provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished. Issued in Fort Worth, Texas, on December 30, 1996.

Larry M. Kelly,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–251 Filed 1–6–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

[Docket No. 95N–0342]

Export Requirements for Medical Devices; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period for a proposed rule that appeared in the Federal Register of November 27, 1995 (60 FR 58308). The document proposed to amend FDA's regulations for investigational devices to streamline requirements for persons seeking to export unapproved medical devices. FDA is seeking comments on whether this rulemaking is still needed in light of recent changes in the export provisions of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments by March 10, 1997.

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

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301–827–3380, electronic mail: PChao@bangate.FDA.gov.

SUPPLEMENTARY INFORMATION:

I. The National Performance Review and the Proposed Rule on Device Exports

At present, two statutory provisions in the act govern the export of devices that are not approved for marketing in the United States.

The first provision, in section 801(e)(2) of the act (21 U.S.C. 381(e)(2)), became law as part of the Medical Device Amendments Act of 1976 (Pub. L. 94–295) and required FDA approval of certain exports of unapproved devices. The second provision, in section 802 of the act (21 U.S.C. 382), was the result of the FDA Export Reform and Enhancement Act of 1996 (the Export Act of 1996) (Pub. L. 104–134, and amended by Pub. L. 104–180).

Before the latter provision became law, FDA had undertaken a program to streamline the requirements for the exportation of unapproved devices under section 801(e) of the act. In the Federal Register of November 27, 1995 (60 FR 58308), FDA issued a proposed rule to simplify the agency's export approval process for certain unapproved devices. The proposed rule was intended, in part, to respond to concerns in the device industry that the statutory requirement of FDA approval of device exports may undermine a firm's ability to compete in international markets and may represent an unnecessary regulatory barrier. (It should be emphasized, however, that FDA's approval times for device export applications have decreased significantly, from an average of 91 days per request in 1992 to 10 days in 1995, and further decreased to 8 days in fiscal year 1996.)

The proposed rule was also intended to implement part of the President's and Vice-President's ''National Performance Review'' pertaining to the exportation of unapproved devices (as announced in an April 1995 report entitled ''Reinventing Drug and Device Regulations''). Under the National Performance Review, the agency would permit the export of unapproved devices to certain advanced industrialized countries without prior FDA review and approval, provided that the device complied with the importing country's laws. The report also stated that the Administration would seek the necessary legislative changes and would consult Congress on the appropriate list of advanced industrialized countries. Furthermore, the 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.''

To implement the administrative reform aspects of the report, FDA proposed to amend § 812.18 (21 CFR 812.18) to state that a person who wishes to export an investigational device subject to part 812—Investigational Device Exemptions (21 CFR part 812) must comply with the requirements in section 801(e)(1) of the act, but that, for purposes of section 801(e)(2), prior FDA approval would be unnecessary if the investigational device to be exported is the subject of an approved IDE (including nonsignificant risk devices which, under FDA regulations, are considered to have an approved IDE) 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 an approved IDE. The proposed rule also stated that, if the device is the subject of an approved IDE and has received a ''CE'' mark from the European Union (EU), the device may be exported to any country in the European Economic Area (EEA).

Proposed § 812.18(b)(1) also would have FDA's Center for Devices and Radiological Health (CDRH) make available a list of countries that have approved the importation of investigational devices that are the subjects of approved IDE's. The list would be maintained electronically.

Proposed § 812.18(b)(2) would require prior FDA approval to export an investigational device if FDA withdrew approval of the IDE or the sponsor terminated any or all parts of investigations because unanticipated adverse device effects present an unreasonable risk to subjects.

In the preamble to the proposed rule, FDA also stated that it would amend the proposed rule to reflect any legislative changes (60 FR 58308 at 58309).

Thus, the changes in the proposed rule would have benefited those companies wishing to export devices: (1) That have an approved U.S. IDE; (2) to countries that have agreed to accept U.S. IDE products; and (3) whose intended use is the same as the U.S. IDE. FDA believed this was as much

relief as could be provided under existing law at the time.

The agency received seven comments on the proposed rule. Most comments supported the rule, but recommended expanding the rule to explicitly mention certain devices (such as intraocular lenses and certain in vitro diagnostic devices), amending the rule so that a ''CE'' mark would permit exportation of the device to any country, or amending the rule to consider marketing authorization by developed countries as permitting exportation to any country. One comment questioned the likelihood that a country would agree to the importation of all devices having approved IDE's.

II. The Export Act of 1996 and Its Impact on the Proposed Rule

On April 26, 1996, the President signed the Export Act of 1996 (Pub. L. 104–134, and later amended by Pub. L. 104–180). The Export Act of 1996 amended, among other things, sections 801 and 802 of the act. The Export Act of 1996 amended section 801(e)(2) of the act to state, in part, that export of an unapproved device could occur only if 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 or ''the device is eligible for export under section 802'' of the act. Section 802 of the act, as amended, authorizes exports of unapproved drugs and devices if certain conditions or requirements are met. Under section 802(b)(1) of the act, an unapproved device may be exported to any country if the device complies with the laws of that country and has valid marketing authorization in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or in any country in the EU or the EEA (often referred to as the ''listed countries''). At present, 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, plus Iceland, Liechtenstein, and Norway. As new countries join the EU or the EEA, they will automatically be treated as listed countries without any need for FDA action. Additionally, the Secretary of Health and Human Services may designate additional countries to be added to the list if certain requirements are met.

Another provision of the Export Act of 1996 pertains specifically to drugs and devices exported for investigational use. Section 802(c) of the act states that a drug or device intended for investigational use in any country described in section 802(b)(1)(A)(i) and (b)(1)(A)(ii) of the act may be exported in accordance with the laws of that country and shall be exempt from regulation under sections 505(i) and 520(g) of the act (21 U.S.C. 355(i) and 360j(g)). Thus, under section 802(c) of the act, as amended, a device may be exported for investigational use to any of the listed countries without prior FDA approval and without compliance with the IDE regulations in part 812.

However, all devices exported under section 802 of the act are subject to certain requirements, under section 802(f) of the act. For example, the device must be manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice (CGMP) requirements or meet international standards as certified by an international standards organization recognized by the agency; must not be adulterated under section 501(a)(1), (a)(2)(A), (a)(3), and (c) of the act (21 U.S.C. 351(a)(1), (a)(2)(A), (a)(3), and (c)); and must comply with section 801(e)(1)(A) through (e)(1)(D) of the act, which require the device to be intended for export, accord to the foreign purchaser's specifications, not be in conflict with the laws of the foreign country to which the device is being exported, be labeled on the outside of the shipping package that the device is intended for export, and not be sold or offered for sale in domestic commerce.

The Export Act of 1996 affects the proposed rule in several ways. First, it accomplished some changes to the proposed rule that the comments requested, particularly those comments that requested that FDA expand the proposed rule to cover other devices and other FDA-regulated products or requested FDA to permit exportation to any country if a device received marketing authorization in the EU or marketing authorization in a ''developed country.'' Second, the Export Act of 1996 also distinguishes between exports under section 801(e) of the act and exports under section 802 of the act. For example, when FDA published the proposed rule on November 27, 1995, devices were subject only to the requirements in section 801(e) of the act. The Export Act of 1996 gives firms an option whether to export a device under section 801(e) of the act or under section 802 of the act, and assigned different requirements to exports under each section of the act. Thus, any final rule on device exports that FDA publishes would have to reflect these changes in the law.

Finally, as stated earlier in this document, section 802(b)(1)(A) of the act authorizes export of an unapproved device to any country if the device complies with the laws of the importing country and the device has a valid marketing approval in any of the 25 countries identified in the act. Devices exported under section 802(b)(1)(A) of the act are also not required to obtain prior FDA approval, although they are subject to certain notification requirements, nor are they required to have an IDE. In contrast, the proposed rule's reference to exports of investigational devices for marketing purposes is limited to devices exported under section 801(e)(1) of the act and presumes that the person exporting the device has an IDE or is considered to have an approved IDE; thus, at a minimum, the proposed rule would have to be changed to reflect the requirements in section 802(b)(1)(A) of the act.

Section 802(c) of the act also has a significant impact on the proposed rule. Under section 802(c) of the act, devices exported for investigational use to any listed country are not subject to the IDE requirements and can be exported without prior FDA approval. In comparison, the proposed rule would have required the exported device to have an approved IDE or to be a nonsignificant risk device and be considered to have an approved IDE, and the streamlined requirements described in the proposal would have applied only to exports to countries that had notified FDA of their willingness to accept IDE devices.

The Export Act of 1996 contains other provisions that affect device exports. For example, devices exported under section 801(e) of the act do not have to comply with CGMP's, but devices exported under section 802 of the act must be in ''substantial conformity'' with CGMP's or meet international standards as certified by an international standards organization recognized by the agency. Devices exported under section 801(e) of the act must: (1) Accord to the foreign purchaser's specifications; (2) not conflict with the laws of the foreign country; (3) be labeled on the outside of the shipping package that the device is intended for export; and (4) not be offered for sale in the United States. In contrast, the labeling for devices exported under section 802 of the act must, in addition to the requirements in section 801(e)(1) of the act, be in accordance with the requirements and conditions of use of the listed country that authorized its marketing as well as the requirements and conditions of use

in the foreign country that will receive the device. The labeling for devices exported under section 802 of the act also must be in the language and units of measurement of the foreign country or in the language designated by that country.

III. Issues for Public Comment

Considering these changes in the export authority for devices, FDA is reopening for 60 days the comment period for the proposed rule. FDA is soliciting public comment on the following issues:

1. Is a final rule still necessary? Given that section 802 of the act now provides additional flexibility for device exports and to export devices without the need to make export requests under section 801(e)(2) of the act, is there still a need to streamline the export procedure under section 801(e)(2) of the act? If so, what specific relief for exports under § 801(e)(2) of the act is sought for U.S. IDE devices that is not preceded by the new legislation?

2. If a final rule is still necessary, what changes to the rule should be made? For example, the proposed rule included a program option under which foreign countries would notify FDA of their willingness to accept devices that are the subject of an approved IDE. However, there is little evidence to suggest that foreign governments will be willing to accept all IDE devices. Conceivably, a foreign government might be inclined to impose conditions on its acceptance of IDE devices, or accept some, but not all, devices. What are some alternatives to this program option? FDA invites interested persons to submit draft language for any suggested regulatory change.

Interested persons may, on or before March 10, 1997 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.

During this comment period and FDA's review of the comments, FDA will issue export permits under section 801(e)(2) of the act using current CDRH procedures. A copy of the procedures may be obtained through the Information Processing and Office Automation Branch (HFZ–307), Division of Program Operations, CDRH, by calling 301–594–4520 or by faxing a request to 301–594–4528. In the event that FDA decides, after considering the comments received, not to issue a final rule or to issue a new proposal, FDA will continue to issue export permits under section 801(e)(2) of the act using current CDRH procedures.

Dated: December 31, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–292 Filed 1–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–208172–91]

RIN 1545–AU71

Basis Reduction Due to Discharge of Indebtedness

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that provide ordering rules for the reduction of bases of property under sections 108 and 1017 of the Internal Revenue Code of 1986. The regulations will affect taxpayers that exclude discharge of indebtedness from gross income under section 108.

DATES: Written comments must be received by April 7, 1997. Outlines of oral comments to be presented at the public hearing scheduled for April 24, 1997, at 10 a.m. must be received by April 3, 1997.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG–208172–91), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–208172–91), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS internet site at http://www.irs.ustreas.gov/prod/tax__regs/comments.html.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations generally, Sharon L. Hall or Christopher F. Kane of the Office of Assistant Chief Counsel (Income Tax & Accounting) at (202) 622–4930; concerning partnership adjustments under section 1017, Brian M. Blum of the Office of Assistant Chief Counsel (Passthroughs & Special Industries) at (202) 622–3050; concerning submissions and the hearing, Evangelista C. Lee of the Regulations Unit at (202) 622–7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)).

Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224. Comments on the collections of information should be received by March 10, 1997. Comments are specifically requested concerning:

Whether the proposed collections of information are necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collections of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

The collections of information in this proposed regulation are in §§ 1.108–4(b), 1.1017–1(e)(2), and 1.1017–1(f)(2)(ii) and (iii). This information is required for a taxpayer to elect to reduce the adjusted bases of depreciable property under section 108(b)(5), to elect to treat section 1221(1) real property as either depreciable property or depreciable real property, and to account for a partnership interest as either depreciable property or depreciable real property. This information will be used to determine