Sample Label 10

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7. Prototype Labels 1–5 and Sample Labels 1–9 of APPENDIX L are amended by the deletion of the words ''Important: Removal of this label before consumer purchase is a violation of Federal law (42 U.S.C. 6302).'' at the bottom of each label and the addition, in their place and in the same typeface and size, of the following words: Important: Removal of this label before consumer purchase violates the Federal Trade Commission's Appliance Labeling Rule (16 CFR Part 305).

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–31202 Filed 11–23–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 98N–0496]

RIN 0910–AB24

Import for Export; Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Subsequent Export

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing reporting and recordkeeping regulations to implement certain sections of the Federal Food, Drug, and Cosmetic Act (the act) as amended by the FDA Export Reform and Enhancement Act of 1996. The proposed rule would require an importer to report to FDA each time it imports an unapproved or otherwise violative article that is to be exported after further processing or incorporation into another product in the United States and to keep records to ensure that the article is so processed or incorporated and then exported, and that any portion of the import that is not exported is destroyed.

DATES: Submit written comments by February 8, 1999. Written comments on the information collection requirements should be submitted by December 24, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503. Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT:

For general information: Marvin A. Blumberg, Division of Import Operations and Policy (HFC–171), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

For information concerning blood products: Kimberly A. Cressotti, Division of Case Management (HFM–610), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6201.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Export Reform and Enhancement Act of 1996 (Pub. L. 104–134, amended by Pub. L. 104–180, August 6, 1996) became law on April 26, 1996. One provision of the new law, now codified at section 801(d)(3) of the act (21 U.S.C 381 (d)(3)), allows importation of any component of a drug, component part or accessory of a device, or other article of device requiring further processing, and any food or color additive, or dietary supplement, if it is to be further processed or incorporated into a product that is to be exported from the United States by the initial owner or consignee in accordance with section 801(e) or 802 of the act (21 U.S.C 382), or section 351(h) of the PHS Act (42 U.S.C. 262 (h)). (For purposes of section 801(d) of the act, FDA interprets the term ''component'' broadly to include anything used in, or in the manufacture of, a drug, biologic, or device, as well as a finished final product that will be further processed in the United States. Thus, for example, the term includes bulk drugs, unapproved foreign versions of drugs approved for use in the United States, active and inactive ingredients of a drug or biologic, pieces of a device, and completed devices.) Under section 801(d)(3) of the act, the initial owner or consignee must submit a statement regarding the imported article to FDA at the time of initial importation. Any component of a drug; any component, part, article, or accessory of a device; any food additive, color additive; or any dietary supplement imported under section 801(d) of the act that is not incorporated or further processed by the initial owner or consignee must be destroyed or exported (see section 801(d)(3)(C) of the act). Section 801(d)(3)(B) of the act further requires the initial owner or consignee to maintain records identifying the use and exportation or disposition of the imported article, including portions that were destroyed, and, upon request from FDA, to submit a report that accounts for the exportation or disposition of the imported article and the manner in which the initial owner or consignee complied with the requirements in section 801(d) of the act.

This provision of the act is generally known as the ''import-for-export'' provision.

Another new provision, now codified at section 801(d)(4) of the act, places additional requirements on the import-for-export of blood, blood components, source plasma, source leukocytes, or a component, accessory, or part (hereinafter referred to as ''blood products''), and of tissue and components or parts of tissue. Section 801(d)(4) of the act prohibits the importation of blood products unless they comply with section 351(a) of the PHS Act or FDA permits the importation under FDA-determined appropriate circumstances and conditions. (Section 351(a) of the PHS Act pertains to the licensing of biological products.)

Section 801(d)(4) of the act also prohibits the importation of tissues and their components, under section 801(d)(3) of the act, unless the importation complies with section 361 of the PHS Act (42 U.S.C. 264). Section 361 of the PHS Act authorizes FDA to issue regulations to control communicable disease, and, for human tissues intended for transplantation, these regulations are found at part 1270 (21 CFR part 1270). FDA, therefore, interprets section 801(d)(4) of the act as meaning that a person importing human tissue for transplantation for further processing or incorporation into a product destined for export must comply with part 1270. Under § 1270.42 published in the **Federal Register** of July 29, 1997 (62 FR 40429), the importer of record must notify the director of the FDA district having jurisdiction over the port of entry or notify his or her designee, and the human tissue must be quarantined until released by FDA.

Human tissue intended for transplantation may be imported and further processed or incorporated into other products without meeting the screening and testing requirements of part 1270 if the human tissue is kept in quarantine at all times (see § 1270.3

(definition of ''quarantine'')). However, as indicated in § 1270.31 (62 FR 40429, July 29, 1997), the owner or consignee in the United States must prepare and follow written procedures for designating and identifying quarantined human tissue and preventing infectious disease contamination or cross-contamination during processing.

FDA considers live animal cells, tissues, and organs intended to be transplanted, implanted, or used for ex-vivo perfusion in humans (xenogeneic products) to be biological products. Nonliving animal cells, tissues, and organs intended for transplantation or implantation into humans may be either biological products or devices. Animal cells, tissues, and organs imported into the United States under section 801(d) of the act which FDA considers to be biological products or devices would be expected to comply with proposed § 1.84(b).

All veterinary biologics (e.g., vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, etc.) and animal–origin materials that could represent a disease risk to U.S. livestock, including animal products, by–products, and biological materials that contain or have been in contact with certain organisms or animal materials) are regulated by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service. An importer must obtain a USDA permit before importing any of these materials.

The proposed rule would establish the requirements for requesting a determination from FDA to allow importation of blood products, and would establish reporting, labeling, and recordkeeping requirements for all imported articles under the import-for-export provision. These would be the minimum requirements necessary to comply with the import-for-export provision in the act and are intended to enable the importer to ensure, and the agency to monitor, that imported substances are further processed or incorporated into one of the specified FDA-regulated products while in the United States, and are then exported or destroyed without entering domestic commerce. Although the act does not define the term ''further processed,'' given the legislative intent to allow manufacturing and processing activities not previously permitted under the act, FDA interprets the term ''further processed'' to cover a wide range of activities, including packaging or labeling of finished products and specialized processing (such as sterilization) of a product. However, the agency does not consider a product to be ''further processed'' if it is merely stored in the United States before being exported elsewhere.

II. Description of the Proposed Rule

A. Request for Determination Regarding the Importation of Blood, Blood Components, Source Plasma, Source Leukocytes, or Their Components, Accessories, or Parts

As stated earlier, section 801(d)(4) of the act prohibits the importation of blood, blood components, source plasma, or source leukocytes, or ''a component, accessory, or part thereof,'' unless they comply with section 351(a) of the PHS Act or meet ''appropriate circumstances and conditions'' as determined by FDA. The agency interprets the phrase concerning compliance with section 351(a) of the PHS Act as requiring products to be licensed, and also interprets section 801(d)(4) of the act to include blood or plasma derivatives or intermediates. With respect to the determination of ''appropriate circumstances and conditions,'' FDA interprets the phrase as applying to unlicensed blood products and will decide on a case-by-case basis whether blood products that do not comply with section 351(a) of the PHS Act should be allowed into the United States under section 801(d)(4) of the act. This decision will be based, in part, on the agency's assessment of the adequacy of the safeguards to prevent diversion into U.S. commerce, contamination of, or commingling with products licensed or approved by FDA for use in the United States.

Consequently, proposed § 1.84(a) would describe the process for requesting a determination that an unlicensed blood product meets the appropriate circumstances and conditions to allow its importation into the United States. Proposed § 1.84(a)(1) would require a person who intends to import an unlicensed blood product into the United States for further processing or incorporation into a product destined for export to request a determination from FDA before importing the blood product. The request, under proposed § 1.84(a)(2), would contain the following:

1. The names and addresses of the foreign manufacturer of the article to be imported and the initial owner or consignee in the United States that would be responsible for the further processing or incorporation of the article into another product;

2. The specific identity of the article to be imported and details as to how it will be further processed or incorporated into a product for export;

3. A description of the standard operating procedures and safeguards that will be used to ensure that the imported articles or products incorporating the imported articles are not diverted to domestic use in the United States and are segregated from, and not comingled with, products or components intended for use in the United States. For example, this may consist of quarantine procedures used for segregating imported blood, blood components, or final products from products intended for use in the United States and validation data for procedures to clean equipment and facilities used for manufacturing both products for use in the United States and for manufacturing products for export;

4. General donor screening documentation or criteria, in English. The request for determination should not include individual donor screening questionnaires;

5. A copy of the product label translated (if necessary) into English (described in greater detail below); and

6. A certification that all blood and blood products will be tested for infectious disease agents such as HIV–1, HIV–2, hepatitis B virus, hepatitis C virus, HTLV–I, HTLV–II, and *Treponema pallidum*. Proposed § 1.84(a) would permit the infectious agent tests to be performed using test kits other than those licensed or approved by FDA; in such cases, a copy of the labeling, including manufacturer's test kit instructions, for the test kit used, translated into English, would be included in the request for determination.

Requests for determination, under proposed § 1.84(a)(3), would be submitted to the Division of Case Management (HFM–610), Center for Biologics Evaluation and Research (CBER). CBER will develop procedures and timeframes for reviewing these requests.

A request for determination would be submitted to and approved by CBER before importation of the first shipment of the unlicensed biological product. Once CBER has approved a request for determination, future shipments of the same product may be imported for export without an additional request for determination so long as the importer, consignee, and all other conditions upon which the determination was based remain unchanged.

Proposed § 1.84(a)(4) would require the initial owner or consignee to maintain records regarding the request for determination and to make those records available to FDA upon request.

Under proposed § 1.84(a)(5), FDA would notify, in writing, the person requesting the determination if the agency grants permission to import the blood product.

These proposed regulations for blood, blood components, source plasma, source leukocytes, or their components, accessories, or parts are intended to help prevent any recurrence of situations in which blood products not approved for use in the United States are used in products that are then distributed into U.S. commerce. In one such case, a manufacturer imported unlicensed source plasma for use in the manufacture of hepatitis test kits, and these kits were later distributed in the United States. Consistent with section 801(d)(4) of the act, the agency is proposing rules to ensure that blood products that are not licensed or approved for use in the United States are not used in products distributed in the United States.

B. Reporting Requirements

As stated earlier, section 801(d)(3)(A) of the act requires the importer to submit, ''at the time of initial importation,'' a statement to the agency indicating that the imported article is intended to be further processed or incorporated by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by such owner or consignee from the United States in compliance with section 801(e) or 802 of the act or section 351(h) of the PHS Act.

Accordingly, proposed § 1.84(b)(1) would require an importer to submit a statement to FDA each time the importer imports an article under the import-for-export provisions of the act. The statement would be required each time the product enters the United States, even if the imported article has been previously imported. The statement, under proposed § 1.84(b)(2), would include, but not be limited to, the following:

1. A formal declaration of the purpose for which the article is being imported prior to export (how it will be further processed, or the name or description of the product into which it will be incorporated in the United States), and that it will not be sold or offered for sale in the United States;

2. The name or description of the article (including any scientific or technical name);

3. Any product coding, batch, lot, or other identifying numbers;

4. The name and address of the foreign manufacturer of the imported article; and

5. The name and address of the initial owner or consignee in the United States responsible for the further processing or incorporation of the article into another product.

For blood products, proposed § 1.84(b)(2) would also require the importer to include a copy of the determination from FDA granting permission to import the product.

The statements would be sent to the FDA district having jurisdiction over the port of entry at which the article will be offered for import. Proposed § 1.84(b)(3) would require the importer to retain a copy of the statement as part of its records for the imported article.

C. Shipping Package Label Requirements

To facilitate identification of articles imported into the United States under the import–for–export provisions in section 801(d)(3) and (d)(4) of the act, FDA is proposing certain label requirements for shipping containers. Under proposed § 1.84(c), the importer, initial owner, or consignee would be responsible for permanently affixing to the shipping container, package or crate a label, in English, indicating that the shipping container, package, or crate contains article(s) that are intended for export from the United States after further processing or incorporation into another product, and may not be sold or offered for sale in the United States. The label would also name or describe the imported article(s); provide any product coding, batch, lot, or other identifying numbers; provide the foreign manufacturer's name and address; identify the imported article's country of origin (if different from that of manufacturer); and contain any appropriate warning or special handling label. For example, if an imported blood product tested positive for an infectious agent, proposed § 1.84(c)(6) would require the shipping package label to indicate the agent for which the product tested positive and prominently display the term ''BIOHAZARD.''

D. Label Requirements for Imported Blood Products

Proposed § 1.84(d) would require a foreign supplier of blood, blood components, source plasma, source leukocytes, or a component, accessory, or part thereof (including blood or plasma derivatives or intermediates) that is not licensed under section 351(a) of the PHS Act and is to be imported under section 801(d)(4) of the act, to label the products, in English, with the following information:

1. A properly descriptive name;

2. Name(s) and address(es) of establishments collecting, preparing, labeling, or pooling the source material;

3. Donor, lot, or pool numbers relating the unit to the donor;

4. The recommended storage temperature (in degrees Celsius);

5. The quantity of the product;

6. The statement, ''Import for Export;''

7. The statement, ''Not for Use in Products Subject to Licensure Under Section 351 of the Public Health Service Act;''

8. The statement, ''For Manufacturing Use Only'' or ''For Manufacturing into Noninjectable Products Only;''

9. A statement indicating that the product has been tested for infectious disease agents, including, but not limited to, HIV–1, HIV–2, hepatitis B virus, hepatitis C virus, HTLV–I, HTLV–II, and *Treponema pallidum*. The infectious agent tests may be performed using test kits other than those licensed or approved by FDA and should be the same tests described in the request for determination under proposed § 1.84(a).

10. If the product tested positive for any infectious agent listed in proposed § 1.84(d)(9), the product's label would indicate the agent(s) for which the product tested positive and display the term ''BIOHAZARD'' prominently and in bold letters; and

11. Any other appropriate warnings or special handling instructions as determined by the importer.

A copy of the label, under proposed § 1.84(a), would be included in the initial request for determination that the blood product meets the ''appropriate circumstances and conditions'' for importation under section 801(d)(4) of the act.

The requirements in proposed § 1.84(d) would be in addition to the shipping package label requirements in proposed § 1.84(c).

FDA also notes that regulations issued by other Federal agencies and departments may apply to the imported products (see, e.g., 9 CFR parts 92 et al.; 19 CFR part 12; 42 CFR part 72; 49 CFR part 173, U.S. Postal Service regulations, 39 CFR parts 124 and 125).

E. Recordkeeping Requirements

Section 801(d)(3)(B) of the act requires that ''the initial owner or consignee responsible for such imported article maintain records that identify the use of such imported article.'' Proposed § 1.84(e) would require the initial owner or consignee responsible for the article imported into the United States under the import-for-export provision to have

a place of business in the United States, to maintain identifying records for 5 years after the date on which the imported article was exported (after further processing or incorporation into another product) or destroyed, and to make the identifying records available for inspection by the agency. The identifying records would include the following information:

1. The name or description of the article (including any scientific or technical name);
2. Any product coding, batch, lot, or other identifying numbers;
3. The name and address of the foreign manufacturer of the imported article;
4. How the article will be or was further processed, and the name or description of any product into which it will be or was incorporated in the United States;
5. The signature of the responsible individual at the importing firm;
6. The name and address of the firm in the United States where the article will be further processed or incorporated into another product;
7. The disposition of the imported article, including quantity and methods of disposition (i.e., manufacturing records showing how specific articles were used or destroyed and the dates of receipt, use, destruction, or re-exportation, as that information becomes available);
8. Any product coding, lot, batch, or other identification number for the further-processed article or product incorporating the imported article;
9. A copy of the label to be applied to the shipping package, container, or crate used to export the further-processed article or product incorporating the imported article (indicating that it contains articles that may not to be sold or offered for sale in the United States and are intended for export only);
10. The name and address of the foreign purchaser of the further-processed article or product incorporating the imported article; and
11. For blood, blood components, source plasma, source leukocytes, or a component, accessory, or part thereof (including blood or plasma derivatives or intermediates) that is not licensed under section 351(a) of the PHS Act and is to be imported under section 801(d)(4) of the act, documentation of the agreement between the foreign material supplier and the U.S. manufacturer. Proposed § 1.84(e)(2)(xi) would require this documentation to outline the specific contractual relationship, the foreign manufacturing specifications, and the U.S. manufacturer's plan for auditing the foreign supplier to ensure compliance with the terms of the contract.

Additionally, proposed § 1.84(e)(2)(xi) would require the initial owner or consignee of imported blood, blood components, source plasma, source leukocytes, or a component, accessory, or part thereof (including blood or plasma derivatives or intermediates) to have written standard operating procedures to ensure that such products or articles incorporating such products are not diverted to domestic use in the United States and are kept segregated from and are not comingled with products or components intended for use in the United States. These procedures could, for example, include quarantine procedures for segregating imported blood, blood components, or final products from products intended for use in the United States and validation data for procedures used to clean equipment and manufacturing facilities that produce both products for distribution in the United States and products for export only.

FDA emphasizes that companies must also comply with the applicable requirements of section 801(e) or 802 of the act or section 351(h) of the PHS Act. (Persons who seek to import tissues or their parts or components must also comply with section 361 of the PHS Act.) Those statutory provisions may impose additional requirements on the exported product as well as requirements on notification to FDA, labeling, and records.

F. Registration and Listing Requirements for Persons Who Import and Further Process or Incorporate Blood Products That Are Not Licensed Under With Section 351(a) of the PHS Act

As an additional condition for importing blood products that are not licensed under section 351(a) of the PHS Act, proposed § 1.84(f) would require that the person in the United States who will be further processing or incorporating the imported article register with the FDA and list the blood product(s) that it will be processing or incorporating into other products or update its registration and listing. The listing would include a description of the imported article as well as the final product for export. The proposal would require that the registration and listing information be sent to the appropriate registration office listed in 21 CFR part 207 or part 607. This registration and listing will enable FDA to track all blood products imported under section 801(d)(4) of the act that are not licensed under section 351(a) of the PHS Act and to monitor the products so that they do not enter domestic commerce. Additionally, for blood products to be exported after further manufacture into final dosage form under section 351(h) of the PHS Act, such registration and listing will enable FDA to evaluate, if appropriate, the person who will be further processing or incorporating the imported article to ensure that compliance with current good manufacturing practices, or, consistent with section 802(f)(1) of the act, conformance with international manufacturing standards as certified by an international standards organization recognized by FDA, as specified by section 351(h)(3) of the PHS Act. Section 802(f)(1) of the act requires all products exported under section 802 of the act to be in substantial conformity with current good manufacturing practices or to meet international standards as certified by an international standards organization recognized by FDA. At this time, FDA has not formally recognized any international standards or international standards organizations for purposes of section 802(f)(1) of the act.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

According to Executive Order 12866, a regulatory action is economically significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered significant under Executive Order 12866 if it raises novel legal or policy issues.

The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In

addition the proposed rule is not a significant regulatory action as defined by the Executive Order. The agency also believes that the recordkeeping and reporting requirements encompassed in the proposed rule will not have a significant effect on the economy. FDA estimates the industry's total recordkeeping and reporting costs to be $40,000 and $61,500, respectively. These estimates are based on an estimated cost of $100 per record and an average wage or $30 per hour for each report (with a total of 2,050 reports). Thus, the proposed rule's cost to industry would be $101,500.

The Regulatory Flexibility Act requires the agency to analyze options that would minimize any significant impact of a rule on small businesses. This proposed rule would entail only minimal reporting and recordkeeping as necessary to identify substances and their use that have been imported under the ''import for export'' provisions of the act. The required reporting and recordkeeping is necessary to enable the importer to ensure, and the agency to monitor, that such imported substances are further processed or incorporated into another product while in the United States, and are then exported or destroyed, as required by the act. Indeed, the ''import-for-export'' provisions of the act that these proposed regulations would implement might create new economic opportunities for U.S. businesses, including small businesses. Thus, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small businesses. Therefore, under the Regulatory Flexibility Act, the agency is not required to conduct further analysis.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description for the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Import for Export; FDA Export Reform and Enhancement Act of 1996; Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Subsequent Export.

Description: The proposed rule would require an importer to report to FDA each time that it is importing an article that is to be exported after further processing or incorporation into another product in the United States, and to keep records enabling him to ensure, and FDA to monitor, that the article is so processed or incorporated and then exported, and that any portion of the import that is not exported is destroyed. This proposed rule is to implement section 801(d)(3) and (d)(4) of the act as amended by the FDA Export Reform and Enhancement Act of 1996.

Description of Respondents: Persons and businesses, including small businesses.

The estimated burden associated with the information collection requirements for this proposed rule is 10,050 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1.— ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1.84(e)	75	5	375	20	7,500
1.84(e)(xi)	25	1	25	20	500
					8,000

[1]There are no operating and maintenance costs or capital costs associated with this collection of information.

TABLE 2.— ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. Of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
1.84(a)	25	1	25	46	1,150
1.84(b)	75	5	375	1	375
1.84(c)	75	5	375	1	375
1.84(d)	25	1	25	5	125
1.84(f)	25	1	25	1	25
					2,050

[1]There are no operating and maintenance costs or capital costs associated with this collection of information.

The above estimates were based on normal operating burdens for the preparation and submission of information to FDA for imported products, the actual number of firms and import for export entries in fiscal year (FY) 1997, and projections of the future number of firms and import for export entries. In FY 1997, 41 firms, on 175 different occasions, brought products into the United States under the import for export authority at an average rate of 4.27 entries per firm (although most firms only used the import for export authority once in FY

1997). The agency anticipates more firms (particularly firms involved with blood and blood products) to use the import for export authority in the future and, therefore, estimates the maximum number of respondents or recordkeepers to be 75 (an increase of 29 over FY 1997).

FDA's estimates for the hours per record or report are based on estimates from persons familiar with export operations. The records or reports would, in many situations, be derived from normal business records for imported products, so the burden should be very minimal and should also be consistent with current recordkeeping practices.

The agency has submitted the information collection requirements of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by December 24, 1998, to OMB (address above).

VI. Request for Comments

Interested persons may on or before February 8, 1999, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments will be on file with the Dockets Management Branch (address above) and may be seen in that office between 9:00 a.m. and 4:00 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 343, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 262, 264.

2. Section 1.84 is added to subpart E to read as follows:

§ 1.84 Import for export: Request for determination and reporting and recordkeeping requirements for unapproved or violative products imported for further processing or incorporation into specified products and subsequent export.

(a) *Request for determination regarding the importation of blood, blood components, source plasma, source leukocytes, or their components, accessories, or parts.* (1) A person who intends to import blood, blood components, source plasma, source leukocytes, or their components, accessories, or parts (including blood or plasma derivatives or intermediates) that are not licensed under section 351(a) of the Public Health Service Act (the PHS Act) shall, before importing the product into the United States under section 801(d)(4) of the Federal Food, Drug, and Cosmetic act (the act), request a determination that such importation is permitted.

(2) The request shall contain the following information:

(i) The names and addresses of the foreign manufacturer of the article to be imported and the initial owner or consignee in the United States that would be responsible for the further processing or incorporation of the article into another product;

(ii) The specific identity of the article to be imported and details as to how the imported article will be further processed or incorporated into a product for export;

(iii) A description of the standard operating procedures and safeguards that the initial owner or consignee in the United States will use or implement to ensure that the imported articles or products incorporating such articles are segregated from and not comingled with products, components, accessories, or parts intended for use in the United States (e.g., quarantine procedures used for segregating imported blood, blood components, or final products from products intended for use in the United States, including validation data for procedures to clean equipment and facilities used in manufacturing products for use in the United States and products for export);

(iv) General donor screening questionnaire or criteria, translated into English, that will be used to screen donors;

(v) A certification that tests for infectious disease will be performed by the foreign supplier on the blood, blood components, source plasma, or source leukocytes, or their components, accessories, or parts (including blood or plasma derivatives or intermediates) at the time of donation and before importation to the United States, and the expected results of such tests. The infectious disease agents that shall be tested for include, but are not limited to: HIV–1, HIV–2, hepatitis B virus, hepatitis C virus, HTLV–I, HTLV–II, and *Treponema palladum*. A request under paragraph (a) of this section may be based upon infectious agent tests performed using test kits other than those licensed or approved by the Food and Drug Administration (FDA). In such cases, a copy of the labeling for the test kit used, translated into English, shall be included in the submission; and

(vi) A copy of the label described in paragraph (d) of this section.

(3) The request for determination shall be submitted to Office of Compliance, Division of Case Management (HFM–610), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

(4) Records pertaining to the request for determination shall be maintained and made available for FDA review upon request.

(5) If FDA determines that the blood, blood component, source plasma, or source leukocyte, or component, accessory, or part meets the appropriate circumstances and conditions to permit its importation into the United States, FDA shall, in writing, notify the person requesting the determination that it has granted permission to import the article.

(b) *Reporting requirements.* (1) A person wishing to import articles specified in paragraphs (b)(l)(i) through (b)(l)(iv) of this section that may not be sold or offered for sale in the United States, but which the initial owner or consignee intends to have further processed or incorporated into a drug, biological product, device, food, food additive, color additive, or dietary supplement in the United States, and which the initial owner or consignee will export from the United States in accordance with sections 801(e) or 802 of the act or section 351(h) of the PHS Act, shall submit to the FDA district with jurisdiction over the port of entry, with each import entry, a statement containing information described in paragraph (b)(2) of this section. The articles for which this reporting requirement apply are:

(i) A component of a drug (including a drug, veterinary drug, and biological for use in humans);

(ii) A component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes;

(iii) A food or color additive; and

(iv) A dietary supplement.

(2) The statement that shall be supplied to FDA with each import entry shall include, but is not limited to, the following information:

(i) A formal declaration of the purpose for which the article is being imported before export (how it will be further processed, or the name or description of the product into which it will be incorporated in the United States) and that it will not be sold or offered for sale in the United States;

(ii) The name or description of the article (including any scientific or technical name);

(iii) Any product coding, batch, lot, or other identifying numbers;

(iv) The name and address of the foreign manufacturer of the imported article (if different from the name of the foreign shipper identified in the import records at the U.S. Customs Service);

(v) The name and address of the initial owner or consignee in the United States and, if different, the address in the United States where the article will be further processed or incorporated into any product listed in paragraph (b)(1) of this section; and

(vi) In addition to the information described in paragraphs (b)(l)(i) through (b)(l)(iv) of this section, for blood, blood components, source plasma, source leukocytes, or a component, accessory, or part thereof (including blood or plasma derivatives or intermediates) that are not licensed under section 351(a) of the PHS Act and are to be imported under section 801(d)(4) of the act, the statement shall include a copy of the determination by the agency granting permission to import the product.

(3) The initial owner or consignee also shall keep a copy of the statement as part of its records for the article.

(c) *Shipping-package label requirements.* The importer, initial owner, or consignee of articles to be imported into the United States for further processing or incorporation into a product for export shall permanently affix, to the articles' shipping container, package or crate, a label that provides the following information in English:

(1) Contains article(s) that are intended for export from the United States after further processing or incorporation into articles intended for export, and may not be sold or offered for sale in the United States;

(2) The name or description of the article(s) (including any scientific or technical name);

(3) The product coding, batch, lot, or other identifying numbers;

(4) The name and address of the responsible foreign manufacturer of the imported article(s);

(5) The country of origin (if different from that of responsible manufacturer); and

(6) Any appropriate warning or special-handling label, such as ''BIOHAZARD'' for products potentially contaminated with an infectious agent.

(d) *Label requirements for blood products.* The foreign supplier of blood, blood component, source plasma, source leukocyte, or a component, accessory, or part thereof (including blood or plasma derivatives or intermediates) that is not licensed under section 351(a) of the PHS Act and is to be imported under section 801(d)(4) of the act, shall label the product in English with the following information:

(1) A properly descriptive name;

(2) Name(s) and address(es) of establishments collecting, preparing, labeling, or pooling the source material;

(3) Donor, lot, or pool numbers relating the unit to the donor;

(4) The recommended storage temperature (in degrees Celsius);

(5) The quantity of the product;

(6) The statement, ''Import for Export;''

(7) The statement, ''Not for Use in Products Subject to Licensure Under Section 351 of the Public Health Service Act;''

(8) The statement, ''For Manufacturing Use Only'' or ''For Manufacturing into Noninjectable Products Only;''

(9) A statement indicating that the product has been tested for infectious disease agents, including, but not limited to: HIV–1, HIV–2, hepatitis B virus, hepatitis C virus, HTLV–I, HTLV–II, and *Treponema palladum*. A request under paragraph (a) of this section may be based upon infectious agent tests performed using test kits other than those licensed or approved by FDA. In such cases, a copy of the label for the test kit used, translated into English, shall accompany the request;

(10) If the product has tested positive for any infectious agent as required in paragraph (d)(9) of this section, the product's label shall indicate the agent(s) for which the product has tested positive, and the term ''BIOHAZARD'' shall be prominently displayed in bold letters; and

(11) Any other appropriate warnings or special handling instructions as determined by the importer.

(e) *Recordkeeping requirements.* (1) The initial owner or consignee who is responsible for the article offered for import shall have a place of business in the United States.

(2) The initial owner or consignee responsible for the article offered for import shall maintain identifying records for 5 years after exportation or destruction of the imported article, and shall make those identifying records available for inspection by the agency. The identifying records shall include the following information:

(i) The name or description of the article (including any scientific or technical name);

(ii) Any product coding, batch, lot, or other identifying numbers;

(iii) The name and address of the foreign manufacturer of the imported article;

(iv) How the article will be or was further processed, and the name or description of any product into which it will be or was incorporated in the United States;

(v) The signature of the responsible individual at the importing firm;

(vi) The name and address of the firm in the United States where the article will be or was further processed or incorporated into another product;

(vii) The disposition of the imported article (i.e., manufacturing records showing how specific articles were used or destroyed and the dates of receipt, use, destruction, or re-exportation, as that information becomes available);

(viii) Any product coding, lot, batch, or other identification number for the further-processed article or product incorporating the imported article;

(ix) A copy of the label to be applied to the shipping package, container, or crate used to export the further–processed article or product incorporating the imported article (indicating that it contains articles that may not be sold or offered for sale in the United States and are intended for export only);

(x) The name and address of the foreign purchaser of the further-processed article or product incorporating the imported article; and

(xi) Additionally, for blood, blood components, source plasma, source leukocytes, or a component, accessory, or part thereof (including blood or plasma derivatives or intermediates) that is not licensed under section 351(a) of the PHS Act and is to be imported under section 801(d)(4) of the act, the records shall include documentation of the agreement between the foreign material supplier and the U.S. manufacturer. The documentation shall outline the specific contractual relationship, the foreign manufacturing specifications, and the U.S. manufacturer's plan for auditing the foreign supplier to ensure compliance with the terms of the contract. The initial owner or consignee shall have written standard operating procedures to ensure that such products are not

diverted to domestic use in the United States and are kept segregated from and not comingled with products or components intended for use in the United States (e.g., quarantine procedures used for segregating imported blood, blood components, or final products from products intended for use in the United States, including validation data for procedures to clean equipment and facilities used for manufacturing products for use in the United States and exported products).

(f) *Registration and listing requirements.* Each person who intends to further process or incorporate blood, blood components, source plasma, source leukocytes, or a component, accessory, or part thereof (including blood or plasma derivatives or intermediates) that is not licensed under section 351(a) of the PHS Act and is to be imported under section 801(d)(4) of the act, shall register with FDA and list the blood product to be further processed or incorporated into other products, or update its registration and listing, and include in the listing a description of the imported material as well as the final product for export. The information shall be sent to the appropriate registration office listed in parts 207 or 607 of this chapter.

Dated: November 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Chapter I

[USCG–1998–4501]

RIN 2115–AF68

Improvements to Marine Safety in Puget Sound-Area Waters

AGENCY: Coast Guard, DOT.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Coast Guard seeks public comment on potential rules that would improve marine safety in Puget Sound-Area waters including Puget Sound, the Strait of Juan de Fuca, passages around and through the San Juan Islands, and the Olympic Coast National Marine Sanctuary. Based on a recent determination by the Secretary of Transportation regarding the status of marine safety in the Puget Sound-area, the Coast Guard will soon begin a comprehensive cost-benefit analysis to study the feasibility of implementing new safety measures, including extended tug escort requirements for certain vessels and a dedicated pre-positioned rescue vessel. Public input will help focus the cost-benefit analysis and help us develop any future proposed rules that may be necessary.

DATES: Comments must reach the Docket Management Facility on or before May 24, 1999. Please submit comments relating to the cost-benefit analysis as soon as possible, preferably by December 24, 1998.

ADDRESSES: You may mail comments to the Docket Management Facility [USCG–1998–4501], U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001, or deliver them to room PL–401, located on the Plaza level of the Nassif Building at the same address, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

The Docket Management Facility maintains the public docket for this rulemaking. Comments, and documents as indicated in this preamble, will become part of this docket and will be available for inspection or copying at room PL–401, located on the Plaza level of the Nassif Building at the same address, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket on the Internet at http://dms.dot.gov.

A copy of the International Private Sector Tug-of-Opportunity System (ITOS) Report to Congress is available in the public docket at the above addresses or on the Internet at http://www.uscg.mil/hq/g-m/nmc/genpub.htm. You may also obtain a copy by calling the project manager at the Coast Guard number in **FOR FURTHER INFORMATION CONTACT**.

A copy of the Puget Sound Additional Hazards Study, formally titled ''Scoping Risk Assessment: Protection Against Oil Spills in the Marine Waters of Northwest Washington State,'' is available in the public docket at the above addresses and from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 800–553–6847, fax 703–321–8547. The report may be ordered as document PB97–205488 and the technical appendices to the report as document PB97–205470.

FOR FURTHER INFORMATION CONTACT: For information concerning this document, call Commander T.M. Close, Human Element and Ship Design Division, U.S. Coast Guard, telephone 202–267–2997. For questions on viewing, or submitting material to, the docket, call Dorothy Walker, Chief, Documents, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages you to participate in this potential rulemaking by submitting written data, views, or arguments. If you submit comments, you should include your name and address, identify this document [USCG–1998–4501] and the specific section or question in this document to which your comments apply, and give the reason for each comment. Please submit all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you want acknowledgment of receipt of your comments, you should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period.

No public meeting is planned. You may request a public meeting by submitting a comment requesting one to the address under **ADDRESSES**. The request should include the reasons why a meeting would be beneficial and recommended locations for the meeting. If it is determined that a meeting should be held, we will announce the time and place in a later notice in the **Federal Register**.

Background and Purpose

During the last two and a half years, the Coast Guard and the Office of the Secretary of Transportation (OST), in cooperation with the State of Washington, the maritime industry, and other local stakeholders, have assessed marine safety in Puget Sound-area waters. The goal of all involved parties is to ensure a high degree of safety and environmental protection for the area's waterways.

On April 26, 1996, the White House issued the ''Department of Transportation Action Plan to Address Vessel and Environmental Safety on Puget Sound-Area Waters.'' This Action Plan consists of three elements. The first element is to establish criteria for and facilitate the development of a private-sector system to provide timely emergency response to vessels in distress in the Strait of Juan de Fuca and near the Olympic Coast National Marine Sanctuary. The second element is to determine the adequacy of all vessel safety and environmental protection