

Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

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ANM OR E Christmas Valley, OR [New]

Christmas Valley Airport, OR

(Lat. 43°14'11" N, long. 120°39'53" W)

That airspace extending upward from 700 feet above the surface within a 14-mile radius of the Christmas Valley Airport.

Issued in Des Moines, Washington, on June 21, 2022.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2022–13614 Filed 6–27–22; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 220616–0135]

RIN 0691–AA92

Direct Investment Surveys: BE–13, Survey of New Foreign Direct Investment in the United States

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend regulations of the Department of Commerce's Bureau of Economic Analysis (BEA) to set forth the reporting requirements for the BE–13, Survey of New Foreign Direct Investment in the United States ("BE–13 survey"). The BE–13 survey collects information on the acquisition or establishment of U.S. business enterprises by foreign investors, and information on expansions by existing U.S. affiliates of foreign companies. The data collected through the survey are used to measure the amount of new foreign direct investment in the United States and ensure complete coverage of BEA's other foreign direct investment statistics. BEA proposes one change to the reporting requirements of the survey that will reduce respondent burden, simplify reporting, and increase the efficiency of the data collection. This mandatory BE–13 survey is required from persons subject to the reporting requirements, whether or not they are contacted by BEA.

DATES: Comments on this proposed rule will receive consideration if submitted in writing on or before August 29, 2022.

ADDRESSES: You may submit comments, identified by RIN 0691–AA92, and referencing the agency name (Bureau of Economic Analysis), by any of the following methods:

- **Federal eRulemaking Portal:**

<https://www.regulations.gov>. Follow the instructions for submitting comments. For Keyword or ID, enter "EAB–2022–0001."

- **Email:** Ricardo.Limes@bea.gov.

- **Mail:** Direct Transactions and Positions Branch, U.S. Department of Commerce, Bureau of Economic Analysis, BE–49NI, Washington, DC 20233.

- **Hand Delivery/Courier:** Direct Transactions and Positions Branch, U.S. Department of Commerce, Bureau of Economic Analysis, BE–49NI, 4600 Silver Hill Road, Suitland, MD 20746.

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 BEA through any of the methods above and also to the Office of Management and Budget (OMB) by submitting comments at www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review" or by using the search function and entering the title of the collection.

Public Inspection: All comments received are a part of the public record and will generally be posted to <https://www.regulations.gov> without change. Personal identifying information voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. BEA will accept anonymous comments (enter N/A in required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT:

Ricardo Limes, Chief, Direct Transactions and Positions Branch (BE–49NI), Bureau of Economic Analysis, U.S. Department of Commerce, 4600 Silver Hill Road, Washington, DC 20233; email Ricardo.limes@bea.gov or 301–278–9659.

SUPPLEMENTARY INFORMATION: The BE–13, Survey of New Foreign Direct Investment in the United States, is a mandatory survey conducted by BEA under the authority of the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108).

The purpose of the BE–13 survey is to collect data on the acquisition or establishment of U.S. business

enterprises by foreign investors and the expansion of existing U.S. affiliates of foreign companies to establish a new facility where business is conducted. The data collected on the survey are used to measure the amount and economic significance of new foreign direct investment in the United States and assess its impact on the U.S. economy. Foreign direct investment in the United States is defined as the ownership or control, directly or indirectly, by one foreign person (foreign parent) of 10 percent or more of the voting securities of an incorporated U.S. business enterprise, or an equivalent interest of an unincorporated U.S. business enterprise, including a branch.

This proposed rule would amend 15 CFR 801.7 to set forth the reporting requirements for the BE–13, Survey of New Foreign Direct Investment in the United States. Under this proposed rule, persons subject to the reporting requirements of the BE–13, Survey of New Foreign Direct Investment in the United States, would be required to respond, whether or not they are contacted by BEA.

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, 44 U.S.C. 3501–3520 (PRA).

Description of Changes

The proposed change amends the regulations for the BE–13 survey. Specifically, BEA proposes to change the reporting requirements of form BE–13E, Fiscal Year End Cost Update for Projects Originally Reported on Forms BE–13B and BE–13D. The form collects updated cost information for greenfield investments—i.e., establishments or expansions of U.S. businesses by foreign investors filed on BE–13B or BE–13D forms, respectively—and is required to be filed annually until the establishment or expansion of the U.S. business enterprise is complete.

BEA proposes to limit the filing requirement of the BE–13E form to three years after the year the investment is initiated. BEA has found that this timeframe would be sufficient to collect the vast majority of the changes to total planned expenditures of greenfield investments and provide data users with insightful statistics on the ultimate cost of these investments. The proposed change would reduce respondent burden and the BEA resources needed to continue to collect and process these

updates, allowing BEA to focus resources on the featured statistics for more recent periods.

BEA will describe any proposed changes to the information collected through the survey (including the addition, deletion, and/or modification of existing questions and definitions) in a public notice and will solicit comments as part of the requirements of the Paperwork Reduction Act (PRA). Any changes to reporting requirements or significant expansions in scope of the surveys would be conducted by rulemaking.

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 sufficient to warrant preparation of a Federalism assessment under E.O. 13132.

Paperwork Reduction Act

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the PRA. The requirement will be submitted to OMB for approval as a reinstatement, with change, of a previously approved collection under OMB control number 0608-0035.

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 PRA unless that collection displays a currently valid OMB control number.

The BE-13 survey, as proposed, is expected to result in the filing of approximately 3,027 reports from U.S. affiliates each year. The respondent burden for this collection of information is expected to vary because of differences in company structure, size, and complexity, but is estimated to average 1.1 hours per response. The burden includes 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 3,027 hours, compared to 2,547 hours for the previous BE-13 survey estimate. The increase in burden hours is due to the increase in the overall number of respondents expected to file, partially offset by a reduction in the number of BE-13E forms expected to be filed.

We are soliciting public comments to permit the Department of Commerce/Bureau of Economic Analysis to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, 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 (RFA), 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.

Most of the U.S. business enterprises that are required to file the survey are units of multinational enterprises. For the few small businesses that are foreign-owned, BEA has attempted to keep burden to a minimum by asking only those questions that are considered essential and for which answers are likely to be readily available from the existing records of the business. The amount of information required to be reported by each U.S. business enterprise is determined by the type and cost of the transaction. When the cost of the acquisition, establishment, or expansion is less than \$3 million, the U.S. business enterprise will only be required to report selected items on the BE-13 Claim for Exemption. The burden for this form is an average of 15 minutes.

Because relatively few small businesses are required to file the survey and because those that are impacted are subject to only a minimal recordkeeping burden, 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 801

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

Paul W. Farello,

Associate Director of International Economics, Bureau of Economic Analysis.

For reasons set forth in the preamble, BEA proposes to amend 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 § 801.7 to read as follows:

§ 801.7 Rules and regulations for the BE-13, Survey of New Foreign Direct Investment in the United States.

The BE-13, Survey of New Foreign Direct Investment in the United States, is conducted to collect data on the acquisition or establishment of U.S. business enterprises by foreign investors and the expansion of existing U.S. affiliates of foreign companies to establish new facilities where business is conducted. Foreign direct investment is defined as the ownership or control by one foreign person (foreign parent) of 10 percent or more of the voting securities of an incorporated U.S. business enterprise, or an equivalent interest of an unincorporated U.S. business enterprise, including a branch. BEA will describe the proposed information collection in a public notice and will solicit comments according to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501–3520). 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-13 survey are given in paragraphs (a) through (d) of this section. More detailed instructions are given on the report forms and instructions.

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE-13, Survey of New Foreign Direct Investment in the United States, contained herein, whether or not they

are contacted by BEA. Also, a person, or their agent, who is contacted by BEA about reporting in this survey, either by sending them a report form or by written inquiry, must respond in writing pursuant to this section. This may be accomplished by filing the properly completed BE-13 report (BE-13A, BE-13B, BE-13D, BE-13E, or BE-13 Claim for Exemption).

(b) *Who must report.* A BE-13 report is required of any U.S. business enterprise, except certain private funds, see exception in item (b.4.), in which:

(1) A foreign direct investment in the United States relationship is created;

(2) An existing U.S. affiliate of a foreign parent establishes a new U.S. business enterprise, expands its U.S. operations, or acquires a U.S. business enterprise, or;

(3) BEA requests a cost update (Form BE-13E) for a U.S. business enterprise that previously filed Form BE-13B or BE-13D.

(4) Certain private funds are exempt from reporting on the BE-13 survey. If a U.S. business enterprise is a private fund and does not own, directly or indirectly, 10 percent or more of another business enterprise that is not also a private fund or a holding company, it is not required to file any BE-13 report except to indicate exemption from the survey if contacted by BEA.

(c) *Forms to be filed.* Depending on the type of investment transaction, U.S. affiliates would report their information on one of five forms—BE-13A, BE-13B, BE-13D, BE-13E, or BE-13 Claim for Exemption.

(1) Form BE-13A—Report for a U.S. business enterprise when a foreign entity acquires a voting interest (directly, or indirectly through an existing U.S. affiliate) in that U.S. business enterprise including segments, operating units, or real estate; and

(i) The total cost of the acquisition is greater than \$3 million; and

(ii) By this acquisition, the foreign entity now owns at least 10 percent of the voting interest (directly, or indirectly through an existing U.S. affiliate) in the acquired U.S. business enterprise.

(2) Form BE-13B—Report for a U.S. business enterprise when it is established by a foreign entity or by an existing U.S. affiliate of a foreign parent; and

(i) The expected total cost to establish the new U.S. business enterprise is greater than \$3 million; and

(ii) The foreign entity owns at least 10 percent of the voting interest (directly, or indirectly through an existing U.S. affiliate) in the new U.S. business enterprise.

(3) Form BE-13D—Report for an existing U.S. affiliate of a foreign parent when it expands its operations to include a new facility where business is conducted and the expected total cost of the expansion is greater than \$3 million.

(4) Form BE-13E—Report for a U.S. business enterprise that previously filed Form BE-13B or BE-13D. Form BE-13E collects updated cost information and will be collected annually for three years after the year of the establishment or expansion of the U.S. business enterprise.

(5) Form BE-13 Claim for Exemption—Report for a U.S. business enterprise that:

(i) was contacted by BEA but does not meet the requirements for filing Forms BE-13A, BE-13B, or BE-13D; or

(ii) whether or not contacted by BEA, met all requirements for filing Forms BE-13A, BE-13B, or BE-13D except the \$3 million reporting threshold.

(d) *Due date.* The BE-13 forms are due no later than 45 calendar days after the acquisition is completed, the new U.S. business enterprise is established, the expansion is begun, the cost update is requested, or a notification letter is received from BEA by a U.S. business enterprise that does not meet the filing requirements for the survey.

[FR Doc. 2022-13713 Filed 6-27-22; 8:45 am]

BILLING CODE 3510-06-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 314

[Docket No. FDA-2021-N-0862]

RIN 0910-AH62

Nonprescription Drug Product With an Additional Condition for Nonprescription Use

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). The proposed rule, if finalized, would establish requirements for a nonprescription drug product that has an ACNU that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the

supervision of a healthcare practitioner. The proposed rule is intended to increase options for applicants to develop and market safe and effective nonprescription drug products, which could improve public health by broadening the types of nonprescription drug products available to consumers.

DATES: Either electronic or written comments on the proposed rule must be submitted by October 26, 2022. Submit comments (including recommendations) on information collection issues under the Paperwork Reduction Act of 1995 by July 28, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 26, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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.