

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. Under the proposed regulations, foreign-owned U.S. businesses would be required to report on the BE-15 survey if they have total assets, sales or gross operating revenues, or net income that exceed \$40 million. According to the Small Business Administration's Table of Small Business Size Standards, in most industries, businesses with \$40 million of assets are not considered small businesses. The only industry for which the reporting requirements for the BE-15 survey would affect small businesses, would be for certain types of banking and finance companies, where the threshold for being considered a small business is \$175 million. BEA estimates that about 60 banking and finance affiliates would be considered small businesses and would have to report on the BE-15. About 20 of these small businesses would be required to file on the BE-15B, and about 40 (half in alternate years) would be required to file on the BE-15(EZ). Based on average burden hours per response of 3.5 hours for the BE-15B and 1.5 hours for the BE-15(EZ) in alternate years, BEA estimates the total respondent burden of the BE-15 on small companies to be 100 hours out of a total estimated respondent burden on all companies of 68,000 hours.

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

List of Subjects in 15 CFR Part 806

Economic statistics, Foreign investment in the United States, International transactions, Penalties, Reporting and recordkeeping requirements.

Dated: July 30, 2008.

J. Steven Landefeld,

Director, Bureau of Economic Analysis.

For 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. Section 806.15(i) is revised to read as follows:

§ 806.15 Foreign direct investment in the United States.

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(i) *Annual report form.* BE-15—Annual Survey of Foreign Direct Investment in the United States: One report is required for each consolidated U.S. affiliate exceeding an exemption level of \$40 million. Form BE-15A must be filed by each majority-owned U.S. affiliate (a “majority-owned” U.S. affiliate is one in which the combined direct and indirect ownership interests of all foreign parents of the U.S. affiliate exceed 50 percent) for which at least one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for U.S. income taxes—exceeds \$275 million (positive or negative). Form BE-15B must be filed by each majority-owned U.S. affiliate for which at least one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for U.S. income taxes—exceeds \$120 million (positive or negative) but no one item exceeds \$275 million (positive or negative), and by each minority-owned U.S. affiliate (a “minority-owned” U.S. affiliate is one in which the combined direct and indirect ownership interest of all foreign parents of the U.S. affiliate is 50 percent or less) for which at least one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for U.S. income taxes—exceeds \$120 million (positive or negative). Form BE-15(EZ) must be filed every other year by each U.S. affiliate for which at least one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for U.S. income taxes—exceeds \$40 million (positive or negative) but no one item exceeds \$120 million (positive or

negative). U.S. affiliates will be mailed Form BE-15(EZ) in years when they are required to file; in alternate years, these U.S. affiliates will be mailed a letter confirming that they are not required to file and asking them to update their contact information with BEA. A BE-15 Claim for Exemption must be filed by each U.S. affiliate to claim exemption from filing a BE-15A, BE-15B, or BE-15(EZ). Following an initial filing, the BE-15 Claim for Exemption is not required annually from those U.S. affiliates that meet the stated exemption criteria from year to year.

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DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 806

[Docket No. 080731960-81014-01]

RIN 0691-AA66

Direct Investment Surveys: BE-11, Annual Survey of U.S. Direct Investment Abroad

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule amends regulations of the Bureau of Economic Analysis, Department of Commerce (BEA) to amend the reporting requirements for the BE-11, Annual Survey of U.S. Direct Investment Abroad. The BE-11 survey is conducted annually and is a sample survey that obtains financial and operating data covering U.S. parent companies and their foreign affiliates. BEA proposes changes in the reporting criteria that will raise the thresholds for reporting.

DATES: Comments on this proposed rule will receive consideration if submitted in writing on or before 5 p.m. November 10, 2008.

ADDRESSES: You may submit comments, identified by RIN 0691-AA66, and referencing the agency name (Bureau of Economic Analysis), by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. For agency, select “Commerce Department—all.”
- *E-mail:* David.Galler@bea.gov.
- *Fax:* Office of the Chief, Direct Investment Division, (202) 606-5318.
- *Mail:* Office of the Chief, Direct Investment Division, U.S. Department of

Commerce, Bureau of Economic Analysis, BE-50, Washington, DC 20230.

- *Hand Delivery/Courier:* Office of the Chief, Direct Investment Division, U.S. Department of Commerce, Bureau of Economic Analysis, BE-50, Shipping and Receiving, Section M100, 1441 L Street, NW., Washington, DC 20005.

Written comments regarding the burden-hour estimates or other aspects of the information-of-collection requirements contained in the proposed rule should be sent to both BEA through any of the methods above and to the Office of Management and Budget (OMB), O.I.R.A., Paperwork Reduction Project 0608-0053, Attention PRA Desk Officer for BEA, via e-mail at pbugg@omb.eop.gov, or by FAX at 202-395-7245.

Public Inspection: All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All personal identifying information (for example, name, address, etc.) voluntarily submitted by the commentator may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. BEA will accept anonymous comments.

FOR FURTHER INFORMATION CONTACT: David H. Galler, Chief, Direct Investment Division (BE-50), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone (202) 606-9835.

SUPPLEMENTARY INFORMATION: This proposed rule would amend 15 CFR part 806.14 to set forth the reporting requirements for the BE-11, Annual Survey of U.S. Direct Investment Abroad. The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

Description of Changes

The BE-11 survey is a mandatory survey and is conducted annually by BEA under the International Investment and Trade in Services Survey Act (22 U.S.C. 3101-3108), hereinafter, "the Act." BEA will send the survey to potential respondents in March of each year; responses will be due by May 31.

In order to align BEA's survey program with available resources, which have declined as a result of a recent reduction in BEA's budget, BEA proposes changes in the reporting criteria: (a) An increase in the threshold

for reporting on the BE-11B(SF) short form and BE-11C form from \$40 million to \$60 million; and (b) an increase in the threshold for reporting on the BE-11B(LF) long form from \$150 million to \$225 million. Majority-owned nonbank affiliates with assets, sales or gross operating revenues, or net income (loss) over \$60 million but less than or equal to \$225 million would be filed on a short form; majority-owned nonbank affiliates with assets, sales or gross operating revenues, or net income (loss) over \$225 million would be filed on a long form. Minority-owned nonbank affiliates with assets, sales or gross operating revenues, or net income (loss) over \$60 million would be filed on a C form. Two reporting thresholds remain unchanged—the threshold for reporting on Form BE-11B(FN) remains at \$250 million and the threshold for reporting only selected items on Form BE-11A remains at \$150 million.

Survey Background

The Bureau of Economic Analysis (BEA), U.S. Department of Commerce, conducts the BE-11 survey under the authority of the International Investment and Trade in Services Survey Act (22 U.S.C. 3101-3108), hereinafter, "the Act." Section 4(a) of the Act requires that the President shall, to the extent he deems necessary and feasible, conduct a regular data collection program to secure current information on international financial flows and other information related to international investment and trade in services, including (but not limited to) such information as may be necessary for computing and analyzing the United States balance of payments, the employment and taxes of United States parents and affiliates, and the international investment and trade in services position of the United States.

In Section 3 of Executive Order 11961, as amended by Executive Orders 12318 and 12518, the President delegated the responsibility for performing functions under the Act concerning direct investment to the Secretary of Commerce, who has re-delegated it to BEA. The annual survey of U.S. direct investment abroad is a sample survey that collects information on a variety of measures of the overall operations of U.S. parent companies and their foreign affiliates, including total assets, sales, net income, employment and employee compensation, research and development expenditures, and exports and imports of goods. The sample data are used to derive universe estimates in nonbenchmark years from similar data reported in the BE-10, Benchmark

Survey of U.S. Direct Investment Abroad, which is taken every five years. The data are needed to measure the size and economic significance of direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies. The data are disaggregated by country and industry of the foreign affiliate and by industry of the U.S. parent.

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This proposed rule does not contain policies with Federalism implications as that term is defined in E.O. 13132.

Paperwork Reduction Act

This proposed rule contains a collection-of-information requirement subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The requirement will be submitted to the OMB for approval as a revision to a collection currently approved under OMB control number 0608-0053.

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection-of-information subject to the requirements of the Paperwork Reduction Act unless that collection displays a currently valid OMB control number.

The BE-11 survey, as proposed, is expected to result in the filing of reports from approximately 1,550 respondents. The respondent burden for this collection of information will vary from one company to another, but is estimated to average 99.3 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Thus the total respondent burden of the survey is estimated at 153,850 hours (1,550 respondents times 99.3 hours average burden). Although the proposed amendments to the reporting rules lower respondent burden, this estimate is somewhat above the burden of 122,900 hours currently carried for this survey in the OMB inventory, due to growth in the number and size of U.S. parent companies and foreign affiliates since the survey was last cleared.

Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the

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.

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(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).

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(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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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