

(4) Submit any material changes in any information previously submitted pursuant to §§ 207.49, 207.53, 207.54, 207.55, or this section; or

(5) Certify that no changes have occurred if no changes have occurred since the last review and update. If a drug is discontinued and we have received the information required under paragraph (b)(2) of this section, no further certifications are necessary for the discontinued drug.

SUBPART E—ELECTRONIC FORMAT FOR REGISTRATION AND LISTING

§ 207.61 How is registration and listing information provided to FDA?

(a) *Electronic format.* (1) Manufacturers, repackers, relabelers, and drug product salvagers that are subject to the registration and listing requirements of this part must provide the following information to us by using our electronic drug registration and listing system, in accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e) and the corresponding requirements in § 11.30:

(i) Establishment registration information in §§ 207.25 and 207.29;

(ii) Information required for an NDC number in § 207.33; and

(iii) Drug listing information in §§ 207.49 (except paragraphs (g) and (h)), 207.53 (except paragraphs (d) and (e)), 207.54, 207.55, and 207.57.

(2) The content of labeling required under § 207.49(g)(1) through (g)(3) must be provided to us in an electronic format, in accordance with part 11 of this chapter, except for the requirements in § 11.10(a), (c) through (h), and (k) and the corresponding requirements in § 11.30. The NDC number must also be provided with the content of labeling for each drug.

(3) Advertisements and labeling (other than the content of labeling) required under §§ 207.49(g) and (h) and 207.53(d) and (e) may be provided to us in paper or electronic format in accordance with part 11 of this chapter, except for the requirements in § 11.10(a), (c) through (h), and (k) and the

corresponding requirements in § 11.30. The NDC number must also be provided with such advertisements and labeling for each drug.

(4) The information provided in electronic format must be in a form that we can process, review, and archive. We may periodically issue guidance on how to provide registration and listing information in electronic format (for example, method of transmission, media, file formats, preparation and organization of files).

(b) *English language.* Registration and listing information must be provided in the English language. Labeling must also be provided in the English language, except as provided in § 201.15(c) of this chapter.

§ 207.65 How is a waiver from the electronic format requirement requested?

(a) If the information under § 207.61(a) cannot be submitted electronically, a waiver may be requested. We may grant a waiver request if the manufacturer, repacker, relabeler, or drug product salvager does not have an e-mail address and access to a computer and an Internet service provider that can access our electronic drug registration and listing system.

(b) Waiver requests must include a telephone number and/or mailing address where we can contact the manufacturer, repacker, relabeler, or drug product salvager.

(c) If we grant the waiver request, we will provide information on how to submit registration and/or listing information.

SUBPART F—MISCELLANEOUS

§ 207.69 What are the requirements for an official contact and a United States agent?

(a) *Official contact.* Manufacturers, repackers, relabelers, and drug product salvagers that are subject to the registration requirements of this part must

designate an official contact for each establishment. The official contact is responsible for:

- (1) Ensuring the accuracy of registration and listing information; and
- (2) Reviewing, disseminating, routing, and responding to communications

from us.

(b) *United States agent.* (1) Each foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager must designate a single United States agent. The United States agent is responsible for:

- (i) Helping us communicate with the foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager;
- (ii) Responding to questions concerning those drugs that are imported or offered for import to the United States; and
- (iii) Helping us schedule inspections.

(2) The United States agent must reside or maintain a place of business in the United States.

(3) A United States agent may not be a mailbox, answering machine or service, or other place where a person acting as the United States agent is not physically present.

(4) If we are unable to contact a foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager directly or expeditiously, we may provide information or documents to the United States agent. We will consider such an action to be equivalent to providing the same information or documents to the foreign manufacturer, foreign repacker, foreign relabeler, or foreign drug product salvager.

§ 207.77 What legal status is conferred by registration and listing?

(a) Registration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or other drugs of the establishment,

nor does it mean that a product may be legally marketed. Any representation that creates an impression of official approval or that a drug is approved or is legally marketable because of registration or listing is misleading and constitutes misbranding.

(b) Assignment of an establishment registration number, inclusion of a drug in our database of drugs, or assignment of an NDC number does not denote approval of the establishment or the drug or any other drugs of the establishment, nor does it mean that the drug may be legally marketed. Any representation that creates an impression that a drug is approved or is legally marketable because it appears in our database of drugs, has been assigned a NDC number, or the establishment has been assigned an establishment registration number, is misleading and constitutes misbranding. Failure to comply with § 207.37 also constitutes misbranding.

(c) Neither registration nor listing constitutes a determination by FDA that a product is a drug as defined by section 201(g)(1) of the act. Registration and listing may, however, be evidence that a facility is manufacturing, repacking, relabeling, or salvaging drugs or that a product is a drug.

§ 207.81 What registration and listing information will we make available for public disclosure?

(a) Except as provided in paragraphs (b) and (c) of this section, the following information will be made available for public disclosure upon request or at our own discretion:

(1) All registration information; and

(2) After a drug is listed, all information obtained for that drug under §§ 207.33, 207.49, 207.53, and 207.54, except for that information obtained under 207.33(d)(1)(ii) and 207.54(b)(1).

(b) Unless information is publicly available or we find that confidentiality would be inconsistent with the protection of the public health, we will not make publicly available 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.

(c) We may determine, in limited circumstances and on a case-by-case basis, that it would be consistent with the protection of the public health and the Freedom of Information Act to exempt from public disclosure specific information in paragraph (a) of this section. In such instances, a manufacturer, repacker, relabeler, or drug product salvager must demonstrate that specific information is exempt or is otherwise prohibited by law from public disclosure. If we agree, we will not make such information publicly available.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

8. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

9. Section 314.81 is amended by revising paragraph (b)(3)(iii) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(iii) *Withdrawal of approved drug product from sale.*

(a) Within 30 calendar days of the withdrawal of an approved drug from sale, applicants who are manufacturers, repackers, or relabelers subject to part

207 of this chapter must submit the following information about the drug in electronic format, in accordance with the applicable requirements described in § 207.61(a):

(1) The National Drug Code (NDC) number;

(2) The identity of the drug by established name and by proprietary name, if any;

(3) The new drug application number or abbreviated application number;

(4) The date of withdrawal from sale. We request that the reason for withdrawal of the drug from sale be included with the information.

(b) Within 30 calendar days of the withdrawal of an approved drug from sale, applicants who are not subject to part 207 of this chapter must submit the information listed in paragraphs (a)(1) through (a)(4) of this section. The information must be submitted on the appropriate form, which must be submitted to the Drug Listing Branch, Food and Drug Administration, CDER Central Document Room, 5901B Ammendale Rd., Beltsville, MD 20705-1266.

* * * * *

§ 314.125 [Amended]

10. Section 314.125 is amended in paragraph (b)(11) by removing the words “or processed”.

**PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE
GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT
MISBRANDED**

11. The authority citation for 21 CFR part 330 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

12. Section 330.1 is amended by revising paragraph (b) to read as follows:

§ 330.1 General conditions for general recognition as safe, effective, and not misbranded.

* * * * *

(b) The establishment(s) in which the drug is manufactured is registered, and the drug is listed, in compliance with part 207 of this chapter. The appropriate National Drug Code (NDC) number must appear on the drug's label in accordance with §§ 201.2, 207.33, and 207.37 of this chapter.

* * * * *

PART 514—NEW ANIMAL DRUG APPLICATIONS

13. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e, 381.

14. Section 514.111 is amended by adding paragraph (a)(12) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(12) The drug will be produced in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the act and part 207 of this chapter.

* * * * *

PART 515—MEDICATED FEED MILL LICENSE

15. The authority citation for 21 CFR part 515 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 515.10 [Amended]

16. Section 515.10 is amended in paragraph (b)(8) by removing the phrase “§§ 207.20 and 207.21” and by adding in its place the phrase “part 207”.

PART 601—LICENSING

17. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

18. Section 601.2 is amended by adding paragraph (f) to read as follows:

§ 601.2 Applications for biologics licenses; procedures for filing.

* * * * *

(f) *Withdrawal from sale of approved biological products.* A holder of a biologics license application (BLA) must report to FDA, electronically in accordance with part 207 of this chapter, the withdrawal from sale of an approved biological product. The information must be submitted to FDA within 30 working days of the biological product’s withdrawal from sale. The following information must be submitted: The holder’s name; product name; BLA number; the National Drug Code number, if applicable; and the date of withdrawal from sale. The reason for the withdrawal of the biological product is requested but not required to be submitted.

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

19. The authority citation for 21 CFR part 607 continues to read as follows:

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

20. Section 607.3 is amended ~~in paragraph (b)~~ ^g by revising the second sentence, ^{in paragraph (b)} and by adding new paragraph (k) to read as follows:

JSP
Jim
8/23/07

§ 607.3 Definitions.

* * * * *

(b) * * * For the purposes of this part only, blood and blood product also means those products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act and that are licensed under section 351 of the Public Health Service Act, as well as licensed biologic components used in the manufacture of a licensed device.

* * * * *

(k) *Importer* means a company or individual in the United States that is the owner, consignee, or recipient of the foreign establishment's blood product that is imported into the United States.

21. Section 607.7 is revised to read as follows:

§ 607.7 Establishment registration and product listing of blood banks and other firms manufacturing human blood and blood products.

All owners or operators of establishments that engage in the manufacturing of blood products are required to register, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act. Registration and listing of blood products shall comply with this part. Registration does not permit any blood bank or similar establishment to ship blood products in interstate commerce.

22. Section 607.22 is revised to read as follows:

§ 607.22 How to register blood product establishments and list blood products.

Initial and subsequent registrations and product listings by a blood product establishment for blood products must be on Form FDA 2830 (Blood Establishment Registration and Product Listing). Manufacturers may obtain, complete, and submit the form in the following ways:

(a) Complete the form online and submit electronically at *http://www.fda.gov/cber/blood/bldreg.htm*; this information must be submitted in

accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e), and the corresponding requirements in § 11.30; or

(b) Download the form from the Internet at *http://www.fda.gov/cber/blood/bldreg.htm*, and mail the completed form to the address in § 607.22(e); or

(c) Request the form by mail using the address in § 607.22(e), or by e-mail at *bloodregis@cber.fda.gov*, and mail the completed form to the address in § 607.22(e).

(d) For subsequent annual registration renewals, FDA will furnish the establishment's most recent Form FDA 2830 before November 15 of each year. The updated Form FDA 2830 must be submitted to FDA before December 31 of that year.

(e) Forms may be requested from and mailed to: Center for Biologics Evaluation and Research (HFM-370), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

23. Section 607.25 is amended by revising paragraph (b)(1) to read as follows:

§ 607.25 Information required for establishment registration and blood product listing.

* * * * *

(b) * * *

(1) A list of blood products by established name as defined in section 502(e) of the act and by proprietary name, if any, which are being manufactured for commercial distribution and which have not been included in any list previously submitted on Form FDA 2830 (Blood Establishment Registration and Product Listing).

* * * * *

24. Section 607.35 is revised to read as follows:

§ 607.35 Blood product establishment registration number.

A permanent registration number will be assigned to each blood product establishment registered in accordance with this part.

25. Section 607.37 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 607.37 Inspection of establishment registrations and blood product listings.

(a) Information submitted on the Form FDA 2830 (Blood Establishment Registration and Product Listing) will be available for inspection under section 510(f) of the act, on the Internet at *http://www.fda.gov/cber/blood/bldregdata.htm*, and at the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The following information submitted under the blood product listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

* * * * *

26. Section 607.39 is revised to read as follows:

§ 607.39 Misbranding by reference to establishment registration, validation of registration, or to registration number.

Registration of an establishment, validation of registration, or assignment of a registration number does not in any way denote approval of the firm or its products nor does it mean that the products may be legally marketed. Any representation that creates an impression of official approval because of establishment registration, validation of registration, or possession of a registration number is misleading and constitutes misbranding.

27. Section 607.40 is amended by revising paragraphs (a), (b), (c), the introductory text of (d), and (d)(3), and by adding new paragraphs (e) and (f) to read as follows:

§ 607.40 Establishment registration and blood product listing requirements for foreign blood product establishments.

(a) Every foreign blood product establishment must comply with the requirements for domestic blood product establishments in subpart B of this part, unless exempt under subpart D of this part.

(b) No blood product may be imported or offered for import into the United States unless it complies with the blood product listing requirements in subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment. Blood products imported or offered for import under the investigational use provisions of part 312 of this chapter are not subject to the requirements in subpart B of this part. All establishment registration and blood product listing information must be in the English language.

(c) Each foreign establishment required to register under paragraph (a) of this section must, as part of the establishment registration and blood product listing, submit the name and address of the establishment, the name of each importer of the foreign establishment's blood products that is known to the establishment, the name of each person who imports or offers for import such blood products to the United States, and the name of the individual responsible for submitting establishment registration and blood product listing information. Any changes in this information must be reported to FDA at the intervals specified for updating establishment registration information in § 607.26.

(d) Each foreign establishment required to register under paragraph (a) of this section must submit the name, address, telephone and fax numbers, and e-mail address of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment must designate only one United States agent.

* * * * *

(3) The foreign establishment or the United States agent must report changes in the United States agent's name, address, telephone and fax numbers, and e-mail address to FDA within 30 calendar days of the change.

(e) Each foreign establishment required to register under paragraph (a) of this section must register and list blood products using the electronic registration and listing system, in accordance with § 607.22(a).

(f)(1) If the foreign establishment cannot submit the information electronically under § 607.40(e), the establishment may request a waiver. FDA may grant a waiver request if the foreign establishment does not have an e-mail address and access to a computer and an Internet service provider that can access the electronic registration and listing system.

(2) Waiver requests must include a telephone number and/or mailing address where the agency can contact the foreign establishment.

(3) If the agency grants the waiver request, the foreign establishment must register and list blood products in accordance with § 607.22(b) or (c).

28. Section 607.65 is amended by redesignating paragraph (f) as paragraph (g) and by adding new paragraph (f) to read as follows:

§ 607.65 Exemptions for blood product establishments.

* * * * *

(f) Persons who engage solely in the production of any plasma derivative, such as albumin, Immune Globulin, Factor VIII and Factor IX, bulk product

substances such as fractionation intermediates or pastes, or recombinant versions of plasma derivatives or animal derived plasma derivatives. This paragraph does not exempt such persons from registration and listing under part 207 of this chapter.

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

29. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

30. Section 610.60 is amended by revising paragraph (a)(2) to read as follows:

§ 610.60 Container label.

(a) * * *

(2) The name, address, license number of the manufacturer, and the NDC number in accordance with part 207 of this chapter.

* * * * *

31. Section 610.61 is amended by revising paragraph (b) to read as follows:

§ 610.61 Package label.

* * * * *

(b) The name, address, license number of the manufacturer, and the NDC number in accordance with part 207 of this chapter.

* * * * *

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

32. The authority citation for 21 CFR part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

§ 1271.1 [Amended]

33. Section 1271.1 is amended in paragraphs (a)(1) and (b)(2) by removing “207.20(f)” and by adding in its place “207.9(c)(2)”.

34. Section 1271.3 is amended by adding paragraphs (mm) and (nn) to read as follows:

§ 1271.3 How does FDA define important terms in this part?

* * * * *

(mm) Importer means a company or individual in the United States that is the owner, consignee, or recipient of the foreign establishment’s HCT/P that is imported into the United States.

(nn) 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.

§ 1271.20 [Amended]

35. Section 1271.20 is amended by removing “207.20(f)” and by adding in its place “207.9(c)(2)”.

36. Section 1271.22 is ~~revised~~ ^{added} to read as follows:

JF per Jim off 8/23/04

JF per Jim off 8/23/04

§ 1271.22 How do I register and submit an HCT/P list?

(a) You must use the electronic registration and listing system at *http://www.fda.gov/cber/tissue/tisreg.htm* in accordance with § 1271.25 for:

- (1) Establishment registration,
- (2) HCT/P listings, and
- (3) Updates of registration and HCT/P listing.

(b) FDA will periodically issue guidance on how to provide registration and listing information in electronic format (for example, method of transmission, media, file formats, preparation, and organization of files).

(c) You must provide the information under paragraph (a) of this section in accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e) and the corresponding requirements in § 11.30.

37. Section 1271.23 is added to part 1271 to read as follows:

§ 1271.23 How is a waiver from the electronic format requirements requested?

(a) You may request a waiver from the requirement in § 1271.22 that information must be provided to FDA in electronic format if you do not have an e-mail address and access to a computer and an Internet service provider that can access the Web-based FDA registration and listing database.

(b) Requests for a waiver must include a telephone number and/or mailing address where FDA can contact the person making the request.

(c) If FDA grants the request for a waiver, FDA will inform you how to submit your registration and/or listing information.

38. Section 1271.25 is amended by revising introductory paragraph (a), paragraphs (a)(2) and (a)(3), and by adding new paragraphs (a)(5), (a)(6), and (d) to read as follows:

§ 1271.25 What information is required for establishment registration and HCT/P listing?

(a) Your establishment registration must include:

* * * * *

(2) Each location, including the street address, telephone and fax numbers, email address, and the postal service zip code of the establishment;

(3) The name, address, telephone and fax numbers, e-mail address, and title of the reporting official;

* * * * *

(5) Each foreign establishment must also submit the name, address, telephone and fax numbers, and e-mail address of each importer that is known to the establishment, and the name of each person who imports or offers for import such HCT/P to the United States for purposes of importation; and

(6) Each foreign establishment must also submit the name, address, telephone and fax numbers, and e-mail address of its United States agent. Each foreign establishment must designate only one United States agent.

(i) The United States agent must reside or maintain a place of business in the United States.

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

(iii) The foreign establishment or the United States agent must report changes in the United States agent's name, address, telephone and fax numbers, and e-mail address to FDA within 30 calendar days of the change.

* * * * *

(d) In addition, if your HCT/P is described under § 1271.20, you must submit the information required under part 207 of this chapter using the procedures under this subpart.

39. Section 1271.26 is revised to read as follows:

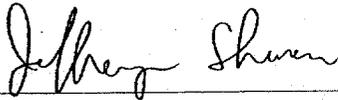
§ 1271.26 When must I amend my establishment registration?

If the ownership or location of your establishment changes, or if there is a change in the United States agent's name, address, telephone and fax numbers, and e-mail address, you must submit an amendment to registration within 30 calendar days of the change.

§ 1271.37 [Amended]

40. Section 1271.37 is amended in the introductory text of paragraph (a) by removing the phrase "Form FDA 3356" and adding in its place the phrase "registration and listing information".

Dated: August 22, 2006



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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