§ 498.128 Collection of penalty and assessment.

(a) Once a determination has become final, collection of any penalty and assessment will be the responsibility of the Commissioner or his or her designee.

(b) In cases brought under section 1129 of the Social Security Act, a penalty and assessment imposed under this part may be compromised by the Commissioner or his or her designee, and may be recovered in a civil action brought in the United States district court for the district where the statement or representation referred in § 498.102(a) was made, or where the respondent resides.

* * * * *

(d) As specifically provided under the Social Security Act, in cases brought under section 1129 of the Social Security Act, the amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, may also be deducted from:

(i) Monthly title II or title XVI payments, notwithstanding section 207 of the Social Security Act as made applicable to title XVI by section 1631(d)(1) of the Social Security Act; or

(ii) A tax refund to which a person is entitled to after notice to the Secretary of the Treasury under 31 U.S.C. 3720A; or

(iii) By authorities provided under the Debt Collection Act of 1982, as amended, 31 U.S.C. 3711, to the extent applicable to debts arising under the Act; or

(iv) Any combination of the foregoing.

(e) Matters that were raised or that could have been raised in a hearing before an administrative law judge or in an appeal to the United States Court of Appeals under sections 1129 or 1140 of the Social Security Act may not be raised as a defense in a civil action by the United States to collect a penalty and assessment under this part.

15. Section 498.129 is added to read as follows:

§ 498.129 Notice to other agencies.

As provided in section 1129 of the Social Security Act, when a determination to impose a penalty and assessment with respect to a physician or medical provider becomes final, the Office of the Inspector General will notify the Secretary of the final determination and the reasons therefore.

16. Section 498.132 is revised to read as follows:

§ 498.132 Limitations.

The Office of the Inspector General may initiate a proceeding in accordance with § 498.109(a) to determine whether to impose a penalty and assessment only—

(a) In cases brought under section 1129 of the Social Security Act, after receiving authorization from the Attorney General pursuant to procedures agreed upon by the Inspector General and the Attorney General; and

(b) Within 6 years from the date on which the violation was committed.

[FR Doc. 95–28309 Filed 11–24–95; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

[Docket No. 95N–0342]

Export Requirements for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations for investigational devices to streamline requirements for persons seeking to export unapproved medical devices. The proposed rule would establish that FDA approval of an investigational device exemption application (IDE) constitutes an agency determination that the export of the unapproved device is not contrary to the public health or safety. The proposed rule would also consider a country as approving importation of an unapproved device if the country has notified FDA that it approves of the importation of unapproved devices with an approved IDE into their countries. Thus, for devices with an FDA-approved IDE, the proposal would eliminate the need for FDA to make independent determinations either that exportation is not contrary to the public health or safety or that an importing country approves the importation of a specific device. The proposed rule is intended to codify and to simplify export requirements for certain unapproved devices pursuant to the President's and Vice-President's ''National Performance Review,'' as reflected in the April 1995 report titled, ''Reinventing Drug & Medical Device Regulations.'' The agency is also requesting comments on other ways of improving the export process for medical devices.

DATES: Written comments by February 12, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

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

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 801(e)(1) (21 U.S.C. 381(e)(1)) of the Federal Food, Drug, and Cosmetic Act (the act) states, in part, that a device intended for export shall not be deemed to be adulterated or misbranded if it: (1) meets the specifications of the foreign purchaser; (2) is not in conflict with the laws of the country to which it is intended for export; (3) is labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in domestic commerce. Section 801(e)(1) of the act does not apply, however, to any device that does not comply with an applicable requirement under sections 514 (21 U.S.C. 360d) (performance standards) or 515 (21 U.S.C. 360e) (premarket approval) of the act, a device which, under section 520(g) of the act (21 U.S.C. 360j(g)), is exempt from sections 514 and 515 of the act, or to a banned device, unless, in addition to the requirements in section 801(e)(1), the agency ''has determined that exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export.'' (See section 801(e)(2) of the act.) This statutory scheme requires parties to submit requests to FDA for exportation of certain unapproved devices and also requires FDA to approve such requests if the requirements in section 801(e) of the act are met.

To enable FDA to determine whether the exportation of a particular device is not contrary to the public health or safety, FDA generally asks that the person seeking to export the device submit, along with the export request, information or data regarding the device's safety. However, if the device is the subject of an IDE approved by FDA and will be marketed or used in clinical trials for the same intended use in the foreign country, FDA does not require submission of safety data with the export request because those safety data are already contained in the IDE.

To determine whether a foreign country has approved importation of a

device, a person who intends to export an unapproved device usually provides FDA a letter from a foreign government official stating that the foreign government does not object to the importation of the device. The letter must identify the device and its intended use and state that the device is not in conflict with the laws of the foreign country (or that there is no objection to importation of the device), that the foreign government has full knowledge of the device's regulatory status in the United States, and that importation is permitted. FDA has recently stated that, for devices with a ''CE'' mark from the European Union, an additional letter from any importing country within the European Economic Area would not be needed.

Each year, FDA receives hundreds of requests for permission to export unapproved devices. In 1992, FDA handled 695 requests, and each request required an average of 91 days to process. In 1993, FDA processed 501 requests, but improved its average processing time to 65 days. In 1994, the agency processed 635 requests, and improved its average processing time significantly further, to 16 days. From January to September, 1995, the agency processed over 570 requests with an average processing time of 10 days.

Yet, even though the average processing time for export requests has significantly improved in recent years, FDA is aware that the domestic industry continues to believe that the agency's export approval obligations may affect a firm's ability to compete in international markets and may represent an unnecessary regulatory barrier. Consequently, in April 1995, FDA, as part of the President's and Vice-President's ''National Performance Review,'' announced that it would propose two new means by which unapproved devices could be exported. First, the agency proposed permitting the export of unapproved devices to certain advanced industrialized countries without prior FDA review and approval, provided that the device complies with the importing country's laws. FDA would seek the necessary legislative changes and would consult Congress on the list of advanced industrialized countries. In August, 1995, the Senate Committee on Labor and Human Resources unanimously reported a bill (S. 593, as amended) that would simplify export requirements for devices. If such legislation is enacted, the agency will amend this rule if necessary.

Second, the National Performance Review report stated that FDA would initiate administrative changes to permit exports to countries that are not on the list of advanced industrialized countries ''if the exporter has an Investigational Device Exemption (IDE) permitting testing on humans in the United States, the importing country has given FDA a letter providing blanket approval for IDE-type devices, and the device is in compliance with the importing country's laws.''

This proposed rule would implement the second half of the Administration's initiative on reinventing device exports and is the part of the initiative that FDA can achieve under current law. The proposal would simplify and streamline the agency's export approval process for certain unapproved devices. The agency requests comments on other ideas for improving the export process for medical devices.

II. Description of the Proposed Rule

Currently, the only FDA regulation on device exports, § 812.18(b), states that, ''A person exporting an investigational device subject to [part 812] shall obtain FDA's prior approval as required by section 801(d) [sic] of the act.'' [1] The proposed rule would amend § 812.18(b) to state that a person that wishes to export an investigational device subject to part 812 must comply with the requirements at section 801(e)(1) of the act, and proposed § 812.18(b)(1) would state that, for purposes of section 801(e)(2) of the act, prior FDA approval is unnecessary if the investigational device to be exported is the subject of an IDE approved by FDA and ''will be marketed or used in clinical trials in the foreign country for the same intended use as that in the approved IDE and is to be exported to a country that has expressed its approval of the importation of investigational devices that are the subject of FDA-approved IDE's.'' However, if the device is the subject of an FDA-approved IDE and has received a ''CE'' mark from the European Union, the device may be exported to any country in the European Economic Area. Proposed § 812.18(b)(1) would also state that the agency would make available a list of countries that have approved the importation of investigational devices that are the subjects of IDE's approved by FDA. The agency expects to maintain this list electronically in the Center for Devices and Radiological Health through the electronic docket administered by the Center's Division of Small Manufacturer's Assistance.

Under § 812.2(b)(1), a nonsignificant risk (NSR) device is considered to have an approved IDE as long as the sponsor complies with the requirements of § 812.2(b)(1)(i) through (vii). Therefore, the streamlined requirements set forth in proposed § 812.18(b)(1) also would apply to NSR devices that comply with § 812.2(b)(1).

Proposed § 812.18(b)(2) would require FDA approval to export an investigational device if FDA withdraws approval of the IDE (under § 812.30(b)) or the sponsor terminates any or all parts of investigations because unanticipated adverse device effects present an unreasonable risk to subjects (under § 812.46(b)). FDA approval to export an investigational device in these situations is required under section 801(e)(2) of the act.

III. Legal Authority

As noted earlier, section 801(e)(2) of the act prohibits the export of certain unapproved devices and banned medical devices unless FDA determines that exportation of the device: (1) Is not contrary to the public health or safety; and (2) has the approval of the country to which it is intended for export. This section was added to the act as part of the Medical Device Amendments of 1976 (Pub. L. 94–295) and the legislative history for the Medical Device Amendments indicates that Congress considered two distinct export provisions. One provision suggested by the House of Representatives would have permitted export of an unapproved device to any foreign country that had an ''appropriate'' health agency where such agency had reviewed and approved the device. FDA would receive notice of the export, but would not be required to approve exportation. In contrast, the Senate provision would have authorized export of unapproved devices if FDA determined that exportation ''was in the interest of public health and safety'' and the device had the approval of the country to which it was being exported. Thus, unlike the House provision, the Senate provision would have required the agency to make certain determinations before the device could be exported. Congress ultimately enacted a provision that was very similar to the Senate version.

The proposed rule is consistent with the legislative history and section 801(e)(2) of the act. FDA would still determine whether exportation of the device was contrary to the public health

[1] When FDA originally issued 21 CFR § 812.18(b), the export authority for devices was at section 801(d) of the act. However, Congress renumbered the export provision as section 801(e) of the act when it added a new section 801(d) as part of the Prescription Drug Marketing Act of 1987. Thus, § 812.18(b) contains an obsolete reference to section 801(d) of the act, and the proposed rule would correct this error.

or safety and whether the foreign country receiving the device approves of the device's importation. The principal difference between the current device export approval process and the proposed rule is that, under the proposed rule, FDA would consider the existence of an FDA-approved IDE to be FDA's determination that exportation of the device is not contrary to the public health or safety. Additionally, the list of countries that FDA would maintain would represent the agency's determination that, for those countries on the list, the country approves of the importation of investigational devices. By making these determinations in advance, through the IDE process and the list of countries, no separate export approval would be required, and so the device export process would be much simplified and streamlined.

Courts have routinely upheld similar ''blanket'' determinations or findings made by administrative agencies. For example, in *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973), the Supreme Court examined, among other things, whether FDA was required to conduct individual hearings for each manufacturer of similar drug products before it could withdraw those drug products from the market. The Court declined to require individual hearings because ''many hearings would be an exercise in futility'' and ''To require separate judicial proceedings to be brought against each * * * would be to create delay where in the interest of public health there should be prompt action.'' (Id. at pp. 621, 624–625.)

Similarly, in *In re Permian Basin Area Rate Cases*, 390 U.S. 747 (1968), the Supreme Court declined to require an agency to engage in individual proceedings, upholding the agency's ability to use a comprehensive and practical regulatory approach. The Court recognized that, ''[C]onsiderations of flexibility and practicality are certainly germane to the issues before us * * * We cannot, in these circumstances, conclude that Congress has given authority inadequate to achieve with reasonable effectiveness the purpose for which it acted.'' (Id. at p. 777 (citations omitted).) (See also *Phillips Petroleum Company* v. *U.S. Environmental Protection Agency*, 803 F.2d 545, 562 (10th Cir. 1986) (The Environmental Protection Agency was ''well within its discretion to use a generic streamlined approach or procedure'' instead of case-by-case determinations as to the necessity of a mechanical integrity test).)

This proposed rule is consistent with these court decisions because FDA is making its determination that an approved IDE provides a satisfactory basis for its required determination that exportation of a device is not contrary to public health or safety. The agency is making this determination through this rulemaking, providing an opportunity for comment to all interested persons. Assuming that the agency issues a final rule, there will be no need for the agency to make case-by-case determinations that such devices do not present a public health or safety concern. Similarly, the need to make an individual determination that a foreign country has approved the device's importation is eliminated where such country has already indicated that it will permit the importation of all FDA-approved IDE devices. Requiring the submission and FDA review of the same information that the agency already has, in these cases, would unnecessarily consume agency and industry resources and delay exportation.

The proposed rule, therefore, is authorized by sections 520(g) and 801(e)(2) of the act and the general rulemaking authority under section 701(a) of the act and is consistent with judicial decisions upholding an agency's authority to develop streamlined, efficient procedures to make determinations applicable to a group or class of persons or products, rather than proceeding on a case-by-case basis.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 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 net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This proposed rule meets the definition of a significant regulatory action in the Executive Order in that it raises novel legal and policy issues arising from Presidential priorities, and so has been reviewed by OMB under 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. Because the proposed rule, if finalized, would simplify and lessen regulatory burdens on persons seeking to export unapproved devices that are the subjects of approved IDE's and that are to be exported to a country that has given a blanket approval to importation of devices that are the subjects of FDA-approved IDE's, the agency certifies that the proposed rule would not impose any additional regulatory burdens on small entities, and so, under the Regulatory Flexibility Act, no further analysis is required.

V. Environmental Impact

The agency has determined, under 21 CFR § 25.24(a)(8), 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.

Interested persons may, on or before February 12, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VI. Paperwork Reduction Act of 1995

This proposed rule would simplify and streamline the device export process, and does not impose any new information collection requirements. The existing information collection requirements in 21 CFR part 812 have been approved under OMB control no. 0910–0078 which expires on May 31, 1996.

List of Subjects

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that Title 21 of the Code of Federal Regulations be amended as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

1. The authority citation for part 812 is revised to read as follows:

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 393); secs. 215, 301, 351, 352, 353–360F of the Public

Health Service Act (42 U.S.C. 216, 241, 262, 263, 263a–263n).

2. Section 812.18 is amended by revising paragraph (b) to read as follows:

§ 812.18 Import and export requirements.

* * * * *

(b) *Exports*. A person exporting an investigational device subject to this part shall comply with section 801(e)(1) of the act, and shall obtain FDA's prior approval, as required by section 801(e)(2) of the act. However, if the investigational device to be exported is the subject of an investigational device exemption application (IDE) approved by FDA:

(1) No prior approval shall be necessary provided that the investigational device to be exported will be marketed or used in clinical trials in the foreign country for the same intended use as that in the approved IDE and is to be exported to a country that has expressed its approval of the importation of investigational devices that are the subjects of FDA-approved IDE's. (For devices that have received a ''CE'' mark from the European Union, the valid granting of a CE mark for a device that is the subject of an FDA-approved IDE shall constitute approval of the device for importation into any country in the European Economic Area.) A list of countries that have approved the importation of investigational devices that are the subjects of IDE's approved by FDA is available from the Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(2) If FDA withdraws approval of the IDE or the sponsor terminates any or all parts of investigations because unanticipated adverse device effects present an unreasonable risk to subjects, exportation of the investigational device may continue only with FDA approval in accordance with section 801(e)(2) of the act.

Dated: November 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–28894 Filed 11–24–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

27 CFR Parts 5, 19, 24, 25, 70, and 250

[Notice No. 816]

RIN 1512–AB40

Registration of Formulas and Statements of Process for Certain Domestically Produced Wines, Distilled Spirits and Beer (95R–019P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is proposing to amend the regulations to require the registration, rather than approval, of formulas and statements of process for certain domestically produced wines, distilled spirits, and beer. ATF believes that the proposed regulations will provide greater flexibility to the industry by enabling proprietors to commence production in a more expeditious manner.

The proposed amendments are part of the Administration's Reinventing Government effort to reduce burden and streamline requirements.

DATES: Written comments must be received on or before January 26, 1996.

ADDRESSES: Send written comments to: Chief, Wine, Beer and Spirits Regulations Branch; Bureau of Alcohol, Tobacco and Firearms; P.O. Box 50221; Washington, DC 20091–0221; ATTN: Notice No. 816.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, Wine, Beer and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202–927–8230).

SUPPLEMENTARY INFORMATION:

Background

Under the current regulations, approved formulas or statements of process are required for certain domestically produced distilled spirits, wines, and beer. Pursuant to regulations in 27 CFR Part 5, an approved formula on ATF Form 5110.38 (Formula For Distilled Spirits Under The Federal Alcohol Administration Act) is required to blend, mix, purify, refine, compound, or treat distilled spirits in a manner which results in a change of character, composition, class or type of the spirits. The formula requirement applies to: (1) Proprietors of distilled spirits plants qualified as processors under 27 CFR Part 19; (2) Persons in Puerto Rico who manufacture distilled spirits products for shipment to the United States in accordance with 27 CFR Part 250; and (3) Persons who ship Virgin Islands distilled spirits products into the United States in accordance with 27 CFR Part 250.

As it relates to wine, the regulations in 27 CFR Part 24 provide that a proprietor must, before commencing production, obtain approval of the formula and process by which special natural wine, agricultural wine, and certain other than standard wines (e.g., Spanish type blending sherry) are to be made. An approved formula is also required under certain conditions in the production of an effervescent (sparkling) wine. Wine formulas are filed on ATF Form 5120.29, Formula And Process For Wine.

With regard to beer, the regulations in 27 CFR Part 25 require that a brewer file a statement of process for any fermented beverage which the proprietor intends to produce and market under a name other than ''beer,'' ''ale,'' ''porter,'' ''stout,'' ''lager,'' or ''malt liquor.'' The statement of process, which is contained in the Brewer's Notice, ATF Form 5130.10, includes the name or designation of the product, the kinds and quantities of materials to be used, the method of manufacture, and the approximate alcohol content of the finished product.

ATF reviews approximately 1,700 formulas and statements of process annually. The Bureau examines the formulas and statements of process to ensure that, among other things, the ingredients used are not only approved by the Food and Drug Administration (FDA), but are used within prescribed limitations established by the FDA. The average turnaround time for processing a formula or statement of process is approximately 3 weeks.

The majority of formulas and statements of process that ATF examines are approved without any substantive changes. The Bureau attributes this, in part, to its continued efforts at providing guidance and information to members of the alcoholic beverage industry. Through the publication of industry circulars and other publications, such as the ''Compliance Matters'' bulletin, ATF is able to apprise the industry of policies or procedures which might affect them. With regard to formulas for wine and distilled spirits, specifically, the Bureau recommends that proprietors review Industry Circular 89–3. This circular clarifies and provides information and guidelines for the completion and submission of formulas. This circular can also be utilized by brewers in the