

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.

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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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## 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](mailto: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