§ 558.500 [Amended]

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

Lauren K. Roth, Associate Commissioner for Policy.

§ 558.500 Withdrawal of approval of application at the sponsor’s request.

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 Dossai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, sujaya.dossai@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(21 CFR 514.116), notice is given that approval of ANADA 200–323, and all supplements and amendments thereto, is hereby withdrawn, effective July 28, 2020.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.

Lauren K. Roth, Associate Commissioner for Policy.

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. The preamble 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

Poloxalene in grams/ton

<table>
<thead>
<tr>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) To deliver 1 to 2 grams per 100 pounds of body weight.</td>
<td>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 bloat producing 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.</td>
<td>054771</td>
</tr>
<tr>
<td>(2) [Reserved]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To deliver 1 to 2 grams per 100 pounds of body weight.