

incorporated U.S. business enterprise, or an equivalent interest in an unincorporated U.S. business enterprise, at the end of the business enterprise's fiscal year that ended in the calendar year covered by the survey. Certain private funds are exempt from reporting on the BE-12 survey. If a U.S. business meets ALL of the following 3 criteria, it is not required to file any BE-12 report except to indicate exemption from the survey if contacted by BEA:

(1) The U.S. business enterprise is a private fund;

(2) The private fund does not own, directly or indirectly through another business enterprise, an "operating company"—*i.e.*, a business enterprise that is not a private fund or a holding company—in which the foreign parent owns at least 10 percent of the voting interest; and

(3) If the foreign parent owns the private fund indirectly (through one or more other U.S. business enterprises), there are no U.S. "operating companies" between the foreign parent and the indirectly-owned private fund.

(c) *Forms to be filed.* (1) Form BE-12A must be completed by a U.S. affiliate that was majority-owned by one or more foreign parents (for purposes of this survey, a "majority-owned" U.S. affiliate is one in which the combined direct and indirect ownership interest of all foreign parents of the U.S. affiliate exceeds 50 percent) if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the following three items for the U.S. affiliate (not just the foreign parent's share) was greater than \$300 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey:

(i) Total assets (do not net out liabilities);

(ii) Sales or gross operating revenues, excluding sales taxes; or

(iii) Net income after provision for U.S. income taxes.

(2) Form BE-12B must be completed by:

(i) A majority-owned U.S. affiliate if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the three items listed in paragraph (c)(1) of this section (not just the foreign parent's share), was greater than \$60 million (positive or negative) but none of these items was greater than \$300 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey.

(ii) A minority-owned U.S. affiliate (for purposes of this survey, 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) if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the three items listed in paragraph (c)(1) of this section (not just the foreign parent's share), was greater than \$60 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey.

(3) Form BE-12C must be completed by a U.S. affiliate if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, none of the three items listed in paragraph (c)(1) of this section for a U.S. affiliate (not just the foreign parent's share), was greater than \$60 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey.

(4) Any U.S. person that is contacted by BEA concerning the BE-12 survey, but is not subject to the reporting requirements, must file a BE-12 Claim for Not Filing. The requirement in this paragraph (c)(4) is necessary to ensure compliance with reporting requirements and efficient administration of the Act by eliminating unnecessary follow-up contact.

(d) *Aggregation of real estate investments.* All real estate investments of a foreign person must be aggregated for the purpose of applying the reporting criteria. A single report form must be filed to report the aggregate holdings, unless written permission has been received from BEA to do otherwise. Those holdings not aggregated must be reported separately on the same type of report that would have been required if the real estate holdings were aggregated.

(e) *Due date.* A fully completed and certified Form BE-12A, BE-12B, BE-12C, or BE-12 Claim for Not Filing is due to be filed with BEA not later than May 31 of the year after the year covered by the survey (or by June 30 for reporting companies that use BEA's eFile system).

[FR Doc. 2022-21113 Filed 9-28-22; 8:45 am]

BILLING CODE 3510-06-P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 220923-0197]

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: Final rule.

SUMMARY: This final rule amends 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 will change the reporting requirements of the survey to 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: This final rule is effective October 31, 2022.

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 final rule amends 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 rule, persons subject to the reporting requirements of the BE-13, Survey of New Foreign Direct Investment in the United States, are required to respond, whether or not they are contacted by BEA.

Description of Changes

This final rule amends the regulations at 15 CFR part 801 by modifying § 801.7. Specifically, BEA changes 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 will 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 change will 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.

On June 28, 2022, BEA published a notice of proposed rulemaking that set forth revised reporting criteria for the BE-13, Survey of New Foreign Direct Investment in the United States (87 FR 38311). No comments were received on the proposed rule.

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 (PRA). OMB approved the revision of the currently approved information collection under BE-13, Survey of New Foreign Direct Investment in the United States, 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 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.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule should be sent to both BEA via email at Ricardo.Limes@bea.gov and to OMB Office of Information and Regulatory Affairs (OIRA), Paperwork Reduction Project 0608-0035, Attention PRA Desk Officer for BEA, via email at OIRA_Submission@omb.eop.gov.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, at the proposed rule stage that this action will not have a significant impact on a

substantial number of small entities. No comments were received on that certification or on the economic impacts of this rule more generally. Therefore, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 801

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

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 § 801.7 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 and 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 paragraph (b)(4) of this section, 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. 2022-21116 Filed 9-28-22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 227

Regulation Crowdfunding, General Rules and Regulations

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 17 of the Code of Federal Regulations, Parts 200 to 239, revised as of April 1, 2022, amend § 227.201 by adding paragraph (z) to read as follows:

§ 227.201 Disclosure requirements.

* * * * *

(z) Any written communication or broadcast script provided in accordance with § 227.206 or, if within 30 days of the initial filing of the offering statement, § 230.241 of this chapter.

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[FR Doc. 2022-21290 Filed 9-28-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 515, 516, 520, 522, 524, 529, and 558

[Docket No. FDA-2022-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January, February, and March 2022. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy of the regulations.

DATES: This rule is effective September 29, 2022.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January, February, and March 2022, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring