

agency, including whether the information will have practical utility; (b) the accuracy of the burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

Written comments regarding the burden-hour estimates or other aspects of the collection of information requirements contained in the proposed rule should be sent to both BEA and OMB following the instructions given in the ADDRESSES section above.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this proposed rulemaking, if adopted, will not have a significant economic impact on a substantial number of small entities. Few small U.S. businesses are subject to the reporting requirements of this survey. U.S. companies that have direct investments abroad tend to be quite large, thereby excluding them from the definition of small entity. The proposed changes to the BE-11 annual survey would not increase the burden on small businesses. The exemption level for the BE-11 survey is set in terms of the size of a U.S. company's foreign affiliates (foreign companies owned 10 percent or more by the U.S. company); if a foreign affiliate has total assets, sales, or net income (loss) greater than the exemption level, it must be reported on Form BE-11B(LF), BE-11B(SF), BE-11B(FN), BE-11B(EZ), or BE-11C. With the increase in the exemption level for the BE-11 survey for nonbank affiliates of nonbank U.S. Reporters from \$40 million to \$60 million, the burden on small businesses would not increase and is likely to decrease since the U.S. parent company required to file the report is typically many times larger than its largest foreign affiliate. BEA estimates that about 1,700 majority-owned nonbank foreign affiliates will shift from being reported on the long form to the short form under the \$225 million exemption level. About 3,000 nonbank foreign affiliates will no longer be required to be reported under the \$60 million exemption level; almost 4,000 foreign affiliates were added to the sample due to growth in the universe since the 2004 BE-10 benchmark survey. About 200 U.S. Reporters will no longer be required to report the annual survey

because all of their affiliates would be exempt.

Because few small businesses are impacted by this rule, and because those small businesses that are impacted are subject to only minimal recordkeeping burdens, the Chief Counsel for Regulation certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 15 CFR Part 806

Economic statistics, Multinational corporations, Penalties, Reporting and recordkeeping requirements, U.S. investment abroad.

Dated: August 20, 2008.

Rosemary Marcuss,

Acting Director, Bureau of Economic Analysis.

For the reasons set forth in the preamble, BEA proposes to amend 15 CFR part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

1. The authority citation for 15 CFR part 806 continues to read as follows:

Authority: 5 U.S.C. 301; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp., p. 173) and E.O. 12518 (3 CFR, 1985 Comp., p. 348).

2. Sections 806.14(f)(3)(ii) introductory text, (f)(3)(ii)(A) and (B), (f)(3)(iv), (f)(3)(v) introductory text, and (f)(3)(v)(A) are revised to read as follows:

§ 806.14 U.S. Direct Investment Abroad.

* * * * *

(f) * * *

(3) * * *

(ii) Forms BE-11B(LF), (SF), and (EZ) (Report for Majority-owned Nonbank Foreign Affiliate of Nonbank U.S. Reporter).

(A) A BE-11B(LF) (Long Form) must be filed for each majority-owned nonbank foreign affiliate of a nonbank U.S. Reporter for which any one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than \$225 million (positive or negative) at the end of, or for, the affiliate's fiscal year, unless the nonbank foreign affiliate is selected to be reported on Form BE-11B(EZ).

(B) A BE-11B(SF) (Short Form) must be filed for each majority-owned nonbank foreign affiliate of a nonbank U.S. Reporter for which any one of the three items listed in paragraph (f)(3)(ii)(A) of this section was greater than \$60 million (positive or negative),

but for which no one of these items was greater than \$225 million (positive or negative), at the end of, or for, the affiliate's fiscal year, unless the nonbank foreign affiliate is selected to be reported on Form BE-11B(EZ).

* * * * *

(iv) Form BE-11C (Report for Minority-owned Nonbank Foreign Affiliate of Nonbank U.S. Reporter) must be filed for each minority-owned nonbank foreign affiliate of a nonbank U.S. Reporter that is owned at least 20 percent, but not more than 50 percent, directly and/or indirectly, by all U.S. Reporters of the affiliate combined, and for which any one of the three items listed in paragraph (f)(3)(ii)(A) of this section was greater than \$60 million (positive or negative) at the end of, or for, the affiliate's fiscal year.

(v) Based on the preceding, an affiliate is exempt from being reported if it meets any one of the following criteria:

(A) For nonbank affiliates of nonbank U.S. Reporters, none of the three items listed in paragraph (f)(3)(ii)(A) of this section exceeds \$60 million (positive or negative). However, affiliates that were established or acquired during the year and for which at least one of these items was greater than \$10 million but not over \$60 million must be listed, and key data items reported, on a supplement schedule on Form BE-11A.

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[FR Doc. E8-21311 Filed 9-10-08; 8:45 am]

BILLING CODE 3510-06-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR 878

[Docket No. FDA-2006-N-0178] (formerly Docket No. 2006N-0362)

General and Plastic Surgery Devices; Reclassification of the Absorbable Hemostatic Device; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until October 14, 2008, the comment period for a proposed rule published in the **Federal Register** of October 31, 2006 (71 FR 63728) to reclassify the absorbable hemostatic device from class III (premarket approval) into class II (special controls). FDA is reopening the

comment period to update comments and to receive any new information. Elsewhere in this issue of the **Federal Register**, FDA is also reopening the comment period on a notice of availability of a draft guidance document that would serve as the special control if FDA reclassifies this device.

DATES: Submit written or electronic comments on the proposed rule by October 14, 2008.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3638.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 31, 2006 (71 FR 63728), FDA published a proposed rule to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) to class II (special controls). FDA invited interested persons to comment on the proposed rule by January 29, 2007. In the **Federal Register** of May, 8, 2007 (72 FR 26011), FDA reopened the comment period for 30 days in response to two requests for additional time for preparation of comments.

On July 2, 2007, FDA received a petition under 21 CFR 10.30 and 10.35 requesting that the agency refrain from issuing a final regulation for the proposed reclassification and the draft special controls guidance for the absorbable hemostatic device until an updated and complete administrative record is made available to the public. The petitioner also requested that FDA reopen the rulemaking for the proposed reclassification to allow submission of comments based on the administrative record. FDA has updated the administrative record in the Division of Dockets Management (see **ADDRESSES**). FDA is also reopening the comment period for 30 days. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on a notice of availability of a draft guidance document that would serve as the special control if the device is reclassified.

II. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.regulations.gov> or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: September 4, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-21200 Filed 9-10-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG-160868-04]

RIN 1545-BF61

Section 6707A and the Failure To Include on Any Return or Statement Any Information Required To Be Disclosed Under Section 6011 With Respect to a Reportable Transaction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations under section 6707A of the Internal Revenue Code (Code), which provide the rules relating to the assessment of penalties under section 6707A for the failure to include on any return or statement any information required to be disclosed under section 6011 with respect to a reportable transaction. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by December 10, 2008.

ADDRESSES: Send submission to: CC:PA:LPD:PR (REG-160868-04), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-160868-04), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-160868-04).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Matthew Cooper (202) 622-4940; concerning submissions of comments and requests for a public hearing, Richard Hurst (202) 622-2949 (TDD telephone) (not toll-free numbers) and his e-mail address is Richard.A.Hurst@irscounsel.treas.gov.

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Procedure and Administration Regulations (26 CFR part 301) relating to section 6707A. Section 811 of the American Jobs Creation Act of 2004, Public Law 108-357 (118 Stat. 1418) added section 6707A to the Code to provide a monetary penalty for the failure to include on any return or statement any information required to be disclosed under section 6011 with respect to a reportable transaction. The temporary regulations set forth the rules relating to the assessment of the penalty as well as the factors that the Commissioner (or the Commissioner's delegate) will consider in deciding whether the penalty should be rescinded based on promoting compliance with the Code and effective tax administration. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply