

Poloxalene in grams/ton	Indications for use	Limitations	Sponsor
(1) To deliver 1 to 2 grams per 100 pounds of body weight.	Cattle: For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle.	Dosage is 1 gram of poloxalene per 100 pounds of body weight daily and continued during exposure to bloat producing conditions. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat dosage if animals are exposed to bloat-producing conditions more than 12 hours after the last treatment. Do not exceed the higher dosage levels in any 24-hour period.	054771
(2) [Reserved]			

**§ 558.500 [Amended]**

■ 24. In § 558.500, remove reserved paragraphs (e)(1)(iii) and (iv).

Dated: July 15, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–15760 Filed 7–27–20; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

[Docket No. FDA–2020–N–0002]

#### New Animal Drugs; Withdrawal of Approval of Abbreviated New Animal Drug Application

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

**ACTION:** Notification of withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of an abbreviated new animal drug application (ANADA) at the sponsor's request because the product is no longer manufactured or marketed.

**DATES:** Withdrawal of approval is effective July 28, 2020.

**FOR FURTHER INFORMATION CONTACT:** Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, [sujaya.dessai@fda.hhs.gov](mailto:sujaya.dessai@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Hikma International Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118, has requested that FDA withdraw approval of ANADA 200–323 for use of a 1-gram bolus of phenylbutazone in horses because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application*

(21 CFR 514.116), notice is given that approval of ANADA 200–323, and all supplements and amendments thereto, is hereby withdrawn, effective July 28, 2020.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: July 15, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–15761 Filed 7–27–20; 8:45 am]

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## DEPARTMENT OF THE TREASURY

### Office of Investment Security

#### 31 CFR Parts 800 and 802

RIN 1505–AC63, 1505–AC64, 1505–AC65

#### Definition of “Principal Place of Business”; Filing Fees for Notices of Certain Investments in the United States by Foreign Persons and Certain Transactions by Foreign Persons Involving Real Estate in the United States

**AGENCY:** Office of Investment Security, Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** The final rule makes a clarifying revision to the definition of “principal place of business” and adopts the interim rule establishing a fee for parties filing a formal written notice of a transaction for review by the Committee on Foreign Investment in the United States.

**DATES:** The final rule is effective on August 27, 2020.

**FOR FURTHER INFORMATION CONTACT:** For questions about this rule, contact: Laura Black, Director of Investment Security Policy and International Relations; Meena R. Sharma, Deputy Director of Investment Security Policy and International Relations; David Shogren,

Senior Policy Advisor; or James Harris, Senior Policy Advisor, at U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220; telephone: (202) 622–3425; email: [CFIUS.FIRRMA@treasury.gov](mailto:CFIUS.FIRRMA@treasury.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### A. Definition of “Principal Place of Business”

On January 17, 2020, the Department of the Treasury (Treasury Department) published two interim rules, each effective February 13, 2020, that provided a definition for the term “principal place of business” as applicable to transactions subject to review by the Committee on Foreign Investment in the United States (CFIUS or the Committee). 85 FR 3112 (January 17, 2020); 85 FR 3158 (January 17, 2020). The preambles to the interim rules provide background on this definition. While the definition took effect on February 13, 2020, the public was provided an opportunity to comment. The Treasury Department received several comments, which are discussed further below.

##### B. Filing Fees for Formal Written Notices

On March 9, 2020, the Treasury Department published a notice of proposed rulemaking amending 31 CFR part 800 and 31 CFR part 802 to establish a fee for “covered transactions” and “covered real estate transactions,” respectively, that are filed with CFIUS as formal written notices. 85 FR 13586 (March 9, 2020). The public was provided an opportunity to comment on the proposed rule and several comments were received. Following consideration of the public comments, on April 29, 2020, the Treasury Department published an interim rule establishing filing fees, effective May 1, 2020. 85 FR 23736 (April 29, 2020). As explained in the preamble to the interim rule, subpart K on filing fees was added to the

regulations at 31 CFR part 800 and 31 CFR part 802, and a limited number of revisions were made to other related sections of those regulations. Additionally, the preamble to the interim rule included a discussion of the public comments received on the proposed fee rule. While the Treasury Department began collecting fees on May 1, 2020, it determined that the public and the Committee would benefit from an additional comment period, which ended on June 1, 2020. Comments received during the additional comment period are discussed below.

The preambles to the proposed rule and the interim rule provide additional information on the Committee's statutory authority and requirements with respect to filing fees, and various factors that were considered in establishing the filing fee regulations.

## II. Summary of Comments and Change From the Interim Rules

During the public comment periods for each of the interim rules discussed above, the Treasury Department received written submissions reflecting a range of views. All comments received by the end of each comment period are available on the public rulemaking dockets at <https://www.regulations.gov>. The section-by-section analysis below discusses the comments and describes a clarifying revision.

### A. Definition of "Principal Place of Business"—Sections 800.239 and 802.232

Several written submissions were received on the interim rules defining the term "principal place of business." In general, commenters expressed support and offered suggestions to clarify or address specific types of investors or scenarios. As described below, in consideration of the comments, one clarifying revision is made in the final rule.

One commenter expressed strong support for the definition in the interim rules, noting that it provides clarity and aligns with business realities. Another commenter noted that paragraph (a) of the definition was reasonable, appropriate, and consistent with CFIUS's historic application of the term, but suggested that the phrase "activities and investments" with respect to investment funds be clarified. In response to this comment, the final rule removes "and investments." The Treasury Department intends that, with respect to investment funds, the word "activities" is inclusive of "investments;" thus, directing and managing investments made by an

investment fund would be captured by the word "activities."

Commenters also made suggestions with respect to paragraph (b) of the definition, which addresses the situation where an entity has made representations to a government that may be inconsistent with its assertion for CFIUS purposes that its principal place of business is in the United States under the criteria set forth in paragraph (a) of the definition. One commenter suggested removing the phrase "or equivalent." Another commenter suggested that the criteria in paragraph (b) of the definition be narrowed to more closely match the language in paragraph (a).

No changes were made to paragraph (b) in response to these comments. Paragraph (b) includes a non-exhaustive list of representations an entity might make to a government, each of which approximate the criteria set forth in paragraph (a). One commenter suggested that an entity maintaining an offshore "registered agent" or "place of business" would preclude it from having a principal place of business in the United States under the definition. The Treasury Department disagrees because the focus of paragraph (b) is a representation of an entity's "principal" or "headquarters" location, or equivalent terms that capture the same concept. The Treasury Department also disagrees with suggestions made by commenters that additional examples of the application of the definition to specific scenarios—such as addressing investment funds with more particularity—would be beneficial, because the particular facts and circumstances would need to be considered.

### B. Filing Fees for Formal Written Notices—Subpart K

Two responsive written submissions were received on the interim rule establishing filing fees. One commenter broadly supported the interim rule and the second commenter suggested changes, which are discussed below.

#### Sections 800.1101 and 802.1101—Amount of Fee

Consistent with the proposed rule and the interim rule, §§ 800.1101 and 802.1101 set forth the fee amount based on the value of the transaction.

One commenter proposed two alternatives to §§ 800.1101 and 802.1101. One suggestion was that the Treasury Department, during an initial phase of filing fee implementation, impose a flat \$10,000 fee for all transactions above a certain threshold. The final rule does not make any change

in response to this comment. The Foreign Investment Risk Review Modernization Act of 2018 (FIRRMA) directs that the fee shall be based on the "value of the transaction," and the approach in the final rule is consistent with the statute. Additionally, FIRRMA provides that the amount of the fee should take into account the expenses of the Committee associated with conducting its activities. The personnel and resource costs to the Committee of reviewing a notice are not insignificant and may often exceed the suggested flat fee. Finally, the fee structure set forth in the final rule provides for a low proportional cost (equal to or less than 0.15% of the transaction value) for all transactions.

The commenter also suggested, in the alternative, that additional fee bands be incorporated into the rule and the fee amounts be lowered. The commenter asserted that the fee structure in the interim rule may provide a disincentive to voluntary filings or encourage parties to restructure transactions to minimize fees. The final rule does not make any changes in response to this comment. In the event that a transaction is restructured to be effectuated in multiple phases, §§ 800.1103(e)(1) and 802.1103(h)(1) address calculation of a fee in such a circumstance.

The Treasury Department considered different approaches to the fee structure—including additional transaction value ranges and lower fee amounts—and decided that the structure in the final rule is the most appropriate for reasons including proportionality and administrability. The commenter's proposed fee structure would have the effect of raising fees on lower value transactions and reducing fees on higher value transactions, as compared to the fee schedule in the interim rule. Additionally, in considering the proposed fee structure, the Treasury Department evaluated that additional fee bands could increase complexity for parties and the Committee in terms of the analysis required to determine which fee amount is relevant to a particular transaction—especially where the precise transaction value may not be known at the time of the filing. The filing fee structure in the interim rule allows the Committee to appropriately generate funding—consistent with FIRRMA—in order to support the work of the Committee, but at the same time, keep the cost as a proportion of transaction value low. In terms of incentives to voluntarily file a notice with CFIUS where a fee is required, the Treasury Department notes that the benefit of filing a notice and paying the fee is the "safe harbor" that

may be obtained upon the conclusion of CFIUS review where there are no unresolved national security concerns. This is of considerable value to transaction parties, particularly those who have determined that filing a notice is appropriate given the circumstances of the transaction and the potential interest the Committee may have in the transaction if not notified. Finally, transaction parties can take advantage of the declaration process, which does not require a fee.

No additional comments were received. Therefore, the final rule adopts the interim rule as published.

### III. Rulemaking Requirements

#### *Executive Order 12866*

This rule is not subject to the general requirements of Executive Order 12866, which covers review of regulations by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB), because it relates to a foreign affairs function of the United States, pursuant to section 3(d)(2) of that order. In addition, this rule is not subject to review under section 6(b) of Executive Order 12866 pursuant to section 7(c) of the April 11, 2018 Memorandum of Agreement between the Treasury Department and OMB, which states that CFIUS regulations are not subject to OMB's standard centralized review process under Executive Order 12866.

#### *Paperwork Reduction Act*

The collection of information contained in this rule was submitted to OMB for review along with the proposed rule, in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1505-0121.

The notice requirements in 31 CFR part 800 and 31 CFR part 802 were approved under the Paperwork Reduction Act with a per respondent burden of 130 hours and 116 burden hours, respectively. In the proposed rule establishing filing fees, the Treasury Department invited public comments with respect to the amended reporting requirements under §§ 800.502(c)(1)(viii) and 802.502(b)(1)(ix). No comments were received. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

#### *Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, RFA) generally requires an agency to prepare an initial

regulatory flexibility analysis unless the agency certifies that the rule will not, once implemented, have a significant economic impact on a substantial number of small entities. The RFA applies whenever an agency is required to publish a general notice of proposed rulemaking under section 553(b) of the Administrative Procedures Act (APA), or any other law. As set forth in the preamble to the proposed rule establishing filing fees at Section III, because rules issued pursuant to the Defense Production Act, such as this rule, are not subject to the APA or another law requiring the publication of a general notice of proposed rulemaking, the RFA does not apply. Nevertheless, for the reasons detailed in the RFA section of the proposed and interim rules, the Secretary of the Treasury certified that the rule, if implemented, "will not have a significant economic impact on a substantial number of small entities," 5 U.S.C. 605(b). This final rule makes limited changes to interim rules already in effect that will not have a significant economic impact on a substantial number of small entities. The Treasury Department also invited public comment on how the proposed rule would affect small entities.

#### *Congressional Review Act*

This rule has been submitted to OIRA which has determined that the rule is not a "major" rule under the Congressional Review Act.

#### List of Subjects

##### *31 CFR Part 800*

Fees, Foreign investments in the United States, Investment companies, Investments, National defense.

##### *31 CFR Part 802*

Fees, Federal buildings and facilities, Foreign investments in the United States, Government property, Investigations, Investment companies, Investments, Land sales, National defense, Public lands, Real property acquisition, Reporting and recordkeeping requirements.

Accordingly, the interim rule amending 31 CFR parts 800 and 802 regarding the establishment of filing fees, which was published in the **Federal Register** at 85 FR 23736 on April 29, 2020, is adopted as final without change. The interim rules amending 31 CFR parts 800 and 802 that were published in the **Federal Register** at 85 FR 3112 and 85 FR 3158 on January 17, 2020 are adopted as final with the following changes:

### **PART 800—REGULATIONS PERTAINING TO CERTAIN INVESTMENTS IN THE UNITED STATES BY FOREIGN PERSONS**

■ 1. The authority citation for part 800 continues to read as follows:

**Authority:** 50 U.S.C. 4565; E.O. 11858, as amended, 73 FR 4677.

#### **Subpart B—Definitions**

##### **§ 800.239 [Amended]**

■ 2. Amend § 800.239 in paragraph (a) by removing "and investments" after "where the fund's activities".

### **PART 802—REGULATIONS PERTAINING TO CERTAIN TRANSACTIONS BY FOREIGN PERSONS INVOLVING REAL ESTATE IN THE UNITED STATES**

■ 3. The authority citation for part 802 continues to read as follows:

**Authority:** 50 U.S.C. 4565; E.O. 11858, as amended, 73 FR 4677.

#### **Subpart B—Definitions**

##### **§ 802.232 [Amended]**

■ 4. Amend § 802.232 in paragraph (a) by removing "and investments" after "where the fund's activities".

Dated: July 10, 2020.

**Thomas Feddo,**

*Assistant Secretary for Investment Security.*

[FR Doc. 2020-15336 Filed 7-27-20; 8:45 am]

**BILLING CODE 4810-25-P**

### **LIBRARY OF CONGRESS**

#### **36 CFR Part 701**

[Docket No. 2020-2]

#### **Amendments Regarding International Service**

**AGENCY:** Library of Congress.

**ACTION:** Final rule.

**SUMMARY:** The Library of Congress is adopting amendments to allow for international service for loans of library materials for blind and other print disabled persons, as authorized by Title XIV of the Library of Congress Technical Corrections Act of 2019.

**DATES:** Effective July 28, 2020.

#### **FOR FURTHER INFORMATION CONTACT:**

Emily Vartanian, Senior Counsel, Library of Congress Office of the General Counsel, 202-707-7205, [evart@loc.gov](mailto:evart@loc.gov).

**SUPPLEMENTARY INFORMATION:** The Librarian of Congress is authorized to make regulations with respect to the Library of Congress (2 U.S.C. 136). Since