

for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as specified in paragraphs (h)(2) through (h)(5) of this AD: For service information that contains steps that are labeled as RC, the provisions of paragraphs (k)(4)(i) and (k)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled "RC Exempt," then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

#### (l) Related Information

For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206-231-3527; email: *alan.pohl@faa.gov*.

#### (m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 737-53A1368, dated February 27, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; internet *https://www.myboeingfleet.com*.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. (5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Des Moines, Washington, on May 29, 2019.

**Michael Kaszycki,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2019-12322 Filed 6-11-19; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF COMMERCE

### Bureau of Economic Analysis

#### 15 CFR Part 801

[190225160-9484-01]

RIN 0691-AA88

#### International Services Surveys: BE-140 Benchmark Survey of Insurance Transactions by U.S. Insurance Companies With Foreign Persons

**AGENCY:** Bureau of Economic Analysis, Commerce.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends regulations of the Department of Commerce's Bureau of Economic Analysis (BEA) to renew the reporting requirements for the mandatory BE-140 Benchmark Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons. This survey applies to the 2018 calendar reporting year. This mandatory benchmark survey, conducted under the authority of the International Investment and Trade in Services Survey Act, covers the universe of transactions in insurance services and is BEA's most comprehensive survey of such transactions. For the 2018 benchmark survey, BEA is making several changes to the data items collected and the design of the survey form.

**DATES:** This final rule is effective July 12, 2019.

**FOR FURTHER INFORMATION CONTACT:** Christopher Stein, Chief, Services Surveys Branch (BE-50), Balance of Payments Division, Bureau of Economic Analysis, U.S. Department of Commerce, 4600 Silver Hill Rd., Washington, DC 20233; phone (301)

278-9189; or via email at *Christopher.Stein@bea.gov*.

**SUPPLEMENTARY INFORMATION:** On March 26, 2019, BEA published a notice of proposed rulemaking that set forth the revised reporting criteria for the BE-140 Benchmark Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons (84 FR 11256). No comments on the proposed rule were received.

This final rule amends 15 CFR part 801 to set forth the reporting requirements for the BE-140 Benchmark Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons for 2018.

The BE-140 Benchmark Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons is a mandatory survey and is conducted once every five years by BEA under the authority provided by the International Investment and Trade in Services Survey Act (P.L.94-472, 90 Stat. 2059, 22 U.S.C. 3101-3108, as amended), hereinafter, "the Act." The Act provides that data reported to BEA on this survey are confidential and may be used only for analytical and statistical purposes. Without prior written permission from the survey respondent, the data collected cannot be presented in a manner that allows individual responses to be identified. An individual respondent's report cannot be used for purposes of taxation, investigation, or regulation. Copies retained by BEA are exempt from legal process. Per the Cybersecurity Enhancement Act of 2015, a respondent's data are protected from cybersecurity risks through security monitoring of the BEA information systems.

A response is required from persons subject to the reporting requirements of the BE-140, whether or not they are contacted by BEA, to ensure complete coverage of transactions in insurance services between U.S. persons (any individual or organization subject to the jurisdiction of the United States) and foreign persons.

In 2012, BEA established regulatory guidelines for collecting data on international trade in services and direct investment (77 FR 24373; April 24, 2012). This final rule, conducted pursuant to the Act, amends those regulations to require a response from persons subject to the reporting requirements of the BE-140, whether or not they are contacted by BEA.

The benchmark survey covers the universe of insurance transactions by U.S. insurance companies with foreign persons and is BEA's most

comprehensive survey of such transactions. In nonbenchmark years, the universe of estimates covering these transactions are derived from the sample data reported on BEA's BE-45 Quarterly Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons. The BE-45 and the BE-140 collect similar information. BEA uses cutoff sampling for the BE-45, meaning that respondents must only report on the BE-45 if they have transactions that exceeded \$8 million in any one of the eight covered insurance transaction categories. The sample of reporters that file on a quarterly basis throughout calendar year 2018 will also be required to report on the 2018 BE-140 survey. BEA reconciles the annual data from the BE-140 survey with the quarterly data reported on the BE-45 survey, by comparing quarterly to annual submissions that are typically completed using audited information.

The benchmark data, which includes data from respondents not subject to filing on an ongoing quarterly basis, will be used, in conjunction with quarterly data collected on the companion BE-45 survey, to produce estimates of insurance transactions for BEA's international transactions accounts (ITAs), national income and product accounts, and industry accounts. These data are also used to monitor U.S. trade in insurance services, to analyze the impact on the U.S. economy and on foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities.

A full list of the insurance transactions covered by the BE-140 survey can be found in the regulatory text for new § 801.12 at the end of this document.

#### Description of Changes

This final rule amends the regulations at 15 CFR part 801 by adding new § 801.12 to set forth the reporting requirements for the BE-140 benchmark survey, and amends the survey form for the BE-140 benchmark survey to satisfy changing data needs and to improve data quality and the effectiveness and efficiency of data collections. These amendments include changes in data items collected and changes to the design of the survey form relative to the 2013 benchmark survey.

BEA adds and modifies some items on the benchmark survey form. The following items are added to the benchmark survey:

(1) Mandatory questions to request additional information from respondents that have direct insurance sales and/or losses. Additional questions, applicable to reporters of direct insurance transactions on Schedule B of the survey, will be added to request an estimate of what percentage of these transactions were: (1) Life insurance, (2) freight insurance, and (3) other direct insurance. To avoid imposing undue reporter burden, the estimates will be requested based on the reporter's knowledge of the U.S. operations, and are not required to be sourced from company records at an individual transaction level.

(2) A new schedule to collect information related to catastrophic losses from hurricanes and other significant natural disasters. The 2018 BE-140 survey will collect information from reporters for a sample of up to 5 catastrophic events that took place during 2018. Catastrophic events include events such as hurricanes, earthquakes, and wildfires, etc. The new schedule is structured to collect data on the loss amount, type of loss (assumed or ceded), the country of the foreign counterparty, the relationship to the foreign counterparty (foreign affiliate, foreign parent group, or unaffiliated), and the date for each event/transaction.

In addition, this final rule makes the following modifications to items collected on the previous BE-140 survey form:

(1) Lowering the threshold for reporting large, infrequent reinsurance transactions. On the 2013 BE-140 benchmark survey, the threshold for reporting these transactions was \$1 billion. For the 2018 BE-140 benchmark survey, in order to collect more comprehensive information, a lower threshold of \$250 million is used. In addition, reporters are required to indicate if the transactions either included a transfer of reserves or were related to a catastrophic event, for up to 10 transactions.

(2) Modifying mandatory Schedule C to collect additional information regarding the expected average maturity of reserves that are transferred and included in the premiums reported on the survey. Information about reserve transfers will be collected for the large, infrequent reinsurance transactions collected at a threshold of \$250 million (modification (1) above). Reporters of such transactions are required to provide additional information about those transactions that included a transfer of reserves at the inception of new reinsurance contracts, or for the recapture or termination of reinsurance contracts. The schedule requests

information about the type of premium/loss (either assumed or ceded), the country of the foreign counterparty, the relationship to the foreign counterparty (foreign affiliate, foreign parent group, or unaffiliated), the expected average maturity of the reserves, the reserve amount, and the date of the transaction. A text field will also be provided to allow the respondent to include additional details about each transaction.

In addition, BEA has redesigned the format and wording of the survey. The new design incorporates improvements made to other BEA surveys. Some enhancements are the result of a recent cognitive review conducted with selected survey respondents during the planning for the 2017 BE-120 Benchmark Survey of Transactions in Selected Services and Intellectual Property with Foreign Persons. Survey instructions and data item descriptions have been changed to improve clarity and ensure the benchmark survey form is consistent with other BEA surveys.

#### Change to the Regulatory Text of the Proposed Rule

BEA received no comments on the proposed rule. We note that we have made a change to paragraph (f), entitled "*Due date*", in new § 801.12, as found in the regulatory text of the proposed rule. The phrase "July 31, 2019 (or by August 31, 2019 for respondents that use BEA's eFile system)" has been replaced with "September 30, 2019". BEA made this change in this final rule to provide respondents additional time to comply with the requirements of the new section.

#### Executive Order 12866

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

#### Executive Order 13132

This final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 13132.

#### Paperwork Reduction Act

The collection-of-information in this final rule was submitted to the Office of Management and Budget (OMB) pursuant to the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3520 (PRA). OMB approved the reinstatement of the information collection under OMB control number 0608-0073.

Notwithstanding any other provisions of 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 PRA unless that collection displays a currently valid OMB control number.

The BE-140 survey is expected to result in the filing of reports from approximately 1,300 respondents. Approximately 1,000 respondents will report mandatory data on the survey, and approximately 300 will file exemption claims. The respondent burden for this collection of information will vary from one respondent to another, but is estimated to average (1) 9 hours for the 600 respondents that file mandatory or voluntary data by country and affiliation for relevant transaction types on the mandatory schedules; (2) 2 hours for the 400 respondents that file mandatory data by transaction type but not by country or affiliation; and (3) 1 hour for other responses. These burden-hour estimates consider 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 for this survey is estimated at 6,500 hours, or 5 hours per response (6,500 hours/1,300 respondents), compared to 4,689 hours, or about 4.5 hours per response (4,689 hours/1,042 respondents) for the previous BE-140 benchmark survey in 2013. The increase in burden hours is due to an estimated increase in the size of the respondent universe from 2013 to 2018, as well as changes to the content of the survey.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the final rule should be sent to both BEA via email at [Christopher.Stein@bea.gov](mailto:Christopher.Stein@bea.gov) and to OMB, O.I.R.A., Paperwork Reduction Project 0608-0073, Attention PRA Desk Officer for BEA, Kerrie Leslie, via email at [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov).

### Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), that this action will not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No final regulatory flexibility analysis was prepared, as no comments were received regarding the determination that this action will not

have a significant economic impact on a substantial number of small entities.

### List of Subjects in 15 CFR Part 801

Economic statistics, Foreign trade, International transactions, Penalties, Reporting and recordkeeping requirements.

Dated June 5, 2019.

**Paul W. Farello,**

*Associate Director of International Economics, Bureau of Economic Analysis.*

For reasons set forth in the preamble, BEA amends 15 CFR part 801 as follows:

### PART 801—SURVEY OF INTERNATIONAL TRADE IN SERVICES BETWEEN U.S. AND FOREIGN PERSONS AND SURVEYS OF DIRECT INVESTMENT

■ 1. The authority citation for 15 CFR part 801 continues to read as follows:

**Authority:** 5 U.S.C. 301; 15 U.S.C. 4908; 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. Revise § 801.3 to read as follows:

#### § 801.3 Reporting requirements.

Except for surveys subject to rulemaking in §§ 801.7, 801.8, 801.9, 801.10, 801.11, and 801.12 reporting requirements for all other surveys conducted by the Bureau of Economic Analysis shall be as follows:

(a) Notice of specific reporting requirements, including who is required to report, the information to be reported, the manner of reporting, and the time and place of filing reports, will be published by the Director of the Bureau of Economic Analysis in the **Federal Register** prior to the implementation of a survey;

(b) In accordance with section 3104(b)(2) of title 22 of the United States Code, persons notified of these surveys and subject to the jurisdiction of the United States shall furnish, under oath, any report containing information which is determined to be necessary to carry out the surveys and studies provided for by the Act; and

(c) Persons not notified in writing of their filing obligation by the Bureau of Economic Analysis are not required to complete the survey.

■ 3. Add § 801.12 to read as follows:

#### § 801.12 Rules and regulations for the BE-140 Benchmark Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons—2018.

The BE-140 Benchmark Survey of Insurance Transactions by Insurance Companies with Foreign Persons will be

conducted covering calendar year 2018. All legal authorities, provisions, definitions, and requirements contained in §§ 801.1 through 801.2 and §§ 801.4 through 801.6 are applicable to this survey. Specific additional rules and regulations for the BE-140 survey are given in paragraphs (a) through (e) of this section. More detailed instructions are given on the report form and in instructions accompanying the report form.

(a) *Response required.* A response is required from U.S. insurance companies subject to the reporting requirements of the BE-140 Benchmark Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons—2018, contained in this section, whether or not they are contacted by BEA. Also, a U.S. insurance company, or its agent, that is contacted by BEA about reporting on this survey, either by sending a report form or by written inquiry, must respond in writing pursuant to this section. This may be accomplished by:

(1) Completing and returning the BE-140 by the due date of the survey; or

(2) If exempt, by completing the determination of reporting status section of the BE-140 survey and returning it to BEA by the due date of the survey.

(b) *Who must report.* A BE-140 report is required of each U.S. insurance company that had insurance transactions with foreign persons in the categories covered by the survey during its 2018 calendar year.

(c) *What must be reported—(1) Transactions exceeding \$2 million.* A U.S. insurance company that had transactions with foreign persons that exceeded \$2 million in at least one of the insurance categories covered by the survey during its 2018 calendar year, on an accrual basis, is required to provide data on the total transactions of each of the covered types of insurance transactions and must disaggregate the totals by country and by relationship to the foreign counterparty (foreign affiliate, foreign parent group, or unaffiliated). The determination of whether a U.S. insurance company is subject to this reporting requirement may be based on the judgment of knowledgeable persons in a company who can identify reportable transactions on a recall basis, with a reasonable degree of certainty, without conducting a detailed manual records search.

(2) *Transactions \$2 million or below.* A U.S. insurance company that had transactions with foreign persons that were \$2 million or less in each of the insurance categories covered by the survey during its 2018 calendar year, on an accrual basis, is required to provide

the total for each type of transaction in which they engaged.

(i) *Voluntary reporting of insurance transactions.* If, during calendar year 2018, total transactions were \$2 million or less in each of the insurance categories covered by the survey, on an accrual basis, the U.S. insurance company may, in addition to providing the required total for each type of transaction, voluntarily report transactions at a country and affiliation level of detail on the applicable mandatory schedule(s).

(ii) [Reserved]

(3) *Exemption claims.* Any U.S. person that receives the BE-140 survey form from BEA, but is not subject to the reporting requirements, must file an exemption claim by completing the determination of reporting status section of the BE-140 survey and returning it to BEA by the due date of the survey. The requirement in this paragraph (b)(3) is necessary to ensure compliance with reporting requirements and efficient administration of the Act by eliminating unnecessary follow-up contact.

(d) *Covered types of insurance services.* Insurance services covered by the BE-140 survey consist of transactions between U.S. insurance companies and foreign persons for:

(1) Premiums earned on reinsurance assumed from companies resident abroad;

(2) Losses incurred on reinsurance assumed from companies resident abroad;

(3) Premiums paid for reinsurance ceded to companies resident abroad;

(4) Losses recovered on reinsurance ceded to companies resident abroad;

(5) Premiums earned from direct insurance sold to foreign persons;

(6) Losses incurred on direct insurance sold to foreign persons;

(7) Receipts for auxiliary insurance services provided to foreign persons; and

(8) Payments for auxiliary insurance services provided by foreign persons.

(e) *Types of transactions excluded from the scope of this survey.* Premiums paid to, or losses received from, foreign insurance companies on direct insurance.

(f) *Due date.* A fully completed and certified BE-140 report, or qualifying exemption claim with the determination of reporting status section completed, is due to be filed with BEA not later than September 30, 2019.

[FR Doc. 2019-12373 Filed 6-11-19; 8:45 am]

BILLING CODE 3510-06-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2015-D-2496]

#### Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled “Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry.” Given the relatively new presence of electronic nicotine delivery systems (ENDS) on the U.S. market and FDA’s final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA expects to receive premarket tobacco product application (PMTA) submissions from manufacturers of ENDS. This guidance is intended to assist applicants to prepare PMTAs for ENDS products.

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 12, 2019.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2015-D-2496 for “Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access