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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.

§ 207.3 Misbranding by reference to registra-
tion or to registration number.

Subpart D—Procedure for Foreign Drug
Establishments

207.40 Establishment registration and drug
listing requirements for foreign estab-
ishments.

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 man-
ufacturing, 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
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(l)(1) and (2)) 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.

(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.


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

(a) Owners and operators of human blood and blood product establishments shall register and list their products with the Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, on Form FDA–2830 (Blood Establishment Registration and Product Listing), in accordance with part 607 of this chapter. Such owners and operators who also manufacture or process other drug products at the same establishment shall, in addition, register and list all such other drug products with the Drug Listing Branch in accordance with this part.

(b) [Reserved]

(c) Owners and operators of establishments engaged in manufacture or processing of medical devices shall register and list their products with the Center for Devices and Radiological Health, FDA, on Form FDA–2891 (Initial Registration of Device Establishments), FDA–2891a (Registration of Device Establishment), and FDA–2892 (Medical
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Device Listing), in accordance with part 807.

(d) Owners and operators of establishments engaged in the manufacture or processing at the same establishment of both drug products and medical devices shall (1) register with the Records Repository Team (HFD–143), Center for Drug Evaluation and Research, FDA, and list their drug products in accordance with this part, and (2) register with the Center for Devices and Radiological Health and list their medical devices in accordance with part 807.


Subpart B—Exemptions

§ 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 blood 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.

§ 207.20 Who must register and submit a drug list.

(a) Owners or operators of all drug establishments, not exempt under section 510(g) of the act or subpart B of this part 207, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register and submit a list of every drug in commercial distribution (except that registration and listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Drug listing is not required for the manufacturing, preparation, propagation, compounding, or processing of an animal feed bearing or containing an animal drug (i.e., a Type B or Type C medicated feed), nor is drug listing required for establishments engaged in drug product salvaging. Drug products manufactured, prepared, propagated, compounded, or processed in any State as defined in section 201(a)(1) of the act must be listed whether or not the output of such establishments or any particular drug so listed enters interstate commerce. No owner or operator may register an establishment if any part of the establishment is registered by any other owner or operator.

(b) Owners or operators of establishments not otherwise required to register under section 510 of the act that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may elect to submit listing information directly to FDA and to obtain a Labeler Code. A distributor who submits drug listing information shall include the registration number of the drug establishment that manufactured, prepared, propagated, compounded, or processed each drug listed. All distributors who submit drug listing information to FDA assume full responsibility for compliance with all of the requirements of this part. Each such distributor at the time of submitting or updating drug listing information as required under § 207.30 shall certify to the registered establishment that the submission has been made by providing a signed copy of Form FDA–2656 (Registration of Drug Establishment) to the registered establishment that manufactures or processes the drug. Each such distributor shall submit the original of Form FDA–2656 showing this certification to FDA, and shall accompany the certification with a list showing the National Drug Code number that the distributor has assigned to each drug product. If a distributor does not elect to submit drug listing information directly to FDA and to obtain a Labeler Code, the registered establishment shall submit the drug listing information. Distributors or registered establishments shall use Form FDA–2656 (Registered Establishments' Report of Private Label Distributors) to submit drug listing information or to request a Labeler Code, or both.

(c) Before beginning manufacture or processing of a drug subject to one of the following applications, an owner or operator of an establishment is required to register before the agency approves or grants it: A new drug application, an abbreviated new drug application, a new animal drug application, an abbreviated new animal drug application, a medicated feed mill license application, a biologics license application, a biologics license application, or a request for addition to the index.

(d) No registration fee is required.

(e) Registration and listing do not constitute an admission, or agreement, or determination that a product is a drug as defined in section 201(g) of the act.

(f) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the
§ 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, request for addition to the index, 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>
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<tr>
<td>J, K, L, or M</td>
<td>April</td>
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<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, and 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, 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 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 not manufactured by a registered blood bank, a quantitative listing of the active ingredient(s). Unless the quantitative listing is expressed as a percentage in the official compendium or the ingredient is a nonantibiotic ingredient in a Type A medicated article for use in the manufacture of animal feeds, the quantity of an ingredient shall be expressed in terms of the amount, not the percent, of that ingredient in each dosage unit or, if the drug is not in unit dosage form, the amount of the ingredient in a specific unit of weight or measure of the drug. For a drug formulation that is a Type A medicated article subject to §207.35(b)(2)(ii), the registrant may limit the quantitative listing of ingredients to each variation of level of active drug ingredient.

(7) For each drug listed, the registration number of every drug establishment within the parent company at which it is manufactured or processed.

(8) For each drug listed, the National Drug Code (NDC) number. If FDA has not assigned an NDC Labeler Code, the registrant shall include a Product Code and Package Code and FDA will assign a Labeler Code as described in §207.35(b)(2)(i).

(c) For each drug product listed that is subject to the imprinting requirements of part 206 of this chapter, including products that are exempted under §206.7(b), drug companies must submit a document that provides the name of the product, its active ingredient(s), dosage strength, National Drug Code number, the name of its manufacturer or distributor, its size, shape, color, and code imprint (if any), and any other characteristic that identifies the product as unique.

§ 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.

§207.35 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
§ 207.35 21 CFR Ch. I (4–1–12 Edition)

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. 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 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.
§ 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 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]

PART 208—MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS

Subpart A—General Provisions

§ 208.3 Definitions.

For the purposes of this part, the following definitions shall apply: