location where the requirements of this AD can be done.

Effective Date

(j) This amendment becomes effective on January 23, 2002.

Issued in Burlington, Massachusetts, on December 7, 2001.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 98N–0583]

Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that establishes the notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States. These regulations implement recent changes in the statutory requirements applicable to certain exports, and also codify recordkeeping requirements for exports of products that cannot be marketed or sold in the United States generally.

DATES: This rule is effective March 19, 2002.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of April 2, 1999 (64 FR 15994), FDA published a proposed rule to establish notification and recordkeeping requirements for products exported under section 801 or 802 of the Federal Food, Drug, or Cosmetic Act (the act) (21 U.S.C. 381 or 382, respectively) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), as amended by the FDA Export Reform and Enhancement Act (Public Law 104–134, as amended by Public Law 104–180).

The FDA Export Reform and Enhancement Act significantly changed and simplified the export requirements for unapproved human drugs, biological products, devices, and animal drugs. For example, before the law was enacted, most exports of unapproved new drugs could only be made to the 21 countries then identified in section 802 of the act, and these exports were subject to numerous restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new human drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA) and certain other requirements are met (see section 802(b)(1)(A) of the act). Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. (The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA.) This provision of section 802 of the act also applies to the export of certain devices that cannot be sold or marketed in the United States.

The FDA Export Reform and Enhancement Act also established recordkeeping and notification requirements. Section 802(g) of the act requires an exporter of a drug or device under section 802(b)(1)(A) of the act to provide a ''simple notification'' to the agency ''identifying the drug or device when the exporter first begins to export such drug or device'' to any of the 25 countries identified in section 802(b)(1)(A) of the act. For exports to other, nonlisted countries, section 802(g) of the act requires the exporter to provide a simple notification ''identifying the drug or device and the country to which such drug or device is being exported.'' This section also requires persons exporting drugs or devices under any provision of section 802 of the act to ''maintain records of all drugs or devices exported and the countries to which they were exported.''

Certain aspects of the proposed rule raised numerous issues. As a result, in the **Federal Register** of June 17, 1999 (64 FR 32442), FDA extended the comment period from June 16, 1999, to July 16, 1999.

FDA received 18 comments on the proposed rule. In addition, the agency received several comments on the export notification and recordkeeping discussions in its draft export guidance document which was published in the **Federal Register** on June 12, 1998 (63 FR 32219, FDA docket number 98D–0307). Drug manufacturers, device manufacturers, device exporters, and food, drug, and device trade associations submitted comments. An animal drug trade association and a biological product company also submitted comments. Because FDA wrote both the proposed rule and the guidance document contemporaneously, the agency considered comments submitted on the proposed rule and related comments submitted on the draft export guidance document when it prepared this final rule.

II. Comments on the Proposed Rule, Including Related Comments Submitted to the Draft Guidance Document

Most comments focused on specific provisions in the proposed rule. However, others made general comments about FDA's export authority or the need for any regulations or addressed other export issues that were not directly related to the proposed rule. A description of the comments, and FDA's responses, follows.

A. General Comments

(Comment 1) Several comments claimed that the proposal was contrary to the letter or intent of the FDA Export Reform and Enhancement Act because it would create ''unnecessary,'' ''cumbersome,'' or ''burdensome'' requirements that would make it more difficult or time-consuming to export products from the United States, place U.S. firms at a competitive disadvantage in global markets, force firms to relocate overseas, or result in lost profits. Some comments said FDA must withdraw the proposal, although others said the agency should significantly revise the proposal to reduce its requirements.

FDA recognizes that the FDA Export Reform and Enhancement Act was designed to facilitate exports of unapproved products from the United States and, through the draft guidance document, proposed rules, and other contacts with individual firms, the agency worked to reduce or eliminate export requirements and facilitate exports. FDA drafted the proposed rule to implement the notification and recordkeeping requirements in section 802 of the act and to establish a single, consistent agency position regarding the types of records it would examine to determine compliance with section

801(e)(1) of the act. In general, FDA sought to establish recordkeeping requirements to inform firms about the types of records that would demonstrate a firm's compliance with the act and to ensure that the records could be linked to a specific export. For example, an export record stating only that ''product X was exported'' would be almost useless if multiple versions of the product exist (because neither FDA nor the exporter would be able to tell what specific version of the product was exported) or if the product was exported to multiple countries (because neither FDA nor the exporter would be able to alert foreign government officials if a problem developed or such communications became necessary).

FDA disagrees, therefore, with those comments asserting that the proposed rule was ''burdensome'' or ''unnecessary.'' The agency's interest is to implement sections 801(e)(1) and 802 of the act and section 351(h) of the PHS Act in a consistent, uniform manner that will generate notifications and records that will be useful in determining compliance with the act and will have some value both to the exporter and the agency. Furthermore, as discussed later in this document, FDA has, in response to other comments, revised or eliminated various requirements. These changes to the final rule should make it easier for exporters to comply with the act.

(Comment 2) Several comments argued that FDA lacks authority to issue any regulations pertaining to exports. One comment conceded that the act imposes substantive requirements and that FDA can exercise its enforcement authority if a manufacturer violates the export requirements, but argued that FDA does not have ''carte blanche'' to require exporters to retain records to defend against a possible FDA enforcement action before the agency alleges that a violation has occurred. The comment added that FDA cannot require records as a substantive requirement so that failure to maintain records would be the basis for regulatory action. Another comment asserted that FDA had failed to show that Congress expected FDA to impose new recordkeeping and reporting requirements on industry or how the requirements would be important in fulfilling FDA's statutory obligations.

Another comment simply stated that the act does not require regulations or the recordkeeping described in the proposed rule.

Other comments cited remarks by one legislator to emphasize that no export restrictions would be preferable.

FDA's authority to issue regulations stems from section 701(a) and (b) of the act (21 U.S.C. 371(a) and (b)). Section 701(a) of the act gives the agency authority to issue regulations for the efficient enforcement of the act unless an exception exists, and section 701(b) of the act specifically authorizes the Departments of Health and Human Services (DHHS) and the Treasury to jointly prescribe and for the DHHS to promulgate regulations for the efficient enforcement of section 801 of the act. Given these provisions of the act, FDA clearly has the authority to promulgate regulations concerning exports and to issue regulations for the efficient enforcement of sections 801 and 802 of the act.

Additional discussion of FDA's authority to issue regulations for the efficient enforcement of section 351(h) of the PHS Act is included in the responses to the comments to § 1.101(c) (21 CFR 1.101(c)) (see section II. D below).

Records enable a person to show, and for FDA to verify, that the person has complied with its legal obligations. The FDA Export Reform and Enhancement Act, with very few exceptions, eliminated any need for prior FDA approval of an export, so determining whether a person has complied with the act must depend on an examination of records. If no records can be required, a firm cannot demonstrate that it met all applicable export requirements, and FDA would be unable to verify such compliance.

Further, section 802(g) of the act clearly states, in part, that, ''Any exporter of a drug or device *shall maintain records* of all drugs or devices exported and the countries to which they were exported'' (emphasis added). The most straightforward interpretation of this provision is that persons exporting drugs or devices under section 802 of the act must keep records on the exported product and the foreign countries receiving the product. As a result, the final rule, at § 1.101(e), describes the types of information that would demonstrate compliance with section 802(g) of the act. Failure to keep the records required by section 802(g) of the act would be a violation of section 802 of the act. As a result, the product would no longer have section 802 of the act's exemption from the applicable misbranding, adulteration, approval, and prohibited act provisions of the act. The product and/or the person responsible could be subject to enforcement action under the act.

FDA acknowledges that one legislator, in his remarks accompanying the passage of the FDA Export Reform and Enhancement Act, indicated a desire to have no export requirements at all. Nevertheless, the FDA Export Reform and Enhancement Act did contain requirements for exports, and one cannot reasonably argue that Congress, in enacting those requirements, intended them to be ignored, rendered meaningless, or made unenforceable. When interpreting legislation, it is a well-settled principle that, ''Absent clear congressional intent to the contrary, we will assume the legislature did not intend to pass vain or meaningless legislation'' (*Coyne & Delany* v. *Blue Cross & Blue Shield of Virginia*, 102 F.3d 712, 715 (4th Cir. 1996); see also *Halverson* v. *Slater*, 129 F.3d 180, 185 (D.C. Cir. 1997) (Congress cannot be presumed to do a futile thing)).

(Comment 3) Two comments argued that the proposal was deficient or had to be withdrawn because FDA had not shown how the proposal protects the public health of U.S. citizens or foreign citizens or benefits consumers.

FDA disagrees with the comments. The rule is intended to implement sections 801(e) and 802(g) of the act and section 351(h) of the PHS Act by describing the types of records that should be kept in order to demonstrate that the export complied with the act and by describing the contents of the simple notification, which must be sent to FDA for certain exports under section 802 of the act. None of these provisions requires a demonstration of the public health benefits for United States or foreign citizens as a prerequisite to rulemaking. Thus, a preamble discussion concerning public health benefits to U.S. citizens or foreign citizens or possible congressional expectations for a regulation is unnecessary.

Nevertheless, the act and, by extension, the final rule indirectly benefits the public health in the United States and in foreign countries. For example, sections 801(e) and 802 of the act permit exports of products that are not approved for use in the United States. (If the products were approved for use and otherwise in compliance with the act's requirements for marketing and sale in the United States, they would not be subject to the export provisions of the act.) Consequently, to the extent that records can show that a product not approved for use in the United States. was, in fact, exported, there would be no U.S. public health concern that a product whose safety or effectiveness has not been established had entered domestic commerce.

As another example, section 351(h) of the PHS Act states, in part, that exports

of a partially processed biological product must conform with current good manufacturing practice (CGMP) requirements. CGMP requirements are, in part, intended to ensure that the product complies with certain adulteration and misbranding provisions. Obviously, consumers benefit by not receiving products that do not comply with these requirements. The final rule, at § 1.101(c)(2), reflects the CGMP requirement adopted by Congress by requiring records demonstrating that the partially processed biological product was manufactured in conformity with CGMPs. If FDA could not require exporting firms to keep CGMP records, there would be no way to demonstrate or to verify that the partially processed biological product met CGMPs, was not contaminated, was correctly labeled and stored, and was otherwise in compliance with section 351(h) of the PHS Act and entitled to the provision's exemption from the requirements of the PHS Act and the act. This demonstration clearly benefits the public health.

(Comment 4) One comment said that the present system is ''working well'' so new regulations are unnecessary. Other comments said the statute was sufficiently clear so no regulations are needed. Another comment asked that foods be excluded from the rule; the comment said, in part, that FDA did not understand the global food market or recognize congressional intent in adopting the FDA Export Reform and Enhancement Act. (The comment also made specific statements against individual provisions in the proposed rule and other claims; FDA addresses those comments elsewhere in this preamble.)

FDA disagrees with the comments. The FDA Export Reform and Enhancement Act affected regulated industries differently. For example, for foods, no significant changes in the export authority occurred, whereas for drugs and devices, the new export provisions offered new authorities for exporting investigational products, products approved by certain foreign countries, and products intended to ''fill the pipeline'' while awaiting approval in a foreign country.

As another example, before the enactment of the FDA Export Reform and Enhancement Act, unapproved new animal drugs were subject to the export requirements in section 802 of the act, and then-section 801(e) of the act did not permit the exportation of animal drugs that were ''unsafe'' within the meaning of section 512 of the act (21 U.S.C. 360b). After the enactment of the FDA Export Reform and Enhancement Act, animal drugs are excluded from section 802 of the act and, except for ''banned'' animal drugs which cannot be exported, now can be exported if they comply with the export requirements in section 801(e)(1) of the act.

Yet, while the new export provisions affected regulated industries differently, certain statutory requirements (such as compliance with section 801(e)(1) of the act) are common to all exports. Other statutory requirements, particularly those in section 802 of the act, are common to drugs and devices, or to drugs, biological products, and devices. In cases where a particular statutory requirement applied to more than one type of product, the agency decided that its interpretation and implementation of that statutory requirement should also be the same, regardless of the product involved. In other words, the rule implementing section 802(g) of the act should be the same for drug exporters as it is for device exporters because both are subject to section 802(g) of the act. Similarly, the requirements in section 801(e)(1) of the act are incorporated by referring to section 802(f) of the act and section 351(h) of the PHS Act, and continue to operate as a freestanding export provision for foods, cosmetics, certain drugs, and devices. The interpretation of section 801(e)(1) of the act should be consistent regardless of the product involved.

So, while the agency's implementation of the export provisions might have been sufficiently clear to some individuals and ''working well'' for certain industries in certain cases, the absence of a single, consistent interpretation of those statutory provisions created the possibility that different FDA centers would implement the same provisions of the act differently. The agency, therefore, formed a multi-center and multi-office group to develop FDA's policies and interpretations for the FDA Export Reform and Enhancement Act. The draft guidance document (which appeared in the **Federal Register** of June 12, 1998 (63 FR 32219)), the proposed ''import for export'' rule (which appeared in the **Federal Register** on November 24, 1998 (63 FR 64930)), and this rule represent the consensus positions and interpretations of the agency's centers and offices.

In short, a rule will help ensure that the export requirements ''work well'' for all, rather than some, regulated industries and that they work the same way for all regulated industries.

As for the comment requesting that FDA exclude food products from the rule, FDA declines to adopt the comment's suggestion. Section 801(e)(1) of the act clearly and unequivocally applies to food exports, so, absent a compelling reason that would warrant separate or different export regulations for food, FDA declines to exclude food products from the final rule.

(Comment 5) One comment said that the proposed rule contained the ''same objectionable provisions'' that were in the draft guidance document on exports.

While the agency disagrees with the comment's characterization of the rule, the proposed rule and guidance document contain the same concepts because FDA prepared the draft guidance document and its export-related proposed rules simultaneously. However, the administrative clearance and publication procedures and statutory requirements that apply to guidance documents are much simpler than those that apply to proposed rules. Consequently, the proposed rules appeared several months after FDA had published the draft guidance document in the **Federal Register**. In preparing this final rule, FDA reviewed both the comments submitted to the proposed rule and relevant comments submitted to the draft guidance document.

(Comment 6) One comment accused the agency of engaging in ''regulatory imperialism'' that is ''neither desired nor needed by other countries'' and that the rule reflected what it called ''FDA's continued belief that the agency is not simply the public-health agency for the United States, but for the entire world.''

FDA disagrees with the comment. The rule implements parts of sections 801(e)(1) and 802 of the act and section 351(h) of the PHS Act. These provisions do not require, or expect, FDA to be a public health agency ''for the entire world,'' but the act and section 351(h) of the PHS Act do establish requirements on exports of products that cannot be legally marketed or sold under the act in the United States, and FDA is charged with enforcing the act and section 351 of the PHS Act. The final rule, as stated earlier, creates a single, uniform interpretation for certain export requirements by describing the types of records the agency would examine in order to determine whether a person complied with the law and by describing the content of the notification, if required by the act, to be sent to FDA.

(Comment 7) Two comments involved investigational products. One comment said the proposal would make it more difficult for U.S. firms to conduct foreign clinical trials for drug and biological products. The other comment said the proposal fails to recognize that food samples are often exported for

testing or for product research and development. This comment said these food products are tested on site under controlled conditions or used for demonstration purposes and are never intended for human consumption in foreign countries. The comment added that these food products are never ''approved'' by foreign governments because they are not intended for retail markets, and said that the proposal overlooked the need for global market development.

For clinical investigations involving human drugs and biological products, the FDA Export Reform and Enhancement Act created several avenues for exporting such products. First, if the drug or biological product has been approved for marketing in any of the countries identified in section 802(b)(1) of the act (the so-called ''listed countries''), the product may be shipped to any country for any purpose; this would include investigational use, and the export would be subject to the rule's notification and recordkeeping requirements.

Second, if the drug or biological product is exported for investigational use in any listed country and is not approved in any listed country, section 802(c) of the act authorizes its export. These exports are not subject to the notification requirement in section 802(g) of the act, but are subject to section 801(e)(1) of the act and to certain other requirements in section 802 of the act. Most drugs and biological products exported for investigational use would probably be subject to this provision of the act and § 1.101(b) and (g).

Third, the clinical investigation could be conducted under an investigational new drug application (IND). In these cases, only the IND requirements at part 312 (21 CFR part 312) would apply.

Fourth, the person could seek permission to export the drug or biological product, without obtaining an IND, under § 312.110. This program, known as the ''312 program,'' pre-dates the FDA Export Reform and Enhancement Act and allows exports for investigational use.

FDA is preparing a proposed rule that would address exports of drugs and biological products for investigational use and also streamline the requirements for the ''312 program.'' Additionally, FDA has revised § 1.101(b)(2) and other parts of this rule to simplify the requirements for demonstrating compliance with section 801(e)(1) of the act. These revisions significantly change the records required for demonstrating compliance with section 801(e)(1) of the act and are discussed later in this document.

As for foods exported for investigational or research uses, the act does not contain any special provisions for such products. There is no apparent legal basis to distinguish them from other food exports.

However, section 801(e)(1)(B) of the act only requires that the product intended for export be ''not in conflict'' with the foreign country's laws. This is considerably different—and far less restrictive than requiring that the exported product be ''approved'' in the foreign country. Market authorization is relevant only for drugs and devices exported under section 802(b)(1) of the act, because that provision of the act allows exports of unapproved drugs or devices if they have received valid marketing authorization from any listed country, and comply with the other applicable requirements of section 802 of the act. Thus, in the food testing and research and development example cited by the comment, the export would comply with section 801(e)(1)(B) of the act if such activities do not conflict with the laws of the importing country. Additionally, as stated earlier, revised § 1.101(b)(2) greatly simplifies the types of records needed to show that the product is not in conflict with the foreign country's laws.

(Comment 8) One comment objected to notifying FDA at all if a device is International Organization for Standardization (ISO)–9001 certified or has received approval from a notified body so that it may be commercially marketed in the EU. The comment said the Conformite European (CE) mark should exempt the device from notification and said that small countries will find it in their best interests to accept the CE mark as their acceptance standard.

FDA declines to exempt CE-marked or ISO–9001 certified devices from the notification requirement. The act requires notification for drugs and devices exported under section 802(b) of the act. The act does not exempt devices that bear a CE mark or meet ISO–9001 standards from the act's export requirements. The agency notes that such devices may qualify for export under section 801(e)(1) of the act. In such instances, no notification would be required as long as the export complies with section 801(e)(1) of the act.

As for the comment's assertion that small countries should accept the CE mark, such matters are outside the scope of this rule. FDA cannot require other countries to accept a CE mark.

(Comment 9) The preamble to the proposed rule described the requirements in section 802(f) of the act. It noted that the act prohibits exports of a drug or device if the product is the subject of a determination by FDA or by the U.S. Department of Agriculture (USDA) that the probability of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States. The preamble to the proposed rule noted that veterinary biological products are subject to USDA jurisdiction (64 FR 15944, col. 3). One comment requested that FDA remove the reference to veterinary biological products.

The statement in the preamble to the proposed rule accurately described the USDA's jurisdiction. However, the reference to veterinary biological products was inappropriate because sections 801(e)(1) and 802 of the act apply only to FDA-regulated products. No changes to the final rule are necessary, though, because the reference to veterinary biological products appeared only in the preamble to the proposed rule.

(Comment 10) Two comments said the rule failed to address or to distinguish between items that are imported as components or ingredients that are used in products destined for export and products that are manufactured solely for export purposes.

In the **Federal Register** of November 24, 1998 (63 FR 64930), FDA published a proposed rule regarding ''import for export'' under section 801(d) of the act. The proposal described the reporting and recordkeeping requirements for articles that are imported into the United States and are later further processed or incorporated into items for export.

The import for export proposal, however, focused on requirements pertaining to the imported article, whereas this final rule pertains to the notification and recordkeeping requirements for exported products. In other words, the import for export provision in section 801(d) of the act does not relieve ''import for export'' products from satisfying the export requirements in sections 801(e) and 802 of the act or section 351(h) of the PHS Act. Thus, one should read this final rule in conjunction with the import for export proposal. FDA intends to finalize the import for export proposal in the near future.

B. Scope (Section 1.101(a))

Section 1.101(a) would describe the provision's scope as covering notifications and records required for human drug, biological product, device,

animal drug, food, and cosmetic exports under sections 801 or 802 of the act or section 351 of the PHS Act.

(Comment 11) One comment asked if a product meeting all applicable marketing requirements in the United States, but labeled in a foreign language and intended for the same uses as those approved by FDA, would be exempt from the rule.

FDA considers a product which is labeled solely in a foreign language and whose foreign-language labeling has not been approved by FDA (where such FDA approval of labeling is required) to be an unapproved product and subject to the act's approval requirements. FDA approval, in general, includes approval of a product's labeling (see, e.g., sections 505(b)(1)(F), (d)(5), and (d)(7); 512(a)(1)(B), (a)(2)(C), and (b)(1)(F); and 515(c)(1)(F), and (d)(2) of the act (21 U.S.C. 355(b)(1)(F), (d)(5), and (d)(7); 360b(a)(1)(B), (a)(2)(C), and (b)(1)(F); and 360e(c)(1)(F), and (d)(2))). Thus, if FDA has not reviewed or approved the foreign-language label, the product is unapproved and would not be exempt from this rule, even if an identical, FDA-approved product with approved labeling exists.

For information regarding the exportation of products legally marketed in the United States that are accompanied by FDA-approved labeling, please see comment 28.

(Comment 12) One comment objected to the rule's scope, saying that it would cover products that foreign countries might regulate differently from FDA. The comment gave an example of patient [disposal] washcloths, which would be medical devices in the United States, but would be cosmetics in Brazil. The comment said FDA should concern itself with compliance with FDA requirements for domestic shipments.

FDA disagrees with the comment. The most logical interpretation of the act is to have FDA regulate products, and determine whether products are exempt from requirements applicable to products marketed, distributed, or sold in the United States because they qualify for export under sections 801(e) or 802 of the act or section 351(h) of the PHS Act, according to their classification or type in the United States. Thus, a product that would be considered a device in the United States remains a device under the export provisions even though a foreign country might regulate it differently or might not regulate it at all. It would be both inefficient and resource-intensive for exporters and FDA to apply the export requirements based on the product category in which a particular foreign country regulates the product. Moreover, such an approach is inconsistent with the structure of the act's export provisions. The export provisions are a means by which an exporter can ship products that would otherwise be subject to the act's domestic provisions. The purposes underlying the export provisions would be undermined if a product could qualify for export under the rules applicable to the product category of the importing country rather than based on how the product is regulated in the United States.

(Comment 13) One comment said the proposal failed to address specific categories of food products. The comment said that food additives and dietary supplements are ''foods'' and subject to section 801(e)(1) of the act, but said color additives are not foods, drugs, or any other product mentioned in proposed § 1.101(a). The comment asked if color additives are exempt from the rule.

The act's definitions of ''food,'' ''drug,'' and ''cosmetic'' include components of such products (see section 201(f)(3), (g)(1)(D), and (i)(2) of the act (21 U.S.C. 321(f)(3), (g)(1)(D), and (i)(2)). Section 201(t)(1)(B) of the act, in general, defines a ''color additive'' as a material that, when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable of imparting color. Most color additives would be components of a food, drug, or cosmetic and, as a result, be subject to the act's export requirements for foods, drugs, or cosmetics. Only those color additives that are not classified as a food, drug, or cosmetic ''component'' fall outside sections 801(e) and 802 of the act. In such circumstances, if the color additive cannot be legally marketed, distributed, or sold in the United States because it does not comply with the act's requirements for color additives, it may not be exported.

(Comment 14) FDA, on its own initiative, has replaced the word ''biologic'' or ''biologics'' with ''biological product'' or ''biological products'' throughout the rule. This change has no substantive effect and is intended only to use the term used in the PHS Act for these products.

C. Recordkeeping Requirements for Human Drugs, Biological Products, Devices, Animal Drugs, Foods, and Cosmetics Exported Under or Subject to Section 801(e)(1) of the Act (Section 1.101(b))

1. General Remarks

Section 1.101(b) would establish the recordkeeping requirements for human drugs, biological products, devices, animal drugs, foods, and cosmetics exported under or subject to section 801(e)(1) of the act.

(Comment 15) Several comments challenged FDA's authority to issue any recordkeeping regulations for section 801(e)(1) of the act. Two comments claimed that the act only requires records under section 802(g) of the act, so FDA cannot issue recordkeeping requirements for section 801(e)(1) of the act. One comment added that the proposed recordkeeping requirements went ''far beyond'' the ''simple recordkeeping'' requirements specified in the act. Two comments argued that the act did not require records or prescribe what records are to be kept, although one comment acknowledged that companies should keep records to demonstrate compliance with the act. According to these comments, companies have the discretion to keep any records they wish to demonstrate compliance with section 801(e)(1) of the act.

FDA has ample legal authority to require records. Section 701(b) of the act provides the principal legal basis for the recordkeeping requirements in § 1.101(b). Section 1.101(b) reflects the basic export requirements in section 801(e)(1) of the act that apply to all exports under sections 801(e) and 802 of the act, regardless of whether the product is a food, human or animal drug, biological product, device, or cosmetic. The agency drafted this provision to provide a single, consistent interpretation of requirements in section 801(e)(1) of the act to both industry and to the agency's own components. This should result in less confusion and fewer disagreements as to whether a particular document adequately demonstrates compliance with section 801(e)(1) of the act (which would occur if no regulation existed and firms had total discretion over what records to keep). FDA has, however, significantly revised § 1.101(b) in response to the comments (by shortening the recordkeeping period and by clarifying the types of records needed to show that the export meets the foreign purchaser's specifications or does not conflict with foreign laws), and discusses those changes later in this document.

For the records required in § 1.101(e), section 701(a) of the act provides rulemaking authority for the efficient enforcement of the act, and this authority is independent of the recordkeeping requirement in section 802(g) of the act. FDA further notes that, contrary to one comment's claim, section 802(g) of the act does not refer to ''simple recordkeeping.'' Instead,

section 802(g) of the act refers to a ''simple notification'' that is to be sent to FDA, and requires drug and device exporters to ''maintain records of all drugs or devices exported and the countries to which they were exported.''

(Comment 16) One comment argued that the proposal contains requirements and recommendations that are irrelevant or inappropriate to specific products, such as bulk agricultural commodities. The comment asked FDA to exclude foods from the rule.

FDA declines to exclude foods from the rule. Section 801(e)(1) of the act specifically includes foods, so it is more practical and appropriate to include foods as part of this rule so that the rule applies equally to all products subject to section 801(e)(1) of the act.

Section 801(e)(1) of the act also does not distinguish between types of food, so it would be inappropriate to create exemptions or exceptions for specific food products. FDA has, however, revised some requirements in § 1.101(b) to make it easier to demonstrate compliance with section 801(e)(1) of the act. FDA is unable to respond further to the comment because it did not identify which requirements were supposedly irrelevant or inappropriate or explain why they were irrelevant or inappropriate.

(Comment 17) Proposed § 1.101(b)(1) would require records to be kept at least 5 years after the date of exportation and made available to FDA for review and copying.

Several comments protested that the 5-year period was excessive. One comment claimed that food manufacturers do not even keep records regarding foreign regulatory requirements and that it would be unrealistic and unacceptable to expect them to do so. Two comments suggested that the retention period be 2 years, while another comment suggested that, for drugs, the period be 1 year after the product's expiration date.

The agency has revised the rule to make the record retention period coincide with the CGMP or quality systems (QS) regulations applicable to the product. So, for example, the CGMP record retention period would apply to drug exports, and the QS regulation record retention period would apply to device exports. FDA decided to use CGMP and QS regulation record retention periods because most records described in § 1.101 would be contained in a company's CGMP or QS regulation records. As a result, firms should find it easier to maintain their export records in the same manner and for the same period of time as their CGMP or QS regulation records.

For food and cosmetic exports, the food CGMP regulations do not contain a recordkeeping requirement, and there is no CGMP regulation for cosmetics. Therefore, because the food CGMP and cosmetic regulations do not require records, FDA has revised § 1.101(b)(1) to require records for food and cosmetic exports to be kept for 3 years after the date of exportation. The 3-year period is consistent with the CGMP record retention period for drugs (see 21 CFR 211.180(a)).

As for the comment claiming that food manufacturers do not keep records of foreign regulatory requirements, neither the proposed nor final rules required them to do so. Section 1.101(b)(2) requires records demonstrating that the product does not conflict with the laws of the importing country. The final rule states that such records can consist of either: (1) A letter from an appropriate foreign government agency, department, or body stating that the product has marketing approval from the foreign government or does not conflict with the foreign government's laws; or (2) a notarized certification by a responsible company official in the United States that the product does not conflict with the importing country's laws and includes a statement acknowledging that he or she is subject to 18 U.S.C. 1001. Thus, showing that the export does not conflict with the foreign country's laws does not require a person to keep records regarding foreign regulatory requirements.

(Comment 18) One comment argued that the recordkeeping obligations do not operate until a firm begins to export a product.

FDA disagrees with the comment. Although the rule does not specify when a firm should begin keeping export records, FDA expects firms to begin creating and keeping records before they export a product under sections 801(e) or 802 of the act or section 351(h) of the PHS Act. For example, to show whether the export meets the foreign purchaser's specifications (as required by section 801(e)(1)(A) of the act), an exporter would keep a copy of the incoming purchase order showing which items the foreign purchaser wanted. It would be illogical for the exporter to ask the foreign purchaser to provide a purchase order when the exporter ships or after the exporter has shipped the products to the foreign purchaser or to start keeping such records after he or she has exported the product.

In other words, a prudent firm should know whether exports are permitted or whether the export meets various obligations under the act or the PHS Act before the firm actually exports the product. Yet, even in the absence of this requirement, most firms would have the foreign purchaser's specifications before they export the product because they would want to ensure that they are manufacturing and exporting the correct item and to reassure the foreign purchaser that the exported item meets the purchaser's needs or expectations. Moreover, for purposes of the act, if a product does not comply with the applicable requirements for domestic marketing, distribution, and sale, and the manufacturer lacks evidence that the product is intended for export and meets the requirements of an applicable export exemption (i.e., sections 801 or 802 of the act or section 351(h) of the PHS Act), the product would be subject to enforcement action for violating the act.

2. Foreign Purchaser's Specifications (Section 1.101(b)(1))

To demonstrate that the exported product meets the foreign purchaser's specifications, § 1.101(b)(1) would require records describing or listing the product specifications requested by the foreign purchaser. The proposal indicated such records could include details about the product (e.g., dosage strength, dosage form, purity, quality, operating parameters, composition) and any manufacturing specifications requested by the foreign purchaser (e.g., type of sterilization process to be used, compliance with a particular manufacturing standard).

(Comment 19) Most comments submitted in response to proposed § 1.101(b)(1) interpreted the provision as requiring extremely detailed product specifications and protested the level of detail that they believed the rule required. For example, some comments said that in vitro diagnostic devices are not manufactured to unique specifications and are instead sold to the general laboratory or scientific community. These comments said package inserts describing product specifications, product labeling, or some indication that the in vitro diagnostic device met design criteria should be acceptable.

Other comments said that, for food products or medical devices, contracts or purchase orders between exporters and foreign purchasers should suffice. One comment added that for devices FDA should not require specifications to be in English; the comment said requiring foreign purchasers to draft original specifications in English would be cumbersome and that product labeling is used worldwide as the basis for product performance characteristics.

One comment from a trade association for human drug manufacturers said CGMP records should suffice, but also claimed that the act does not authorize FDA to require any records. In contrast, another comment said that some foreign purchasers have limited requirements and may not require detailed product specifications.

One comment said that recipes, manufacturing specifications, and processes are proprietary information protected under ''international agreements'' and should not be available to FDA for review and copying. The comment accused FDA of trying to obtain proprietary information with the intent to share such information with foreign entities.

Only one comment stated that the records described in proposed § 1.101(b)(1) would not present any problem. The comment explained that a manufacturer would require a detailed specification for the custom manufacture of any product that is not regularly manufactured or sold in the United States.

FDA believes that many comments misinterpreted the rule. FDA's principal interest is to link a record to a particular export to verify that the exported product met the foreign purchaser's specifications. For example, if the foreign purchaser sought 5,000 bottles of drug X tablets, with each tablet at a 50 milligram (mg) dose, FDA would look for records to show that a particular shipment of drug X to the foreign purchaser consisted of 5,000 bottles of 50 mg of drug X tablets. Records stating only that drug X was shipped to the foreign purchaser would not be satisfactory because they would provide no information regarding the foreign purchaser's specifications or how the export shipment met those specifications.

The final rule does not prescribe any particular degree of detail in the foreign purchaser's specifications. The agency has revised § 1.101(b)(1) to clarify that the records need only contain sufficient detail to match the foreign purchaser's specifications to a particular export. If CGMP records contain information on the foreign purchaser's specifications, they may be sufficient under § 1.101(b)(1).

As for translations, the specifications should be translated, if necessary, to facilitate a determination as to whether the exported product meets the foreign purchaser's specifications. The agency has no preference whether the foreign purchaser or the U.S. manufacturer or exporter does the translation. However, the U.S. manufacturer or exporter should know whether the exported product meets the foreign purchaser's specifications, so it is reasonable to expect that the U.S. manufacturer or exporter would understand the foreign purchaser's specifications and be able to communicate those specifications in English.

FDA disagrees with the comment that claimed that FDA wants to obtain proprietary information in order to transmit that information to foreign entities. Such claims are totally unfounded. FDA is very conscious of its legal obligations to protect trade secrets and confidential commercial information (see section 301(j) of the act (21 U.S.C. 331(j)), 21 CFR part 20) and has regulations governing communications with foreign governments (see 21 CFR 20.89). Those regulations contain several safeguards, such as sponsor consent, to protect any exchanges of confidential commercial information with foreign governments.

(Comment 20) One comment asked how often foreign purchasers must provide product specifications. The comment explained that specifications are only as detailed as necessary to meet the purchaser's needs, so that if the foreign purchaser changes or amends its specifications, the foreign purchaser should be expected to provide an amendment to the U.S. manufacturer. The comment suggested that FDA interpret the rule to require foreign purchasers to provide complete specifications only with the initial order. If the foreign purchaser subsequently changed the specifications, the foreign purchaser would only provide the changes to the manufacturer (rather than a complete set of specifications). The comment added that batch records would be kept in accordance with existing recordkeeping requirements and would be made available during an inspection.

FDA does not expect complete specifications to accompany every order of the same product. For example, if an exporter signs a contract to ship the same item to a foreign purchaser on a monthly basis, the agency would not expect the exporter to obtain complete specifications for each monthly shipment, but would expect the exporter to have specifications that applied to the initial shipment and records showing that subsequent shipments correspond to the same initial specifications. The agency's principal interest is to link records to specific export shipments to verify that a particular exported product met the foreign purchaser's specifications. The level of detail in the specifications may vary between orders, but the agency expects manufacturers to be able to demonstrate that the exported product met the foreign purchaser's specifications.

3. Not in Conflict With the Foreign Country's Laws (Section 1.101(b)(2))

Proposed § 1.101(b)(2) would require the exporter to maintain documentation that demonstrates that the exported product does not conflict with the importing country's laws. The proposal stated that this would normally consist of a letter from the appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws. The proposal would not consider letters or other documents from nongovernmental bodies or persons, such as company officials or attorneys in the foreign country, to be satisfactory for this purpose.

(Comment 21) Many comments objected strongly to proposed § 1.101(b)(2). In general, most comments said it would be difficult, time-consuming, burdensome, or impossible to obtain a letter from a foreign government. Other comments argued that foreign governments might not regulate the exported product so one could not demonstrate that the product was not in conflict with foreign laws or that foreign governments might not be willing to provide a letter due to disinterest, lack of staff, or a desire to protect domestic industry. A few comments suggested that manufacturers should not be responsible for determining whether a product does not conflict with foreign laws, arguing that importers, purchasers, or distributors in the foreign country should bear that responsibility.

Many comments advocated alternative approaches that would eliminate any need for a letter from the foreign government. Most comments favored a certification, declaration, letter, or memo by a company official in the foreign country, a distributor in the foreign country, by a foreign subsidiary, an attorney (either in the United States or in the foreign country), a notified body (if the export were to Europe or Japan), or a foreign government official, or some combination of these firms or persons. These comments often explained that firms are responsible for meeting local requirements and supported the use of certifications or letters from company officials.

One comment suggested using only contractual documents between the exporter and importer. The comment said previous FDA guidance to the grain handling industry used this approach.

Another comment said a copy of a valid import license should be sufficient because these licenses usually require inspection by the foreign government. The comment explained that a manufacturer will not ship a product if its export costs are significant, and it will not ship a product that does not comply with local requirements because the cost of returning the product would be too great.

One comment said a label stating ''For export only'' should suffice to show that the product does not conflict with the foreign country's laws.

Section 1.101(b)(2) was intended to provide the most reliable indicator that the exported product did not conflict with the foreign country's laws. However, in light of the comments, FDA has revised § 1.101(b)(2) to accept, as an alternative to a letter from the foreign government, a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. The certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willfully make a false or fraudulent statement, or make or use a false document, in any matter within the jurisdiction of a department or agency of the United States. This statutory provision also makes it a criminal offense to knowingly and willfully falsify, conceal, or cover up by any trick, scheme, or device a material fact in any matter within the jurisdiction of a department or agency of the United States. This revision should address the concerns expressed in most comments and eliminate any potential delays or obstacles in demonstrating compliance with section 801(e)(1)(B) of the act. FDA reserves the authority to request additional documentation demonstrating that the export is not in conflict with the foreign country's laws if questions arise regarding a certification.

FDA declines to amend the rule to accept contracts as evidence that an export is not in conflict with a foreign country's laws. While parties entering contracts usually intend to execute legally binding obligations, they do not necessarily take into account whether the export complies with foreign laws.

(Comment 22) A few comments disputed FDA's authority to require a letter from a foreign government. They noted that a particular legislator considered such a requirement to be objectionable or simply declared that FDA exceeded its legal authority.

As stated earlier, FDA has revised § 1.101(b)(2) to accept certifications from company officials as an alternative to a letter from a foreign government agency.

Additionally, as discussed earlier, FDA has ample legal authority under section 701 of the act to issue regulations for the efficient enforcement of the act.

(Comment 23) One comment interpreted § 1.101(b)(2) as being satisfied if the foreign country had issued an approval letter or published some document indicating that the product was approved.

Copies of approval letters or other government-issued documents indicating government approval are acceptable to show that the product is not in conflict with the foreign country's laws, but, as stated earlier, the final rule also allows firms to provide a certification from a responsible company official that the product is not in conflict with the foreign country's laws. FDA reiterates that section 801(e)(1)(B) of the act does not require the foreign government to ''approve'' the exported product for commercial marketing; it only requires that the export ''not be in conflict'' with the foreign country's laws.

Market authorization from a foreign government is relevant under section 802(b)(1) of the act, which authorizes the export of drugs and devices that have received marketing authorization from a listed country. However, the final rule does not contain any detailed provisions pertaining to the market authorization aspect of section 802(b)(1) of the act.

(Comment 24) Proposed § 1.101(b)(2) also would require the letter from the foreign government to be in English or for the person exporting the article to have an English-language translation. One comment objected to the English-language translation requirement. The comment said World Trade Organization (WTO) notification processes do not require translations and that, for exported food products, English-language translations are not always available or necessary.

Section 1.101(b)(2) accepts certifications from company officials in the United States to show that the export does not conflict with the importing country's laws, and the final rule requires the certification to be in English or for an English-language translation to be available. This should not be objectionable because a U.S. exporter is likely to have a responsible official capable of writing a certification in English.

FDA is not persuaded that WTO notification processes are relevant to the rule because this rule concerns compliance with U.S. law by U.S. companies. Section 801(e)(1)(B) of the act requires the exported food, drug, device, or cosmetic to not be in conflict with the laws of the country to which it is intended for export, and § 1.101(b)(2) describes how a U.S. firm demonstrates compliance with section 801(e)(1)(B) of the act.

(Comment 25) One comment said proposed § 1.101(b)(2) would adversely affect clinical trials conducted outside the United States by affecting the supplies of exported drugs for investigational use.

Because FDA has revised § 1.101(b)(2) to accept certifications as an alternative to a letter from a foreign government, the agency does not anticipate any significant problems or delays in executing the certifications, so there should be no adverse impact on exporting drugs for investigational use. Additionally, FDA intends to issue a proposed rule concerning exports of investigational new drugs. The proposal would describe some new regulatory approaches for exporting investigational new drugs and would streamline existing requirements for such exports.

4. ''For Export Only'' Label (Section 1.101(b)(3))

Proposed § 1.101(b)(3) would require the records to include copies of any labels or labeling statements, placed on the shipping packages, that show that the packages are intended for export. The proposal indicated that statements such as ''For export only'' may be sufficient for this purpose.

(Comment 26) Two comments said that raw or processed agricultural commodities cannot be labeled. The comments said that FDA should accept a statement on the bill of lading, export declaration, or other shipping document. One comment suggested that the label, alone, should be sufficient and that FDA should not require firms to show that the export does not conflict with the foreign country's laws.

FDA agrees and has revised the rule to permit the statement to be attached to a bill of lading, export declaration, or other document accompanying the exported product if the product, as it is ordinarily shipped, cannot be labeled.

As for the comment's statement that FDA should not require firms to show that an export does not conflict with a foreign country's laws, FDA points out that section 801(e)(1)(B) of the act expressly requires that a food, drug, device, or cosmetic intended for export to be ''not in conflict with the laws of

the country to which it is intended for export.'' If a product intended for export fails to comply with section 801(e)(1)(B) of the act, the product may be considered to be adulterated or misbranded, and section 301(a) of the act prohibits the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded food, drug, device, or cosmetic.

5. ''Not Sold or Offered for Sale in the United States'' (Section 1.101(b)(4))

Proposed § 1.101(b)(4) would require records showing that the product is not sold or offered for sale in the United States. The preamble to the proposal said that these records could pertain to the product, its labeling, and similar products sold in the United States. The idea was to show that the exported product, when compared to those sold in the United States, was different from products sold domestically.

(Comment 27) Several comments objected to the proposed requirement, arguing that the act does not require any records or labeling to show that the exported product is not sold or offered for sale in the United States.

In contrast, other comments stated that it is difficult to assemble records to ''prove a negative,'' namely that a particular product is not sold or offered for sale in the United States, particularly when a company does not sell a similar product in the United States or only exports products. Some comments suggested that FDA accept copies of shipping records, product labeling, price lists or catalogs, product listings submitted to FDA, or certifications from the exporter. Most comments recommended that the labeling statement in § 1.101(b)(3)—that the product is ''For export only''—be acceptable, although some would add a product label stating, ''Not for sale in the United States.'' Two comments said records relating to the production, destruction, and export of products or showing how exported products are segregated from those sold in the United States should be acceptable.

After further consideration, FDA agrees that it would be difficult and impractical to require records of products sold domestically, product labels, or similar information in order to demonstrate that a particular export is ''not sold'' in the United States. The agency has revised the rule to state that production and shipping records relating to the exported product will be sufficient and that promotional material will be helpful in determining whether a product is ''offered for sale'' in the United States. The agency notes that information concerning products sold or offered for sale in the United States that are similar to an exported product may be used by the agency in determining compliance with section 801(e)(1) of the act. The final rule does not require an exporter to retain records concerning similar products sold or offered for sale in the United States, but other provisions in the act may require such records to be retained.

(Comment 28) FDA interpreted section 801(e)(1)(D) of the act as requiring exported products to be different from products sold in the United States. One comment questioned FDA's interpretation. The comment said that section 801(e)(1)(D) of the act is only intended to prevent diversion of products into domestic commerce. The comment argued that preventing the sale of foreign-market versions of products sold in the United States ''perversely'' establishes a more restrictive regime for products sold in the United States than products not sold or offered for sale in the United States.

Two comments disagreed with FDA's position as it pertains to multiple batches of the same product. (In the draft guidance document, FDA indicated that section 801(e)(1)(D) of the act would not be met if a manufacturer made five batches of the same drug and sought to sell some batches in the United States and to export the others; the draft guidance document indicated that the U.S. sales would show that the product is, in fact, sold in the United States contrary to section 801(e)(1)(D) of the act.) The comments argued that section 801(e)(1)(D) of the act should be interpreted as applying only to specific products that are or were sold or offered for sale in the United States, so products that are intended for export may, in fact, be exported even though the same product or different batches of the product are sold in the United States.

After considering the comment, FDA is clarifying its interpretation of section 801(e)(1)(D) of the act. If the product is legally sold in the United States, and the same product is intended for export for the same approved use and is accompanied by the FDA-approved labeling, FDA may consider the product to be sold or offered for sale in the United States. In most circumstances, the product would not have to meet the requirements of section 801(e)(1) of the act because the product to be exported is the same product that can be legally sold in the United States and does not need to qualify for an exemption from the act's requirements. By stating that the product is ''accompanied'' by the FDA-approved label, FDA does not require the FDA-approved label to be affixed to each exported product, but the agency does expect the FDA-approved label to be included in the export shipment. The agency recognizes that no interest would be served by requiring firms to attach FDA-approved labels to exported products if those labels would have to be removed or altered for the product to be sold in a foreign country.

In contrast, if the product to be exported involves a use that is not approved in the United States, or is labeled solely in a foreign language and whose foreign language labeling has not been approved by FDA, then the product is ''unapproved'' and falls within the act's export provisions. In these cases (as we stated in our response to comment 11 earlier), the product must comply with section 801(e)(1)(D) of the act, and FDA would not consider the product to be sold or offered for sale in the United States within the meaning of section 801(e)(1)(D) of the act.

As for batches of the same product, FDA is clarifying its position to state that batches of a product that are segregated from products intended for domestic commerce or produced on manufacturing lines that are dedicated to export markets, may meet the requirement in section 801(e)(1)(D) of the act as long as the batch intended for export differs from the domestic product. (For example, the product intended for export is not made under the same CGMPs that apply to the product marketed in the United States.)

FDA will revise its guidance document on the FDA Export Reform and Enhancement Act to reflect these positions.

D. Additional Recordkeeping Requirements for Partially Processed Biological Products Exported Under Section 351(h) of the Public Health Service Act (Section 1.101(c))

Proposed § 1.101(c) would establish recordkeeping requirements, in addition to those required under § 1.101(b), for partially processed biological products exported under section 351(h) of the PHS Act.

(Comment 29) One comment would delete all recordkeeping requirements for partially processed biological products. The comment said that proposed § 1.101(b)'s recordkeeping requirements are based on section 802(g) of the act, but that provision is inapplicable to partially processed biological products.

FDA disagrees with the comment. FDA licenses biological products under the authority of section 351 of the PHS Act. The PHS Act requires that biological products be licensed and be

safe, pure, potent, and manufactured in facilities designed to ensure that the product continues to be safe, pure, and potent. Biological products are approved for marketing under the provisions of the PHS Act. However, because most biological products also meet the definitions of ''drugs'' or ''devices'' under the act, they are also subject to regulation under the act. As part of the FDA Export Reform and Enhancement Act, Congress substantially revised section 351(h) of the PHS Act, the provision that allows exports of partially processed biological products not otherwise in compliance with section 351 of the PHS Act and the act. Prior to the amendments, exports of partially processed biological products required FDA approval and were limited to those countries listed in the previous version of section 802 of the act. As amended, section 351(h) of the PHS Act exempts exported partially processed biological products from the requirements of the chapter of the PHS Act and the requirements of the act if certain requirements are met. Section 351(h) of the PHS Act states that a partially processed biological product which:

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States, shall be subject to no restriction on the export of the product under this chapter or the Federal Food, Drug, and Cosmetic Act * * * if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act * * *.

The records in § 1.101(b) will show whether a product complies with section 801(e)(1) of the act, and section 351(h) of the PHS Act clearly requires exports of partially processed biological products to comply with section 801(e)(1) of the act. If FDA could not require such records, an exporter could not show, and FDA could not verify, that an exported, partially processed biological product complies with section 801(e)(1) of the act.

Furthermore, it would be both unfair and illogical to interpret section 801(e)(1) of the act in a manner that would impose more requirements on persons who export foods, drugs, devices, and cosmetics, and comparatively fewer (if any) requirements on persons who export partially processed biological products.

The act and the PHS Act authorize additional recordkeeping requirements to demonstrate compliance with the other requirements for the export of partially processed biological products under section 351(h) of the PHS Act. Partially processed biological products are drugs under the act, and section 351(h) of the PHS Act allows such products to be exempt from both the PHS Act and from the act if certain requirements are met. The rule's recordkeeping requirements for exports under section 351(h) of the PHS Act will allow FDA to determine efficiently whether the terms of the exemption have been met and whether any violations of the act exist, which would be the case if the export does not comply with the exemption in section 351(h) of the PHS Act. The issuance of these regulations, therefore, is authorized under section 701(a) of the act, which gives FDA the authority to issue regulations for the efficient enforcement of the act.

Recordkeeping requirements to implement section 351(h) of the PHS Act are also authorized by section 361 of the PHS Act (42 U.S.C. 264). Under that section, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States. Because of their nature, partially processed biological products pose a potential risk of transmitting diseases because they may not have been treated to inactivate infectious agents or other harmful agents. FDA has determined that it may appropriately and effectively regulate partially processed biological products intended for export, and the risks associated with their movement in interstate commerce, by imposing recordkeeping requirements specific to exports under section 351(h) of the PHS Act.

FDA has, however, rewritten § 1.101(c)(2) through (c)(4) to adopt parallel sentence structure. These changes are intended to make the rule easier to read and have no substantive impact on the rule.

(Comment 30) Proposed § 1.101(c)(1) would require persons exporting a partially processed biological product under section 351(h) of the PHS Act to maintain records demonstrating that the product for export is a partially processed biological product, that is, ''not in a form applicable to the prevention, treatment, or cure of disease or injuries of man.''

One comment said it would be impractical to create records to show that a product is a partially processed biological product. The comment said that a partially processed biological product ''is just that, a partially processed biologic.''

FDA disagrees with the comment. Before Congress enacted the FDA Export Reform and Enhancement Act, FDA interpreted the term ''partially processed biologic'' in section 351(h) of the PHS Act as including products that require purification, inactivation, fractionation, or significant chemical modification before the partially processed biological product can be used in making a final product. To demonstrate that a product was a partially processed biological product, a firm provided either an explanation or documentation explaining the need to purify, inactivate, fractionate, or chemically modify the partially processed biological product before it could be used in a final product.

While the FDA Export Reform and Enhancement Act eliminated the need to submit an export application to FDA, it did not alter the term ''partially processed biologic'' or suggest any changes to FDA's interpretation of the term. Consequently, FDA expects firms to have records demonstrating that the product intended for export is, indeed, a partially processed biological product that is eligible for export under section 351(h) of the PHS Act. Those records may consist of an explanation or documentation explaining the need to purify, inactivate, fractionate, or chemically modify the partially processed biological product before it could be used in a final product.

(Comment 31) Proposed § 1.101(c)(4) would require a firm to maintain copies of all labeling that accompanies the partially processed biological product for export, such as a container label with the statement, ''Caution: For Further Manufacturing Use Only,'' and any package insert and to make such copies and package inserts available to FDA during an inspection.

One comment said the proposed requirement was unauthorized under the act and the PHS Act. The comment said that manufacturers should not have to keep copies of all labeling that accompanies an exported product.

FDA disagrees with the comment. The requirement to maintain copies of all product labeling is consistent with CGMP requirements. For example, as part of the batch product and control record requirements for drugs, 21 CFR 211.188(b)(8) requires retention of complete labeling control records, including specimens or copies of all labeling used in batch products. Section 351(h) of the PHS Act expressly requires that exported partially processed

biological products be in conformity with CGMP requirements. The recordkeeping requirement adopted for exports in this rule is, therefore, consistent with existing CGMP requirements that apply to partially processed biological products exported under section 351(h) of the PHS Act. As discussed in greater detail in the response to comment 42 (below), the final rule does not require exporters to maintain duplicate sets of records for export and CGMP purposes. Records required under this rule may be part of the exporter's CGMP or QS regulation records.

The requirement to maintain copies of all product labeling is also consistent with the requirement in section 351(h)(2) of the PHS Act that a partially processed biological product intended for export not be ''intended for sale in the United States'' and the requirement in section 351(h)(3) of the PHS Act that the exported product be ''intended for further manufacture into final dosage form outside the United States.'' Without copies of all labeling, FDA would be unable to determine that the product is labeled in a manner consistent with these requirements. Section 1.101(c)(4) provides a practical approach for implementing sections 351(h)(2) and (h)(3) of the PHS Act because the labeling will help show that the product is not intended for sale in the United States, while the suggested cautionary statement will help demonstrate that the product is intended for further manufacture outside the United States. This cautionary statement is consistent with the statement required on other products intended for further manufacture, such as source plasma (see 21 CFR 640.70(a)(2)), and is also consistent with FDA's authority under section 361(h) of the PHS Act to make and enforce regulations to prevent the introduction, transmission, or spread of communicable disease.

Although FDA suggests the inclusion of the statement, ''Caution: For Further Manufacturing Use Only,'' on the label of exported partially processed biological products, the proposed rule did not mandate the use of that particular statement. The agency included a cautionary statement to give exporters specific information on label statements that may be sufficient to show that the product is intended for further manufacturing into a final dosage form outside the United States, as required by section 351(h)(3) of the PHS Act. The final rule, at § 1.101(c)(4), clarifies that exporters may use other records demonstrating that the exported partially processed biological product is intended for further manufacturing into a final dosage form outside the United States.

(Comment 32) One comment interpreted this provision as requiring valid marketing authorization for the partially processed biological product and stated that the act does not require valid marketing authorization for such products. The comment said that firms might export partially processed biological products for research purposes, for use in clinical evaluations, or for product evaluation before marketing. The comment suggested that an attestation by a company official in the foreign country suffice in place of valid marketing authorization.

The comment misinterprets the rule. Section 1.101(b)(2) and section 801(e)(1)(B) of the act only require that the product not be in conflict with the foreign country's laws. FDA does not interpret this to mean that the exported product must have valid marketing authorization in the foreign country to which it is being exported. FDA recognizes that some countries lack affirmative approval mechanisms for certain products and that some countries do not ''approve'' certain products, particularly products used for research or investigational purposes.

For biological products that may be regulated as devices (and devices generally), the Center for Devices and Radiological Health (CDRH) has information on countries that are nonresponsive to inquiries seeking permission either to market or to conduct clinical tests on devices. Because regulatory conditions pertaining to devices are rapidly changing in many countries, FDA recommends that firms first attempt to obtain authorization from an appropriate government official. If a firm is unsuccessful in establishing communications with a government official and/or obtaining any type of written authorization, or denial of authorization, from a foreign government, it may contact the Division of Program Operations, CDRH, for guidance.

FDA also reiterates that the final rule, as revised, accepts a certification from a responsible company official in the United States that the product does not conflict with the importing foreign country's laws.

E. Notification Requirements for Drugs, Biological Products, and Devices Exported Under Section 802 of the Federal Food, Drug, and Cosmetic Act (Section 1.101(d))

Proposed § 1.101(d) would establish the notification requirements for drugs, biological products, and devices exported under section 802 of the act. In brief, proposed § 1.101(d)(1) would require exporters to provide written notification to the agency that identifies the article's name, identifies its generic name if the article is a drug or the article's type if the product is a device, describes the product's strength and dosage form (if the product is a drug or biological product) or the product's model number (if the product is a device), and identifies the country that is to receive the exported article.

The proposed rule acknowledged that, for exports to listed countries under section 802(b)(1) of the act, section 802(g) of the act requires the notification to identify only the drug, biological product, or device being exported, and does not expressly require the notification to identify the country to which the drug, biological product, or device is being exported. (In contrast, for drugs, biological products, or devices exported to nonlisted countries under section 802 of the act, section 802(g) of the act requires both identification of the exported product and the country to which the product is being exported.) Nevertheless, proposed § 1.101(d) would require that all export notifications under section 802(g) of the act identify the product and the importing country. FDA explained that it took this action because section 802(a)(2) of the act requires FDA to notify the ''appropriate public health official'' in the foreign country receiving an exported drug, biological product, or device if FDA disapproves a marketing application for the drug, biological product, or device, and section 802(f) of the act requires FDA to consult with the ''appropriate public health official in the affected country'' in the event that an exported drug, biological product, or device presents an imminent hazard to the public health. FDA further noted that similar consultation obligations exist if the product's labeling is not in accordance with the requirements and conditions for use in the country in which the drug, biological product, or device has valid marketing authorization and the country to which the drug, biological product, or device is being exported or if the drug, biological product, or device is not promoted in accordance with the labeling requirements of section 802(f) of the act. Thus, to facilitate these notifications and consultations with foreign officials (particularly in the event that FDA disapproves a drug, biological product, or device that has been exported, or the exported product presents an imminent hazard to the public health of the

receiving country), proposed § 1.101(d)(1)(iv) would require all notifications to identify the country or countries that are to receive the exported product.

(Comment 33) Many comments strongly objected to identifying a listed country. Most stated that the act did not require the notification to identify listed countries. Some comments dismissed FDA's rationale regarding its statutory obligation to consult foreign government officials as unlikely to occur or dismissed it without explanation. One comment described the proposed requirement to require notifications to identify the listed country as ''casting a wide net to catch a few guppies at tremendous cost to the other fish,'' and said FDA could conduct an inspection of the firm to obtain the information on the listed countries receiving an exported product. Another comment said that identifying a listed country would mean that FDA is questioning the foreign country's judgment. Others implied that identifying a listed country would be burdensome or would complicate export notifications.

A few comments said firms could voluntarily disclose the identity of the listed country in the notification, but could not be required to do so. One comment suggested that the notification state that the foreign country has provided valid marketing authorization, without identifying the listed country. Only one comment agreed with FDA's rationale to have the notifications identify all countries, including listed countries.

FDA agrees that, if it had to consult a foreign government as required by the act, it could inspect a firm's export records to determine whether listed countries received a particular export. This approach, however, would be much more time-consuming and costly both for the industry and the agency because FDA would have to schedule the inspection, the firm would have to locate and assemble export records, and FDA would have to examine those records before it learned the listed country's identity. Consultation with the listed country, as required by the act, would be delayed, and this could present public health concerns if the agency's obligation to consult the foreign government was due to an imminent hazard finding or if FDA disapproved the product because it was not safe or effective.

The agency also notes that export declarations required by the Bureau of the Census for certain exports and submitted to the U.S. Customs Service identify the ultimate consignee, by name and address, and, depending on the form used, the foreign port of unloading or intermediate consignees (see 15 CFR 30.7 (''Information Required on Shipper's Export Declarations'')). Assuming that firms use these export declarations, it would seem that identifying a listed country would be less burdensome or less problematic than identifying consignees by name and address. It is also difficult to see how requesting identification of a listed country in a notification sent to FDA, when the export declaration given to the U.S. Customs Service identifies the consignee and foreign port, can be characterized as ''questioning'' the judgment of a foreign country.

Nevertheless, given the distinction drawn in the statute and objections to this provision, FDA has revised § 1.101(d) to require identification of unlisted countries only. Firms may voluntarily identify a listed country in a notification, but are not required to do so. If a firm chooses to withhold the identification of a listed country, FDA suggests, but does not require, the firm to state in its notification that the export went to a listed country. (This will enable FDA to determine quickly that the firm did not neglect to identify an unlisted country.) If the statutory obligation to consult with a country receiving an exported product is triggered, FDA will conduct an inspection of the exporting firm to identify which listed countries it must contact.

(Comment 34) One comment said that approved products that are exported should not be the subject of an export notification, even if the product is exported for an unapproved use. The comment said that requiring notifications for these products would be inconsistent with Congressional intent to relieve manufacturers of export obligations and would be beyond FDA's jurisdiction. The comment said that foreign health authorities are ''fully empowered to approve labeling and/or indications that they deem appropriate.''

The comment is only partially correct. Approved products that are exported for their approved indications and are otherwise in compliance with the act's requirements for marketing, distribution, and sale in the United States are not subject to the export requirements in section 802 of the act. For these exports, no notification is necessary.

However, exports of an ''approved'' product for an unapproved use are subject to section 802 of the act. For example, section 802 of the act applies to drugs that require approval under section 505 of the act (21 U.S.C. 355) ''before such drug * * * may be introduced or delivered for introduction into interstate commerce.'' The act defines ''interstate commerce,'' in part, as ''commerce between any State or Territory and any place outside thereof.'' Exports fall within the definition of ''interstate commerce'' because the shipment originates in a State and is destined to a ''place outside.'' Additionally, contrary to the comment's suggestion, the exported drug is not ''approved'' by FDA because the intended use in the foreign country was not the subject of a FDA-approved application. To phrase this another way, FDA's approval processes includes approval of the drug's indications for use, so the fact that the agency may have approved the drug for other uses does not relieve the manufacturer from compliance with section 505 of the act when unapproved uses are concerned.

The agency notes that, as an alternative to section 802 of the act, such exports may be permitted under section 801(f) of the act. Exports under section 801(f) of the act must comply with the requirements in section 801(e)(1) and (f) of the act, but do not require notification to FDA. If a product can be exported under either section 802 or 801(f) of the act, the exporter has the option of determining which export authority to use.

(Comment 35) The proposed rule would require persons exporting a product in anticipation of market authorization in a listed country under section 802(d) of the act to comply with the notification requirements in proposed § 1.101(d)(1). The preamble to the proposed rule explained that this requirement would be consistent with an interpretation of section 802(g) of the act that considers the nexus between section 802(b)(1) and (d) of the act. Section 802(g) of the act requires exporters of drugs, biological products, and devices to provide a simple notification to the agency when they export a product to a listed country or to an unlisted country under section 802(b)(1) of the act. Section 802(b)(1) of the act permits exports when the drug, biological product, or device has valid marketing authorization in a listed country, whereas section 802(d) of the act permits exports to a listed country in anticipation of market authorization. FDA stated that a literal interpretation of section 802(g) of the act would not require an exporter to notify FDA when it shipped a product to a listed country in anticipation of market authorization, but would instead require the exporter to notify FDA when the exporter shipped the same product to the same country once it has marketing

authorization. The preamble to the proposed rule stated that it would be more simple and efficient, both for exporters and FDA, if exporters notify FDA when they export a product in anticipation of market authorization under section 802(d) of the act rather than wait for marketing authorization in the listed country and then notify FDA when the product is exported under section 802(b)(1) of the act. FDA's intent was to allow firms to submit the notification when they first exported a product in anticipation of market authorization and to eliminate any need for them to submit a notification later when they received marketing authorization.

Many comments objected to requiring a notification for exports under section 802(d) of the act, stating that the act did not authorize such notifications. Some said that FDA could not justify requiring such notification on the grounds that it would be more efficient or simpler. One comment viewed the proposed notification requirement as a prohibition on exports that would delay the availability of products. Another comment interpreted the rule as requiring two notifications—one for exports in anticipation of market authorization, and a second when the product received marketing authorization.

Only one comment agreed with the proposal, but reiterated that a subsequent notification once the product received marketing authorization should not be required.

FDA has revised the final rule to limit notifications to products exported under section 802(b) of the act. In other words, no notification is required if the export is made in anticipation of market authorization under section 802(d) of the act. A person who exports a product in anticipation of market authorization, and later receives marketing authorization, would only submit the notification to FDA when the first export occurs to a particular foreign country following marketing authorization in that country.

(Comment 36) One comment said that section 802(d) of the act permits anyone to export a product in anticipation of market authorization, regardless of who applied for market authorization.

Section 802(d) of the act is commonly referred to as allowing firms to ''fill the pipeline'' so that a product will be available immediately upon market authorization by a foreign country. If the comment's interpretation of section 802(d) of the act were correct, any firm could export the product so long as one firm was seeking market authorization. In other words, under the comment's interpretation, if firm A were seeking market authorization to sell a drug called X, firms B, C, and D could export drug X to the same foreign country under the guise of ''anticipating'' market authorization. The comment's interpretation of section 802(d) of the act also would place little weight on the term ''anticipation'' of market authorization. Arguably, if a firm has not applied for market authorization, it cannot be characterized as ''anticipating'' market authorization. The inclusion of the word ''anticipation'' in section 802(d) of the act suggests that the firm exporting the drug or device is, in fact, the entity that is seeking market authorization or would be capable of distributing that drug or device upon marketing authorization.

Consequently, FDA interprets section 802(d) of the act as follows. If the foreign country's product approval process is specific to an application (i.e., to have marketing authorization, a firm must submit an application, and the application must be approved), then a firm seeking to invoke section 802(d) of the act to export a drug or device to a foreign country must be seeking market authorization in that foreign country.

If, however, the foreign country's product approval process would allow multiple products on the market upon market authorization (i.e., once marketing authorization occurs, any person can market a drug or device that meets the conditions of that marketing authorization), then a firm seeking to invoke section 802(d) of the act to export a drug or device to such a foreign country does not have to be the firm that sought marketing authorization in that foreign country.

This interpretation of section 802(d) of the act acknowledges both the marketing authorization process in a foreign country and gives appropriate weight to the words ''in anticipation of market authorization.''

(Comment 37) Proposed § 1.101(d)(1) would require a notification to identify the exported product by name. If the exported product were a drug or biological product, the proposal would require the notification to provide a generic name and a description of the product's strength and dosage form. If the exported drug were a device, the proposal would require the notification to identify the type of device and to provide its model number.

One comment stated that, because FDA is generally not able to examine sales and marketing information, it would be appropriate for the notification to contain information on the product, classification, lot code or unique identifying number, country of exportation, and whether or not the product was accepted.

FDA declines to revise the rule as suggested by the comment. The product-specific information described in § 1.101(d)(1) should be sufficient to identify a particular export. Firms are free to provide information on a lot code or a unique identifying number, but the final rule does not require this. Furthermore, because the act presumes that the United States is the country from which the product is exported and because section 801(e)(1)(B) of the act requires the exported product to be ''not in conflict'' with the foreign country's laws, FDA declines to require firms to identify the country of exportation or to state whether the product was ''accepted.''

(Comment 38) FDA, on its own initiative, has revised § 1.101(d)(1)(ii) to replace ''generic name'' with ''abbreviated or proper name.'' In proposing to require the export notification to contain the product's ''name'' and its ''generic name,'' FDA intended to require persons exporting a human drug to identify the product by its trade name and its abbreviated chemical name and to require persons exporting a biological product to identify the product by its trade name and its proper name. However, the term ''generic name'' created some confusion within FDA as to whether FDA was specifically interested in generic drug products. Consequently, FDA has revised § 1.101(d)(1)(i) to require the notification to identify the product's trade name while § 1.101(d)(1)(ii) now requires the notification to contain the exported product's ''abbreviated or proper name.'' The agency has made a similar change to § 1.101(e)(1)(i) and (e)(1)(ii).

The agency has also inserted language referring to biological products in § 1.101(d)(1) to clarify that investigational biological products may be exported under section 802(c) of the act and that biological products may be exported in anticipation of marketing authorization under section 802(d) of the act.

(Comment 39) A few comments addressed the frequency of export notifications. Two comments said notifications should be required only for the first export of a product. The comments stated that subsequent exports should not result in notifications, although the comments were unclear whether the subsequent export could be to a different country than the initial export.

Section 802(g) of the act requires an exporter of a drug or device to provide

a simple notification to FDA under two different scenarios. In one scenario, the exporter must provide the simple notification when it first begins to export the drug or device to any listed country. This means that subsequent exports of the same drug or device to the same listed country or to any other listed country do not result in a simple notification to FDA. To illustrate how this works, assume that company X, under section 802(b) of the act, wants to export a drug to listed country A. Company X must provide a simple notification to FDA identifying the drug to be exported. If company X later wants to export the same drug to listed country B under section 802(b) of the act, the company does not have to send a simple notification to FDA because company X already provided a simple notification when it exported the drug to listed country A and because country B is a listed country.

In the other scenario, when the export is to an unlisted country, section 802(g) of the act requires the exporter to provide the simple notification when it first begins to export the drug or device to that unlisted country, and the notification must identify the unlisted country. The act, therefore, requires a simple notification whenever the exporter first ships a drug or device to an unlisted country. Thus, to use the same illustration, if company X, under section 802(b) of the act, wants to export a drug to unlisted country D, company X must provide a simple notification that identifies the drug being exported and must also identify unlisted country D. Subsequent exports of the same drug to unlisted country D would not require company X to send a simple notification to FDA. However, if company X later wants to export the same drug to unlisted country E under section 802(b) of the act, company X must provide another simple notification to FDA, and the simple notification must identify the drug being exported and unlisted country E.

(Comment 40) In the preamble to the proposed rule, FDA invited comment on possible alternatives to this notification requirement that would satisfy the consultation, notification, and recordkeeping obligations and requirements in section 802 of the act. The agency was especially interested in alternatives that would reduce the paperwork burden, such as electronic submissions and recordkeeping or periodic notifications (e.g., monthly, quarterly), and the details of such alternatives.

One comment suggested that FDA accept export notifications that covered more than one country. Another comment suggested that FDA accept notifications on an annual basis, or no more often than a biannual basis, that the notifications be submitted in tabular form and submitted directly, if not electronically, to FDA. One comment suggested that FDA develop an interactive website so exporters could ''fill in the blanks.'' Another comment suggested using Operational and Administrative System for Import Support (OASIS) system entries as notifications under section 802(g) of the act and would have annual reports submitted by exporters serve as confirmation of the export; the comment said that the notifications described in the proposed rule would add significant costs to manufacturers.

FDA appreciates the comments' suggestions. The agency does not object if a simple notification covers more than one country; nothing in the act or these regulations prevents firms from identifying more than one country in a simple notification. Furthermore, if the foreign purchaser's specifications change after the first shipment, and the new specifications result in a drug or device that is not significantly different from the first exported drug or device, an exporter may, but is not required to, provide a new notification. For example, assume that company X is exporting an electronic device to listed country A. Later, the foreign purchaser revises its product specifications to change the voltage requirements for the device. The revised product specifications call for an electronic device that is substantially similar to the original electronic device, so FDA would not require another notification.

In contrast, if company X is exporting a combination drug to listed country A, and the foreign purchaser revises its product specifications to substitute a different active ingredient, the drug to be exported has changed significantly, and FDA would expect the exporter to provide a new simple notification to cover the changed drug product when the exporter ''first begins'' to export the changed drug product.

As for electronic submissions and other technology, FDA intends to explore options for facilitating notification to FDA, but is unable to create an interactive, web-based system at this time. The agency is also unable to adapt the OASIS system to cover notifications because the OASIS system focuses on imports, not exports, and is operationally separate from FDA's administrative oversight of exports.

As for annual or semiannual submissions, the agency considered these options, but section 802(g) of the act appears to contemplate more timely notifications. The act requires notifications when the exporter ''first begins'' to export the drug or device under section 802(b)(1) of the act, so the most logical interpretation of the phrase ''first begins'' would mean that exporters must provide the notification to FDA when they actually export the drug or device.

(Comment 41) FDA, on its own initiative, has revised the address for export notifications involving biological products and devices regulated by the Center for Biologics Evaluation and Research. The final rule replaces ''Office of Compliance'' with ''Office of Compliance and Biologics Quality.'' This change reflects the current office name.

F. Recordkeeping Requirements for Products Subject to Section 802(g) of the Act (Section 1.101(e))

Proposed 1.101(e) would establish additional recordkeeping requirements for exported drugs, biological products, and devices subject to section 802(g) of the act. These records would include, but not be limited to: (1) Records concerning the product's name, (2) the product's generic name if the product is a drug or a biological product or the type of device if the product is a device, (3) a description of its strength and dosage form and the product's lot or control number (if the product is a drug or biological product) or the product's model number (if the product is a device), (4) the consignee's name and address, and (5) the date on which the product was exported and the quantity of product exported.

(Comment 42) Several comments objected to most or all of the proposed recordkeeping requirements. Some comments argued that manufacturers already keep CGMP records and that none of the information sought in proposed § 1.101(e) is required or even authorized by law. Another comment said the proposed recordkeeping requirement was ''excessive'' because it required too many documents be kept. Another comment said FDA should only require companies to keep records of exports to countries where they directly export drugs; if the drugs were subsequently exported elsewhere by the importing company, the importing company would be responsible for records of shipments to third countries.

One comment sought clarification, asking if the records required by § 1.101(e) are distinct from the quality system regulation records required for devices under 21 CFR part 820.

Section 802(g) of the act clearly states that, ''Any exporter of a drug or device shall maintain records of all drugs or

devices exported and the countries to which they were exported.'' The most straightforward interpretation of this provision is that export records must be kept for drugs and devices exported under section 802 of the act and that those records must also contain information regarding the countries receiving the exported product. Thus, FDA disagrees with those comments claiming that the records sought in § 1.101(e) are not required or authorized by the act.

Moreover, persons exporting drugs or devices, particularly persons who manufacture the exported drug or device, should already possess the information sought in § 1.101(e). For example, § 1.101(e)(1)(i) requires records containing the product's name. Most prudent exporters know the names of the products being exported. Section 1.101(e)(1)(ii) and (e)(1)(iii) requires records to contain more specific information about the drug or device, such as the drug's strength and dosage form or the type of device and its model number. A manufacturer who is exporting products should know the product's abbreviated name or proper name, strength, dosage form, and lot or control number (if the product is a drug or biological product) or the type of device and model number (if the product is a device), because this information is related to CGMPs for the product (see, e.g., 21 CFR 211.100 (written procedures for production and process control), 211.110 (sampling and testing of in-process materials and drug products), 820.70 (production and process controls for devices), and 820.160 (requiring device manufacturers to maintain distribution records which include or refer to the location of the consignee's name and address, the identification and quantity of devices shipped, the date shipped, and control numbers used). Additionally, section 802(f)(1) of the act prohibits exportation of a drug or device, under section 802 of the act, if the drug or device is not manufactured, processed, packaged, and held in substantial conformity with CGMP requirements. Thus, an exporter who is in substantial conformity with CGMPs should already possess the information described in § 1.101(e)(1)(ii) and (e)(1)(iii). Finally, § 1.101(e)(1)(iv) and (e)(1)(v) require the records to include the consignee's name and address, the date on which the product was exported, and the quantity of product exported. Presumably, an exporter knows where it is sending a product, when it ships the product, and how much was shipped.

FDA emphasizes that § 1.101(e) does not require exporters to keep duplicate sets of records—one for export purposes and another for CGMP purposes—nor does it require exporters to create new records if the exporter keeps the information described in § 1.101(e) elsewhere. The records sought by § 1.101(e) may be part of the exporter's CGMP or QS regulation records.

Furthermore, to give exporters additional flexibility in meeting this requirement, FDA has amended § 1.101(e)(2) to state that the records may be kept at the site from which the products were exported ''or manufactured.'' This change will accommodate firms who manufacture products for export and are responsible for the product's exportation, but who send the product to another location for packaging or other operations before exportation occurs.

(Comment 43) Two comments asked FDA to clarify what it wanted regarding a consignee's name and address. The comments explained that devices are often exported to distribution centers, and so the comment suggested that distribution centers should be acceptable as consignees. Other comments said FDA cannot require any records identifying a consignee. The comments asserted that the act does not require or even authorize FDA to require such information.

FDA does not object if a distribution center in a foreign country is listed as a ''consignee'' under this rule. Identification of the consignee's name and address is intended to help FDA in the event that it has to consult foreign government officials regarding an exported product. The consignee's name and address will inform government agencies where the exported drug or device was first sent and will help speed efforts to recover or to prevent the distribution of potentially hazardous products.

As for those comments objecting to identifying a consignee, FDA's general rulemaking authority in section 701(a) of the act provides sufficient statutory authority to require these records. FDA also believes that exporters would retain records identifying the consignee, by name and address, as part of their normal business practices because, presumably, the consignee ordered the drugs or devices and must pay for and receive the exported product. FDA further notes that export declarations submitted to the U.S. Customs Service must identify ultimate consignees by name and address, and, depending on the form used, may even identify intermediate consignees. Thus, exporters should have information regarding a consignee's name and address.

(Comment 44) Proposed § 1.101(e)(2) would require exporters to keep records at the site from which the products were exported and to maintain those records for at least 5 years after the date of exportation.

Several comments objected to the 5-year period. Two comments advocated a 2-year period in order to be consistent with the QS regulation requirements. One comment suggested retaining records for 3 years after the product's expiration date. Another comment criticized the agency for not providing a rationale for the 5-year period; this comment said that 5-year period might be too long in some situations, but not long enough in others, and said the time period was inappropriate without some rationale and a link to the act.

The records required in § 1.101(e) are similar, if not identical to, some records that are kept for CGMP or QS regulation purposes. To make recordkeeping easier for firms, FDA has revised the rule to state that these records must be retained in accordance with the record retention period for CGMP or QS regulation records. FDA reiterates that firms may use their CGMP or QS regulation records for dual purposes (i.e., to demonstrate compliance with CGMP or QS regulation requirements and to demonstrate compliance with the export regulations in § 1.101) and do not have to keep dual sets of records.

(Comment 45) One comment said that proposed § 1.101(e) did not apply to investigational new drugs exported under section 802(c) of the act, but said that companies maintain records on such exports due to other obligations, such as CGMP requirements.

FDA disagrees with the comment's interpretation. The relevant portion of section 802(g) of the act states that ''any exporter of a drug or device'' shall maintain records; this differs from the other sentences in section 802(g) of the act which refer to exporters of drugs or devices exported under section 802(b)(1)(A) of the act. As a result, § 1.101(e) does apply to exports of investigational drugs under section 802(c) of the act.

G. Miscellaneous Comments

Several comments addressed issues concerning implementation of the rule or other export matters.

(Comment 46) One comment asked how the rule relates to other export documents issued by FDA. Another comment said interpreting sections 801 and 802 of the act is complicated by the lack of clear implementing regulations; the comment said it is difficult to determine which requirements apply to a given product and asked FDA to

develop a rule to implement the export act.

FDA prepared four agency wide documents to implement the FDA Export Reform and Enhancement Act. The agency developed a draft guidance document describing its interpretation of the export provisions; the guidance document is not binding on regulated industries or on FDA. For binding requirements, FDA prepared three regulations: (1) A rule to implement the ''import for export'' requirements in section 801(d) of the act, (2) a rule pertaining to export notifications and recordkeeping (which is presented here), and (3) a rule pertaining to exports of investigational new drugs (which FDA intends to publish in the **Federal Register** in the future). In general, the regulations would describe the types of records that should be kept or the contents of submissions that are sent to FDA. The agency published a draft guidance document in the **Federal Register** of June 12, 1998 (63 FR 32219). FDA published a proposed import for export regulation in the **Federal Register** on November 24, 1998 (63 FR 64930), and intends to publish a proposed rule on investigational new drug exports in the immediate future.

Other export-related documents issued by FDA include a rule on investigational device exports (now codified at § 812.18(b) (21 CFR 812.18(b))) and a Compliance Policy Guide, CPG 7150.01, ''Certification for Exports,'' on export certificates.

FDA agrees that implementing sections 801 and 802 of the act is difficult because the statutory requirements apply to different products in different ways. For example, most human drugs are subject to the export requirements in sections 802 and 801(e)(1) of the act, but insulin and antibiotics for human use and animal drugs are only exported under section 801(e) of the act. Most devices can be exported under section 801(e) or section 802 of the act, and either choice carries its own set of requirements. FDA prepared the guidance document in an effort to sort out the various requirements for each product and drafted the regulations to create binding requirements where such requirements were necessary. The agency decided against drafting a single rule because there was little overlap or commonality between subjects. For example, the import for export requirements are not relevant for exports of investigational new drugs, so a single rule would have been inappropriate and confusing.

(Comment 47) One comment asked FDA to phase-in the rule to minimize its impact on commerce.

The final rule is effective March 19, 2002. This should give firms sufficient time to comply with the rule.

(Comment 48) One comment said FDA should conduct educational seminars or programs, in conjunction with the U.S. Customs Service and with the support of various trade associations, or do a televised program whose agenda is developed by industry and Federal agencies.

FDA has, in the past, participated in conferences and educational programs that have discussed export matters, and individual centers have prepared guidance documents and other materials on selected topics. For example, CDRH has prepared a videotape on export issues. The agency intends to continue its participation in educational conferences and programs to the extent that its resources permit.

(Comment 49) One comment would revise § 1.101 to require only a simple notification for drugs and devices exported for investigational use. The comment said that drugs and biological products that are exported for investigational use and are the subject of an IND are regulated more strictly than drugs and biological products that are exported for investigational use without an IND. The comment said that FDA authorization is needed under § 312.110, but drugs that are exported without an IND only require a simple notification to FDA. Consequently, the comment would revise the export provisions in both parts 312 and 812 (21 CFR part 812) to require only simple notifications for drugs and devices exported for investigational use.

The agency declines to revise § 1.101 as suggested by the comment. Section 802(g) of the act only requires simple notifications for exports under section 802(b)(1) of the act. FDA expects most exports of drugs or devices for investigational use in a listed country will fall under section 802(c) of the act; this means that exports of investigational drugs or devices to a listed country do not require a person to provide a simple notification to FDA. If, however, a firm exports a drug or device for investigational use under section 802(b)(1) of the act, the firm will have to provide a simple notification to FDA.

Additionally, as stated earlier, FDA intends to publish a proposed rule in the **Federal Register** to revise § 312.110 to describe various approaches for exporting investigational new drugs. FDA has already revised § 812.18(b) to state that exports of investigational devices are subject to either sections 801 or 802 of the act, so no further changes to § 1.101 are necessary.

(Comment 50) The draft guidance document discussed FDA's position on transshipment of investigational drugs and devices (the shipment of an export from one country to a second country, followed by the shipment of the same product from the second country to a third country) (see 63 FR 62219 at 32228). The draft guidance document interpreted section 802(c) of the act as not allowing transshipment from a listed country to an unlisted country because the act does not suggest that the listed countries are mere transfer points or conduits for investigational drugs and devices destined for unlisted countries and because allowing transshipment from listed to unlisted countries would undermine the statutory limitation on investigational drug and device exports to listed countries. The proposed rule on export notifications and recordkeeping was silent on this issue.

Nevertheless, two comments submitted to the proposed rule (instead of the draft guidance document) objected to FDA's position on transshipment. The comments argued that shipments between listed and unlisted countries are matters covered by foreign law and that FDA's interpretation would restrict a firm's ability to conduct clinical trials outside the United States or otherwise defeat congressional intent and deprive foreign governments of the ''right'' to determine whether subsequent exports should be made.

The issue of transshipment of investigational drugs and devices is not relevant to the final rule. Nevertheless, the unrestricted transshipment of investigational drugs and devices from listed to unlisted countries would undermine the express limitation in section 802(c) of the act. Section 802(c) of the act allows exports of drugs and devices ''intended for investigational use in any [listed] country * * * in accordance with the laws of that country.'' The key statutory phrase is that the drug or device must be intended for investigational use in a listed country. In a transshipment scenario, the drug or device is intended for investigational use in an unlisted country, and this would be contrary to section 802(c) of the act.

However, if the investigation in the unlisted country is subject to the laws and regulations of the listed country—in other words, if persons in the listed country remain responsible for the conduct of the clinical trial and the investigation complies with the listed country's laws—shipment to an unlisted country is not contrary to the act. To illustrate how this works, assume that an investigational new drug is exported

to a listed country, i.e., ''country LC.'' If the investigational new drug is then shipped to an unlisted country (''country X''), but the investigation is conducted in accordance with country LC's laws and regulations, shipment to country X is permitted under section 802(c) of the act. FDA reaches this interpretation because the investigation is intended for use in the listed country, albeit in a broad sense, and remains subject to the listed country's laws.

If, however, the investigational drug is simply shipped to a warehouse in country LC and then shipped to country X, without anyone in country LC being responsible for the investigation or having the investigation remain subject to country LC's laws, then the export would not comply with section 802(c) of the act. The statutory requirements in section 802(c) of the act would not be met because the investigational use was never intended to be in the listed country and is not subject to country LC's laws.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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. Paperwork Reduction Act of 1995

The proposed rule estimated the costs associated with submitting notifications to FDA and maintaining records. FDA based its estimates on the number of notifications received by FDA in 1996 or 1997 (depending on the last year for which complete figures were available at the time of the proposed rule) and consultations with industry sources (64 FR 15944 at 15946). The Office of Management and Budget (OMB), in reviewing FDA's Paperwork Reduction Act documents, neither approved nor rejected FDA's request for approval of a new information collection. Instead, OMB stated that it had concerns regarding the burden and utility of the collection which shall be assessed in light of public comments received. FDA received several comments on the agency's estimates.

(Comment 51) For the recordkeeping requirements for human drugs, biological products, animal drugs, devices, foods, and cosmetics exported under or subject to section 801(e)(1) of the act, FDA estimated that there would be an average of 318 recordkeepers per year, at a annual frequency of 2.8 records per respondent, at 1 hour per record. One comment said that FDA ''grossly underestimated'' the recordkeeping burden because the rule presents significant burdens on food manufacturers and creates ''an entirely new recordkeeping bureaucracy for exporters of food products.'' The comment stated that translating letters alone will take more than 1 hour per product.

FDA disagrees with the comment. Section 801(e)(1) of the act is not a new statutory requirement, particularly when applied to food exports, so it does not present a new or significant burden on food manufacturers or create ''an entirely new recordkeeping bureaucracy.'' Additionally, the final rule reduces any burden on exporters by revising certain requirements; for example, the final rule clarifies that the foreign purchaser's specifications should provide sufficient detail to be linked to a particular export and that a responsible company official may certify that the export does not conflict with the importing country's laws.

While FDA concedes that § 1.101(b) does, in one instance, seek English-language translations of foreign documents, presumably a prudent U.S. company would translate foreign-language documents as part of its ordinary business practice, if only to ensure that the foreign-language document is what it purports to be or that the U.S. company truly understands the contents of the foreign-language document or that the U.S. company would be able to translate the foreign-language document into English.

As for the burden hour estimate for § 1.101(b), FDA, as explained below, has increased the burden hour estimate to 24 hours per record.

(Comment 52) The preamble to the proposed rule estimated the total information collection burden to be 2,659 hours and that no capital costs or operating and maintenance costs would result.

Several comments said FDA underestimated the total and that firms would incur new costs. Two trade associations, representing device manufacturers and drug manufacturers, indicated that the estimated information collection burden and costs for a single firm would be significant. For example, one device firm was said to market its products in 90 countries and in approximately 600 different packaging and labeling configurations. According to the comment, to meet the proposed recordkeeping requirements, the firm would need new records for at least 500 configurations, at $30 per hour and 4 hours per record (for a total update cost of $60,000) and recordkeeping costs would be $100 per hour for 500 records, or an additional $50,000. For new products, estimated record preparation costs would be $30 per hour x 4 hours x 84 products (or $10,080) and recordkeeping costs of $8,400. As another example, a trade association representing the drug industry interpreted the rule as requiring detailed records on product specifications and translations. The comment said that one drug company estimated that it spends 160 employee hours of ''regulatory time'' and 80 person hours of ''legal time'' alone to obtain documentation necessary to export to a single multicenter trial in Latin America and Eastern Europe. (The comment did not explain what ''regulatory time'' or ''legal time'' are.) The comment did not provide an estimate of the information collection burden because it said that FDA's requirements were open-ended; instead, it declared FDA's estimates to be ''unrealistic.'' Two comments also said that drug companies would need to spend $50,000 to $100,000 in capital costs alone to upgrade their computers to comply with the proposed requirements.

FDA reiterates that its estimates were based on the number of export notifications FDA has received and on information provided by industry sources. Those industry sources varied in terms of the amount of time required to maintain a record or to submit a notification, and none indicated that computer upgrades would be necessary. The averages must be compared against the estimates provided in the comments, which are based on information from a single company.

The agency also disagrees, in part, with the estimates provided by a single device firm. In general, devices may be exported under section 801(e) or 802 of the act. The agency reiterates that, for devices, the requirements in section 801(e)(1) of the act are not new; consequently, if the devices are exported under section 801(e) of the act, the comment's claim that hundreds of ''new'' records would be required cannot be accurate unless the firm has not been retaining any documents to show its compliance with section 801(e)(1) of the act. In contrast, if the firm is exporting devices under section 802(b) of the act, section 802(g) of the act would require the firm to submit a notification to FDA. Yet FDA's export notification records do not reveal a significant number of device exports or a significant number attributable to one firm. The average number of export notifications received was 244 per year. This average covers both drug and device firms and is far lower than the

500 export configurations claimed by the single device firm in the comment.

Nevertheless, FDA has increased the recordkeeping burden hour estimate for § 1.101(b) from 2 hours to 24 hours. This estimate exceeds the 4-hour estimate submitted by the device firm and is consistent with a comment (described below in comment 53) from a drug company.

FDA declines to adopt the 240-hour figure provided by a drug company for exports of a drug for investigational use because FDA cannot determine what activities are covered by the comment's estimate or whether the comment's estimate even involves activities that are covered by the rule. For example, the comment stated that it devoted considerable time assembling documents to export drugs to a single multicenter trial in Latin America and Eastern Europe. The comment's reference to Latin America and Eastern Europe suggests that the firm is not exporting the drugs under section 802(c) of the act because section 802(c) of the act pertains solely to exports of investigational new drugs and devices to listed countries, and Latin American and Eastern European countries are not listed countries. So, to export a drug for investigational use, the firm must be exporting the investigational new drugs under an IND or under § 312.110, or the exported drugs have marketing authorization from a listed country. (It is possible that the firm could export an investigational new drug under section 802(b)(1) of the act if the drug received market authorization from a listed country, but the comment did not indicate that the investigational new drug has such market authorization.) Yet this final rule does not address exports under an IND or § 312.110, and therefore, if the firm's comment is relevant to this rule, the firm would have to be exporting drugs that have marketing authorization from a listed country and using those drugs for investigational use in Latin America and Eastern Europe. Assuming this to be the case, the changes in the final rule, such as accepting a certification from a responsible company official in place of a letter from a foreign government and clarifying FDA's expectations regarding a foreign purchaser's specifications, should reduce the firm's information collection burden.

(Comment 53) One comment said that FDA underestimated the rule's financial impact. The comment explained that, for a single firm, ''notifications'' for section 801(e) of the act (which FDA presumes to be ''records'' because section 801(e)(1) of the act does not require notification) will result in five files and five records per year and require 24 to 32 hours for each export file. For notifications under section 802(g) of the act, there will be 10 files and 7 records per year, at 0.75 hours per export notification and 16 hours per export file. For partially processed biological products, the comment claimed its averages as 18 files and 5 records per year, at 16 hours per export file.

FDA has increased the burden hour estimate for records under § 1.101(b) to 24 hours per record. The agency declines to use the higher estimate of 32 hours because the final rule simplifies the types of records that are required to show compliance with section 801(e)(1) of the act. For example, the final rule accepts a company official's notarized certification that the exported product is not in conflict with the foreign country's laws, whereas the proposed rule would have required a letter from a foreign government official.

FDA did not revise the estimates for § 1.101(d). Although the comment suggests that the average number of notifications is greater than 2.4 per respondent, the comment's claimed average of five notifications per year may be accurate for that particular firm and may not be applicable to all firms exporting products. FDA based its estimate on the total number of notifications received and the total number of firms submitting notifications. FDA further notes that its estimate of 1 burden hour per notification is actually greater than the comment's estimate of 0.75 burden hours per notification. The comment's average time may reflect that firm's efficiency in processing notices, and FDA will not assume that all firms are as efficient.

As for partially processed biological products, although the comment suggests that the average number of notifications is greater than 2.4 per respondent, the comment's claimed average of five notifications per year may be accurate for that particular firm and may not be applicable to all firms exporting products. FDA based its estimate on the total number of notifications received and the total number of firms submitting notifications. The agency is, however, increasing the burden hour estimate for § 1.101(e) from 2 to 16 hours as suggested by the comment.

This final rule contains information collection requirements which are subject to review by OMB under the Paperwork Reduction Act of 1995. The title, description, and respondent description of 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 the collection of information.

Title: Exports: Notification and Recordkeeping Requirements.

Description: The final rule establishes the notification and recordkeeping requirements for persons exporting a human drug, biological product, device, animal drug, food, or cosmetic under section 801(e) or 802 of the act or section 351(h) of the PHS Act.

Description of Respondents: Businesses.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1.101(b)	316	2.8	885	24	21,240
1.101(c)	8	2	16	2	32
Subtotal—Regulatory					21,272
1.101(d)	244	2.4	586	1	586
1.101(e)	175	3.3	578	16	9,248
Subtotal—Statutory					9,834
Total					31,106

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

The estimates are based on the number of notifications received by the relevant FDA centers in 1996 or 1997 (depending on the last year for which figures were available) as well as consultations with and comments from industry sources.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted a copy of this rule to OMB for its review of these previously approved information collection requirements.

V. Analysis of Impacts

FDA has examined the impacts of this rule under Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96–354). 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 new benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes this rule is consistent with the regulatory philosophy and the principles identified in the Executive order. In addition, OMB has decided that the rule is a significant regulatory action as defined in the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule establishes the notification and recordkeeping requirements for persons exporting various FDA-regulated products under sections 801(e) and 802 of the act and section 351(h) of the PHS Act. The notification and recordkeeping requirements are minimal and involve information that should already be in an exporter's possession (such as the name of the product being exported, a description of the product being exported, and the date of exportation). Thus, FDA certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The agency has determined that the final rule is not a significant action as defined in the Unfunded Mandates Reform Act, and will not have an effect on the economy that exceeds $100 million in any one year.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

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 and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is 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, 241, 243, 262, 264.

2. Section 1.101 is added to subpart E to read as follows:

§ 1.101 Notification and recordkeeping.

(a) *Scope.* This section pertains to notifications and records required for human drug, biological product, device, animal drug, food, and cosmetic exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act (the act) or (21 U.S.C. 381 and 382) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) *Recordkeeping requirements for human drugs, biological products, devices, animal drugs, foods, and cosmetics exported under or subject to section 801(e)(1) of the act.* Persons exporting an article under section 801(e)(1) of the act or an article otherwise subject to section 801(e)(1) of the act shall maintain records as enumerated in paragraphs (b)(1) through (b)(4) of this section demonstrating that the product meets the requirements of section 801(e)(1) of the act. Such records shall be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, except that records pertaining to the export of foods and cosmetics under section 801(e)(1) of the act shall be kept for 3 years after the date of exportation. The records shall be made available to the Food and Drug Administration (FDA), upon request, during an inspection for review and copying by FDA.

(1) Records demonstrating that the product meets the foreign purchaser's specifications: The records must contain sufficient information to match the foreign purchaser's specifications to a particular export;

(2) Records demonstrating that the product does not conflict with the laws of the importing country: This may consist of either a letter from an appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws, or a notarized certification by a responsible company official in the United States that the product does not conflict with the laws of the importing country and that includes a statement acknowledging that he or she is subject to the provisions of 18 U.S.C. 1001;

(3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export: This may consist of copies of any labels or labeling statements, such as ''For export only,'' that are placed on

the shipping packages or, if the exported product does not have a shipping package or container, on shipping invoices or other documents accompanying the exported product; and

(4) Records demonstrating that the product is not sold or offered for sale in the United States: This may consist of production and shipping records for the exported product and promotional materials.

(c) *Additional recordkeeping requirements for partially processed biological products exported under section 351(h) of the Public Health Service Act.* In addition to the requirements in paragraph (b) of this section, persons exporting a partially processed biological product under section 351(h) of the Public Health Service Act shall maintain, for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, and make available to FDA, upon request, during an inspection for review and copying by FDA, the following records:

(1) Records demonstrating that the product for export is a partially processed biological product and not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) Records demonstrating that the partially processed biological product was manufactured in conformity with current good manufacturing practice requirements;

(3) Records demonstrating the distribution of the exported partially processed biological products; and

(4) Copies of all labeling that accompanies the exported partially processed biological product and other records demonstrating that the exported partially processed biological product is intended for further manufacture into a final dosage form outside the United States; this may include a container label with the statement, ''Caution: For Further Manufacturing Use Only'' and any package insert.

(d) *Notification requirements for drugs, biological products, and devices exported under section 802 of the act.* (1) Persons exporting a human drug, biological product, or device under section 802 of the act, other than a drug, biological product, or device for investigational use exported under section 802(c) of the act, or a drug, biological product, or device exported in anticipation of marketing authorization under section 802(d) of the act, shall provide written notification to FDA. The notification shall identify:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of the product's strength and dosage form or, if the product is a device, the product's model number; and

(iv) If the export is to a country not listed in section 802(b)(1) of the act, the country that is to receive the exported article. The notification may, but is not required to, identify countries listed in section 802(b)(1) of the act or state that the export is intended for a listed country without identifying the listed country.

(2) The notification shall be sent to the following addresses:

(i) For biological products and devices regulated by the Center for Biologics Evaluation and Research—Division of Case Management (HFM–610), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, rm. 200N, Rockville, MD 20852–1448;

(ii) For human drug products—Division of Labeling and Nonprescription Drug Compliance (HFD–310), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855–2737;

(iii) For devices—Division of Program Operations (HFZ–305), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

(e) *Recordkeeping requirements for products subject to section 802(g) of the act.* (1) Any person exporting a product under any provision of section 802 of the act shall maintain records of all drugs, biological products, and devices exported and the countries to which the products were exported. In addition to the requirements in paragraph (b) of this section, such records include, but are not limited to, the following:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of its strength and dosage form and the product's lot or control number or, if the product is a device, the product's model number;

(iv) The consignee's name and address; and

(v) The date on which the product was exported and the quantity of product exported.

(2) These records shall be kept at the site from which the products were exported or manufactured, and be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product. The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

Dated: March 1, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

Dated: April 10, 2001.[1]

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 01–31026 Filed 12–18–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[KS 0145–1145a; FRL–7120–2]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Control of Emissions From Hospital/Medical/Infectious Waste Incinerators; State of Kansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a revision to the state of Kansas' section 111(d) plan for controlling emissions from existing hospital/medical/infectious waste incinerators. The state revised its existing plan to establish increments of progress and a new compliance date for two HMIWI sources. Approval of the revised state plan will ensure that these requirements are Federally enforceable.

DATES: This direct final rule will be effective February 19, 2002. unless EPA receives adverse comments by January 18, 2002. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Comments may be mailed to Wayne Kaiser, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Copies of documents relative to this action are available for public inspection during normal business

[1] **Editorial Note:** This document was received at the Office of the Federal Register on December 12, 2001.