A list of all code imprints.

(2) The following types of information submitted in accordance with the drug listing requirements will not be available for public disclosure (except that any of the information will be available for public disclosure if it has become a matter of public knowledge or if FDA finds that confidentiality would be inconsistent with protection of the public health):

(i) Any information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505 or 512 of the act.

(ii) A list of a drug product’s inactive ingredients.
(iii) A list of drugs containing a particular inactive ingredient.
(b) Requests for information about registrations and drug listings of an establishment should be directed to the Information Management Team (HFD–095), Office of Information Technology, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or, with respect to the information described in paragraph (a) of this section, to the FDA district office responsible for the geographic area in which the establishment is located.

§ 207.39 Misbranding by reference to registration or to registration number.

Registration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of registration or possession of registration number or NDC number is misleading and constitutes misbranding.

Subpart D—Procedure for Foreign Drug Establishments

§ 207.40 Establishment registration and drug listing requirements for foreign establishments.

(a) Foreign drug establishments whose drugs are imported or offered for import into the United States shall comply with the establishment registration and drug listing requirements in subpart C of this part, unless exempt under subpart B of this part or unless the drugs enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U. S. commerce.

(b) No drug may be imported or offered for import into the United States unless it is listed as required in subpart C of this part and manufactured, prepared, propagated, compounded, or processed at a registered foreign drug establishment; however, this restriction does not apply to a drug imported or offered for import under the investigational use provisions in part 312 of this chapter, or the investigational new animal drug use provisions in part 511 of this chapter, or to a component of a drug imported under section 801(d)(3) of the act. Foreign drug establishments shall submit all listing information, including labels and labeling, and registration information in the English language.

(c) Each foreign drug establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart C of this part. Each foreign drug establishment shall designate only one United States agent.

1. The United States agent shall reside or maintain a place of business in the United States.

2. Upon request from FDA, the United States agent shall assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment’s products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. If the agency is unable to contact the foreign drug establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign drug establishment.

3. The foreign drug establishment or the United States agent shall report changes in the United States agent’s name, address, or phone number to FDA within 10-business days of the change.

[66 FR 59157, Nov. 27, 2001]