Myanmar Economic Corporation, a.k.a., the following one alias:—MEC. 
Corner of Ahlone Road and Strand Road, Ahlone Township, Yangon, Myanmar.

Myanmar Economic Holdings Limited, a.k.a., the following eight aliases:—MEHL;—Myanmar Economic Holdings Limited;—Myanmar Economic Holdings Public Company Limited;—Myanmar Business Holdings Public Company Limited;—Myanmar Economic Holdings Public Company Limited;—UMEH;—Union of Myanmar Economic Holdings Company Limited; and —Union of Myanmar Economic Holdings Limited.
189–191 Maha Bandoola Road, Botataung Township, Yangon, Burma.

For all items subject to the EAR. (See § 744.11 of the EAR).

Myanmar Economic Holdings Limited, a.k.a., the following eight aliases:
189–191 Maha Bandoola Road, Botataung Township, Yangon, Burma.

For all items subject to the EAR. (See § 744.11 of the EAR).

Matthew S. Borman, 
Deputy Assistant Secretary for Export Administration.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 524, 526, 529, 556, and 558
[Docket No. FDA–2020–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor
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 April, May, and June 2020. 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 and readability of the regulations.
DATES: This rule is effective March 8, 2021.
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. Approval Actions
FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April, May, and June 2020, as listed in table 1.

<table>
<thead>
<tr>
<th>Approval date</th>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>Species</th>
<th>Effect of the action</th>
<th>Public documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 10, 2020</td>
<td>141–533</td>
<td>Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.</td>
<td>ASERVO EQUIHALER (ciclesonide inhalation spray)</td>
<td>Horses ..........</td>
<td>Original approval for the management of clinical signs associated with severe equine asthma in horses.</td>
<td>FOI Summary.</td>
</tr>
</tbody>
</table>
II. Changes of Sponsor

Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–084 for SENTINEL (lufenuron and milbemycin oxime) Flavor Tabs, NADA 141–204 for the SENTINEL Flavor Tabs and CAPSTAR (nitenpyram) Flea Management System, and NADA 141–333 for SENTINEL SPECTRUM (lufenuron, milbemycin oxime, and praziquantel) Chews to Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940. Also, Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215 has informed FDA that it has transferred ownership of, and all rights and interest in, A 200–348 for ECOMECTIN (ivermectin) Cattle Pour-On to Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria. The animal drug regulations will be amended to reflect these changes of sponsor.

III. Technical Amendments

FDA is making the following amendments to improve the accuracy and readability of the animal drug regulations:

- The entries in 21 CFR 510.600(c), 520.304, and 520.812 for Dechra Veterinary Products LLC are being amended to reflect the firm’s current drug labeler code.
- The entries in 21 CFR 510.600(c) for Cronus Pharma Specialties India Private Ltd. are being amended to reflect the firm’s current address.
- Conditions for use in 21 CFR 520.100 for use of amprolium crumbles in calves are being removed because no approved NADA exists for this dosage form product.
- The regulations in part 526 (21 CFR part 526) for intramammary dosage form drugs are being amended to reflect a current format and improve readability.
- The section in part 529 (21 CFR part 529) for sevoflurane anesthetic gas is being redesignated to reflect a current organizational scheme for dosage form new animal drugs.
- Cross references in part 556 (21 CFR part 556) to related approved uses of new animal drugs are being amended as conforming changes to improve the accuracy of the regulations.
- The table in 21 CFR 558.4 is being amended to reflect the correct format for displaying assay limits for component drugs in fixed-ratio, combination drug Type A medicated articles and Type B and Type C medicated feeds for beef steers and heifers fed in confinement for slaughter.
- Three tabular entries in 21 CFR 558.68 are being amended to reflect the approved conditions of use of certain feed use combinations, which had been removed in error.

### Table 1—Original and Supplemental NADAs and ANADAs Approved During April, May, and June 2020—Continued

<table>
<thead>
<tr>
<th>Approval date</th>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>Species</th>
<th>Effect of the action</th>
<th>Public documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 28, 2020</td>
<td>200–510</td>
<td>Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.</td>
<td>Chlortetracycline Type B and Type C medicated feeds.</td>
<td>Cattle</td>
<td>Supplemental approval for use of DERACIN (chlortetracycline) Type A medicated articles in the manufacture of Type B and Type C medicated feeds for control of bacterial pneumonia in beef cattle and replacement dairy heifers.</td>
<td>N/A.</td>
</tr>
<tr>
<td>June 2, 2020</td>
<td>200–682</td>
<td>Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.</td>
<td>VETMULIN 12.5% (tiamulin hydrogen fumarate) Liquid concentrate.</td>
<td>Swine</td>
<td>Original approval as a generic copy of NADA 140–916.</td>
<td>FOI Summary.</td>
</tr>
<tr>
<td>June 18, 2020</td>
<td>141–535</td>
<td>Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.</td>
<td>Chlortetracycline, sulfamethazine, and lasalocid Type B and Type C medicated feeds.</td>
<td>Cattle</td>
<td>Original approval for use of AUREO S 700 (chlortetracycline and sulfamethazine) and BOVATEC (lasalocid) in the manufacture of Type B and Type C medicated feeds for beef steers and heifers fed in confinement for slaughter.</td>
<td>FOI Summary.</td>
</tr>
</tbody>
</table>
IV. Legal Authority

This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities. This rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires Federal Register publication of the conditions of use of an approved or conditionally approved new animal drug and the name and address of the drug’s sponsor in a “notice, which upon publication shall be effective as a regulation.” A notice published pursuant to section 512(i) is not subject to the notice-and-comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 551 et seq. See section 512(ii) of the FD&C Act (21 U.S.C. 360b(ii)); 21 CFR 10.40(e)(3); S. Rep. 90–1308, at 5 (1968).

The document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as “an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.”

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, 526, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 516, 520, 522, 524, 526, 529, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for part 510 continues to read as follows:


2. In §510.600—

a. In the table in paragraph (c)(1):

b. In the table in paragraph (c)(2):

i. Add an entry in numerical order for “017033”;

ii. Remove the entry for “026637”;

iii. Revise the entries for “069043” and “069254”; and

iv. Add an entry in numerical order for “086101”.

The additions and revisions read as follows:

§510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

<table>
<thead>
<tr>
<th>Drug labeler code</th>
<th>Firm name and address</th>
</tr>
</thead>
<tbody>
<tr>
<td>069043</td>
<td>Cronus Pharma Specialities India Private Ltd., Sy No-99/1, GMR Hyderabad Aviation SEZ Ltd., Mambidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad Telangana 501218, India</td>
</tr>
<tr>
<td>017033</td>
<td>Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211</td>
</tr>
<tr>
<td>086101</td>
<td>Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland</td>
</tr>
<tr>
<td>069254</td>
<td>Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405</td>
</tr>
</tbody>
</table>

(2) * * *
PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

3. The authority citation for part 516 continues to read as follows:


4. Add § 516.812 to subpart E to read as follows:

§ 516.812 Enrofloxacin.

(a) Specifications. Each milliliter (mL) of solution contains 100 milligrams (mg) enrofloxacin.

(b) Sponsor. See No. 000859 in § 510.600(c) of this chapter.

(c) Conditions of use in cattle—(1) Amount. Administer, by subcutaneous injection, a single dose of 12.5 mg/kilogram of body weight (5.7 mL/100 pounds of body weight). Administered dose volume should not exceed 20 mL per injection site.

(2) Indications for use. For the treatment of clinical anaplasmosis associated with Anaplasma marginale in replacement dairy heifers under 20 months of age and all classes of beef cattle except beef calves less than 2 months of age and beef bulls intended for breeding (any age). Not for use in 20 months of age or older including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in drinking water as follows:

* * * * *

(d) Calves. Administer concentrate solution or soluble powder as a drench or in drinking water as follows:

* * * * *

7. In § 520.304, revise paragraph (b), remove reserved paragraph (c), and redesignate paragraph (d) as paragraph (c).

The revision reads as follows:

§ 520.304 Carprofen.

(a) Specifications—(1) Each tablet contains:

(ii) 22.7, 68.0, or 136.0 milligrams (mg) enrofloxacin; or

(iii) 22.7, 68.0, or 136.0 mg enrofloxacin.

(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 008659 for use of products described in paragraph (a)(1)(i), (a)(2), and (a)(3) of this section.

(2) No. 017033 for use of product described in paragraph (a)(1)(ii) of this section.

(3) No. 058198 for use of product described in paragraph (a)(1)(iii) of this section.

(4) No. 086101 for use of product described in paragraph (a)(2) of this section.

* * * * *

§ 520.1443 [Amended]

9. In § 520.1443, in paragraph (b), remove “051311” and in its place add “000061”.

§ 520.1447 [Amended]

10. In § 520.1447, in paragraph (b), remove “051311” and in its place add “000061”.

§ 520.1510 [Amended]

11. In § 520.1510, in paragraph (b)(2), remove “051311” and in its place add “000061”.

§ 520.2455 [Amended]

12. In § 520.2455, in paragraph (b)(4), remove “No. 061133” and in its place add “Nos. 016592 and 061133”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

13. The authority citation for part 522 continues to read as follows:


§ 522.536 [Amended]

14. In § 522.536, in paragraph (b), remove “No. 052483” and in its place add “Nos. 015914 and 052483”.

15. In § 522.1077:

a. Revise paragraphs (a)(3), (b), (d), and (e)(1)(i);  

b. Remove paragraph (e)(1)(ii); 

c. Redesignate paragraphs (e)(1)(iii) through (e)(1)(vii) as paragraphs (e)(1)(vi) through (e)(1)(xvii); and

d. Revise newly redesignated paragraphs (e)(1)(ii) and (iii).
§ 522.1077 Gonadorelin.
(a) * * *
(3) 50 µg of gonadorelin as gonadorelin diacetate tetrahydrate (equivalent to 43 µg of gonadorelin); or * * * * * * * * (b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter.
(1) No. 000063 for use of the 43-µg/mL product described in paragraph (a)(1) as in paragraphs (e)(1)(i) and (iii) of this section.
(2) No. 068504 for use of the 100-µg/mL product described in paragraph (a)(2) as in paragraph (e)(1)(iv) of this section.
(3) No. 061133 for use of the 50-µg/mL product described in paragraph (a)(3) as in paragraphs (e)(1)(i) of this section.
(4) No. 000010 for use of the 43-µg/mL product described in paragraph (a)(3) as in paragraphs (e)(1)(i) and (v) of this section.
(5) No. 054771 for use of the 50-µg/mL product described in paragraph (a)(4) as in paragraphs (e)(1)(ii) and (vii) of this section.
* * * * * *
(d) Special considerations—(1) Concurrent luteolytic drug use is approved as follows:
(i) Cloprostenol injection for use as in paragraph (e)(1)(iii) of this section as provided by No. 000061 in § 510.600(c) of this chapter.
(ii) Cloprostenol injection for use as in paragraph (e)(1)(iv) of this section as provided by No. 068504 in § 510.600(c) of this chapter.
(iii) Cloprostenol injection for use as in paragraph (e)(1)(v) of this section as provided by Nos. 000010 in § 510.600(c) of this chapter.
(iv) Dinoprost injection for use as in paragraphs (e)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.
(2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
[e] * * *
(1) Indications for use and amounts—
(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin (No. 000061) or 100 µg gonadorelin diacetate tetrahydrate (Nos. 000010 and 061133) by intramuscular or intravenous injection.
(ii) For the treatment of ovarian follicular cysts in cattle: Administer 100 µg gonadorelin hydrochloride by intramuscular injection.
(iii) For use with cloprostenol sodium to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in beef cows and lactating dairy cows: Administer to each cow 86 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 86 µg gonadorelin by intramuscular injection. * * * * * * * * * * *
§ 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS
PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS
(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter.
(1) Nos. 000061 in § 510.600(c) of this chapter.
(2) Nos. 000859 and 017030 for use of the 50-µg/mL product described in paragraph (a)(2) as in paragraph (e)(1)(iv) of this section.
(3) No. 061133 for use of the 50-µg/mL product described in paragraph (a)(3) as in paragraphs (e)(1)(i) of this section.
(4) No. 000010 for use of the 43-µg/mL product described in paragraph (a)(3) as in paragraphs (e)(1)(i) and (v) of this section.
(5) No. 054771 for use of the 50-µg/mL product described in paragraph (a)(4) as in paragraphs (e)(1)(ii) and (vii) of this section.
* * * * * *
(d) Special considerations—(1) Concurrent luteolytic drug use is approved as follows:
(i) Cloprostenol injection for use as in paragraph (e)(1)(iii) of this section as provided by No. 000061 in § 510.600(c) of this chapter.
(ii) Cloprostenol injection for use as in paragraph (e)(1)(iv) of this section as provided by No. 068504 in § 510.600(c) of this chapter.
(iii) Cloprostenol injection for use as in paragraph (e)(1)(v) of this section as provided by Nos. 000010 in § 510.600(c) of this chapter.
(iv) Dinoprost injection for use as in paragraphs (e)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.
(2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
[e] * * *
(1) Indications for use and amounts—
(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin (No. 000061) or 100 µg gonadorelin diacetate tetrahydrate (Nos. 000010 and 061133) by intramuscular or intravenous injection.
(ii) For the treatment of ovarian follicular cysts in cattle: Administer 100 µg gonadorelin hydrochloride by intramuscular injection.
(iii) For use with cloprostenol sodium to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in beef cows and lactating dairy cows: Administer to each cow 86 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 86 µg gonadorelin by intramuscular injection. * * * * * * * * * * *
§ 524.1146 Imidacloprid and moxidectin.
(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter.
(1) No. 000859 and 017030 for use of the 50-µg/mL product described in paragraph (a)(2) as in paragraph (e)(1)(iv) of this section.
(2) Nos. 000859 and 017030 for use of the product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.
(3) No. 000859 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(3) of this section.
* * * * * *
§ 524.1193 [Amended]
18. In § 524.1193, in paragraph (b)(2), remove “016592, 054925, and 058005” and in its place add “016592 and 054925”.
19. Add § 524.2080 to read as follows:
§ 524.2080 Ropinorphine.
(b) Sponsor. See No. 052483 in § 510.600(c) of this chapter.
(c) Conditions of use—(1) Amount. Using the table provided in labeling, administer the number of eye drops topically, corresponding to body weight, that results in a target dose of 3.75 mg per square meter (mg/m2) (dose band 2.7 to 5.4 mg/m2). If the dog does not vomit within 20 minutes of the first dose, then a second dose may be administered.
(2) Indications for use. For the induction of vomiting in dogs.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
§ 524.2098 [Amended]
20. In § 524.2098, in paragraph (b), remove “Nos. 054771, 055529, and 061651” and in its place add “Nos. 051072, 054771, 055529, and 061651”.
PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS
§ 526.88 Amoxicillin.
(a) Specifications. Each single-dose, 10-milliliter syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams (mg) amoxicillin.
* * * * * *
(d) Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows—(1) Amount. Infuse the contents of one syringe (equivalent to 62.5 mg amoxicillin) into each infected quarter every 12 hours for a maximum of 3 doses.
* * * * * *
(3) Limitations. Milk taken from animals during treatment and for 60 hours (5 milkings) after the last treatment must not be used for food. Treated animals must not be slaughtered for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
22. In § 526.88, revise the section heading, paragraph (a), the paragraph (d) subject heading, and paragraphs (d)(1) and (d)(3) to read as follows:
§ 526.88 Amoxicillin.
(a) Specifications. Each single-dose, 10-milliliter syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams (mg) amoxicillin.
* * * * * *
(d) Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows—(1) Amount. Infuse the contents of one syringe (equivalent to 62.5 mg amoxicillin) into each affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.
(2) Indications for use. For the treatment of clinical mastitis associated with coagulase-negative staphylococci, Streptococcus dysgalactiae, and Escherichia coli; and the treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and S. dysgalactiae.
(3) Limitations. Milk taken from cows during treatment (a maximum of 8 daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Follow the infusing label use for up to 8 consecutive days, a 2-day preslaughter withdrawal period is
required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Special considerations. Federal law prohibits extralabel use of this drug in lactating dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows—(1) Amount. Infuse the contents of one syringe (300 mg ceftriaxone equivalents) into each affected quarter at the time of dry off.

(2) Indications for use. For the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with *Staphylococcus aureus*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) Limitations. Milk taken from cows completing a 30-day dry-off period may be used for food with no milk discard due to ceftriaxone residues. Following intramammary infusion, a 16-day preslaughter withdrawal period is required for treated cows. No preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Special considerations. Federal law prohibits extralabel use of this drug in dry dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

24. In §526.363, revise paragraphs (a) and (d) to read as follows:

§526.365 Cepahpirin benzathine.

(a) Specifications. Each single-dose, 10-milliliter syringe contains 200 milligrams (mg) cepahpirin sodium activity.

* * * * *

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.165 of this chapter.

(d) Conditions of use in dry cows—(1) Amount. Infuse the contents of one syringe (200 mg cepahpirin activity) into each quarter infected immediately after the quarter has been completely milked out. Do not milk out for 12 hours. Repeat once only in 12 hours.

* * * * *

26. Revise §526.464 to read as follows:

§526.464 Cloxacillin benzathine.

(a) Specifications. Each single-dose, 7.5- or 10-milliliter syringe contains cloxacillin benzathine equivalent to 500 milligrams (mg) cloxacillin.

(b) Sponsor. See No. 000010 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.165 of this chapter.

(d) Conditions of use in dry cows—(1) Amount. Infuse the contents of one syringe (equivalent to 500 mg cloxacillin) into each quarter immediately after last milking, but no later than 30 days before calving.

(2) Indications for use. For the treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* including penicillin resistant strains in dairy cows during the dry period.

(3) Limitations. Animals infused with this product must not be slaughtered for food within 10 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

27. Remove §526.464a.

§525.464b [Redesignated as §526.464]

28. Redesignate §526.464b as §526.465 and revise the section heading and paragraphs (a) and (d) to read as follows:

§526.465 Cloxacillin sodium.

(a) Specifications. Each single-dose, 10-milliliter syringe contains cloxacillin sodium equivalent to 200 milligrams (mg) cloxacillin.

* * * * *

(d) Conditions of use in lactating cows—(1) Amount. Infuse the contents of one syringe (equivalent to 200 mg cloxacillin) into each infected quarter. Treatment should be repeated at 12-hour intervals for a total of 3 doses.

(2) Indications for use. For the treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*, nonpenicillinase-producing strains.

(3) Limitations. Milk taken from treated animals within 48 hours (4 milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

29. Revise §526.820 to read as follows:

§526.820 Erythromycin.

(a) Specifications—(1) Each single-dose, 6-milliliter (mL) syringe contains 300 milligrams (mg) erythromycin (as the base).

(2) Each single-dose, 12-mL syringe contains 600 mg erythromycin (as the base).

(b) Sponsors. See Nos. 054771 and 061133 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.230 of this chapter.

(d) Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows—(1) Amount. Infuse the contents of one 6-mL syringe (300 mg erythromycin base) into each infected quarter. Repeat infusion at 12-hour intervals for a maximum of 3 infusions.

(2) Indications for use. For the treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in lactating cows.

(3) Limitations. Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food.

(e) Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows—(1) Amount. Infuse the contents of one 12-mL syringe (600 mg erythromycin base) into each infected quarter at the time of drying off.

(2) Indications for use. For the treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in dry cows.

(3) Limitations. For use in dry cows only.

30. In §526.1130, revise paragraph (a), the paragraph (d) subject heading, and paragraphs (d)(1) and (2) to read as follows:
§ 526.1130 Hetacillin.

(a) Specifications. Each single-dose, 10-milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams (mg) ampicillin.

(d) Conditions of use in lactating cows—(1) Amount. Infuse the contents of one syringe (equivalent to 62.5 mg ampicillin) into each infected quarter. Repeat at 24-hour intervals for a maximum of 3 treatments.

(2) Indications for use. For the treatment of acute, chronic, or subclinical mastitis in lactating cows caused by susceptible strains of Staphylococcus agalactiae, Streptococcus dysgalactiae, Staphylococcus aureus, and Escherichia coli.

§ 526.1590 Novobiocin.

(a) Specifications. Each single-dose, 10-milliliter syringe contains novobiocin equivalent to 100,000 units of penicillin G.

(b) Sponsor. See Nos. 010515 and 061133 in § 510.610(c) of this chapter.

(c) Related tolerances. See § 556.510 of this chapter.

(d) Conditions of use in lactating cows—(1) Amount. Infuse the contents of one 10-milliliter syringe (equivalent to 100,000 units penicillin G) into each infected quarter. Treatment may be repeated at 12-hour intervals for not more than 3 doses, as indicated by clinical response.

(2) Indications for use. For the treatment of mastitis caused by Streptococcus agalactiae, S. dysgalactiae, and S. uberis in lactating cows.

(3) Limitations. For intramammary infusion in lactating cows only. Discard all milk for 60 hours (5 milkings) after the latest treatment. Animals intended for human consumption must not be slaughtered within 3 days of latest treatment.

§ 526.1696 Penicillin G procaine.

(a) Specifications. Each single-dose, 10-milliliter syringe contains penicillin G procaine equivalent to 100,000 units of penicillin G.

(b) Sponsor. See § 510.610(c) of this chapter.

(c) Related tolerances. See § 556.510 of this chapter.

(d) Conditions of use in lactating cows—(1) Amount. Infuse the contents of one 10-milliliter syringe (equivalent to 100,000 units penicillin G) into each infected quarter. Treatment may be repeated at 12-hour intervals for not more than 3 doses, as indicated by clinical response.

(2) Indications for use. For the treatment of mastitis caused by Streptococcus agalactiae in dry cows.

(3) Limitations. For udder installation for the treatment of mastitis in dry cows only. Infuse each quarter at the time of drying off, but not less than 30 days prior to calving. Do not slaughter treated animals for food for 30 days following udder infusion.

§ 526.1696d Penicillin G procaine and dihydrostreptomycin.

(a) Specifications. Each single-use, 10-milliliter syringe contains a suspension of:

- Penicillin G procaine equivalent to 200,000 units penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams dihydrostreptomycin; or
- Penicillin G procaine equivalent to 1 million units penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram dihydrostreptomycin.

(d) Conditions of use for syringe described in paragraph (a)(1) of this section in dry cows—(1) Amount. Infuse the contents of one syringe (equivalent to 200,000 units penicillin G and 300 milligrams dihydrostreptomycin) into each quarter at the last milking prior to drying off.

(2) Indications for use. For the treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by Staphylococcus aureus and Streptococcus agalactiae.

(3) Limitations. For use in dry cows only. Not to be used within 6 weeks of calving. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment or within 24 hours after calving.

(e) Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows—(1) Amount. Infuse the contents of one syringe (equivalent to 1 million units penicillin G and 1 gram dihydrostreptomycin) into each quarter at the last milking prior to drying off.

(2) Indications for use. To reduce the frequency of existing infection and to prevent new infections with Staphylococcus aureus in dry cows.

(3) Limitations. Not for use in lactating cows. Not to be used within 6 weeks of calving. Milk taken from cows within 96 hours (8 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion or within 96 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 526.1696c [Removed]

§ 526.1696d [Redesignated as § 526.1697]

34. Redesignate § 526.1696d as § 526.1697 and revise the section heading and paragraphs (a) and (d) and add paragraph (e).

The revisions and addition read as follows:

§ 526.1697 Penicillin G procaine and dihydrostreptomycin.

(a) Specifications. Each single-use, 10-milliliter syringe contains a suspension of:
§ 526.1698 Penicillin G procaine and novobiocin.

(a) Specifications. Each single-use, 10-milliliter syringe contains a suspension of:

(1) Penicillin G procaine equivalent to 100,000 units penicillin G and 150 milligrams (mg) novobiocin as novobiocin sodium; or

(2) Penicillin G procaine equivalent to 200,000 units penicillin G and 400 mg novobiocin as novobiocin sodium.

* * * * *

(d) Conditions of use in lactating cows—(1) Amount. Infuse the contents of one syringe (50 mg pirlimycin) into each infected quarter. * * *

* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

§ 529.443 Ciclesonide.

(a) Specifications. A non-pressurized metered dose inhaler and drug cartridge combination containing a solution of 30 milligrams/milliliter of the prodrug ciclesonide. Each actuation releases 343 micrograms (mcg) of ciclesonide.

(b) Sponsor. See No. 000010 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. Administer an initial dose of 8 actuations (2,744 mcg ciclesonide) twice daily for 5 days, followed by 12 actuations (4,116 mcg ciclesonide) once daily for 5 days.

(2) Indications for use. For the management of clinical signs associated with severe equine asthma.

(3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 529.2150 [Redesignated as § 529.2110]

40. Redesignate § 529.2150 as § 529.2110.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

§ 556.170 [Amended]

44. In § 556.170, in paragraph (c), remove “520.543” and in its place add “520.534”.

§ 556.180 [Amended]

45. In § 556.180, in paragraph (c), remove “558.205” and in its place add “558.198”.

§ 556.185 [Amended]

46. In § 556.185, in paragraph (c), remove “558.198” and in its place add “558.205”.

§ 556.226 [Amended]

47. In § 556.226, in paragraph (c), remove “522.812” and in its place add §§ 516.812 and 522.812.

§ 556.300 [Amended]

48. In § 556.300, in paragraph (c), remove §§ 522.1044a, 520.1044b, 520.1044c, and 520.1044d and in its place add §§ 520.1044a, 520.1044b, 522.1044, 524.1044e, and 529.1044b.

§ 556.360 [Amended]

49. In § 556.360, in paragraph (c), add “520.1265,” after “520.1260.”

§ 556.510 [Amended]

50. In § 556.510, in paragraph (c), remove “526.1699a, 526.1699b, 526.1699c, and 526.1699d” and in its place add “526.1699, 526.1697, and 526.1698.”

§ 556.670 [Amended]

51. In § 556.670, in paragraph (c), remove §§ 520.2218 and add §§ 520.445, 520.2218” in its place.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

52. The authority citation for part 558 continues to read as follows:


53. In § 558.68, revise paragraphs (e)(1)(ii), (iii), and (v) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(e) * * *

(1) * * *
§ 558.28 Chlortetracycline.

In § 558.128, revise paragraphs (e)(4)(xv) and (xvi) to read as follows:

<table>
<thead>
<tr>
<th>Chlortetracycline amount</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(xvi) 350 mg/head/day</td>
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<td></td>
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<td></td>
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<td>069254</td>
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<tr>
<td></td>
<td></td>
<td>2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by A. marginale susceptible to chlortetracycline.</td>
<td>Withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADAs 046–699 and 049–287, No. 066104 under NADA 092–286, and No. 069254 under NADA 048–480: withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADA 048–761 and No. 069254 under NADA 138–935 and ANADA 200–510: zero withdrawal period.</td>
<td>054771</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>069254</td>
</tr>
<tr>
<td>(xvi) 20 to 350 g/ton</td>
<td></td>
<td>Beef cattle and replacement dairy heifers: For control of bacterial pneumonia associated with shipping fever complex caused by Pasteurella spp. susceptible to chlortetracycline.</td>
<td>Feed to provide chlortetracycline at the rate of 350 mg per head per day. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal period.</td>
<td>054771</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>069254</td>
</tr>
<tr>
<td>Chlortetracycline and sulfamethazine amount each combination in grams/ton</td>
<td>Indications for use</td>
<td>Limitations</td>
<td>Sponsors</td>
<td></td>
</tr>
<tr>
<td>---</td>
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<td></td>
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<tr>
<td>(i) To provide 350 milligrams per head per day.</td>
<td>Beef cattle: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever, and for improved feed efficiency.</td>
<td>Feed for 28 days. Withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.</td>
<td>054771 069254</td>
<td></td>
</tr>
<tr>
<td>(ii) 35 to 105 g/ton, each. Lasalocid, 10 to 30.</td>
<td>Beef steers and heifers fed in confinement for slaughter: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever, and for improved feed efficiency.</td>
<td>Feed continuously for 28 days to provide 350 mg chlortetracycline, 350 mg sulfamethazine, and 300 to 300 mg lasalocid per head per day. Do not allow horses or other equines access to Type C feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established. Withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.</td>
<td>054771</td>
<td></td>
</tr>
<tr>
<td>(iii) 35 to 42.2 g/ton, each. Lasalocid, 25 to 30.</td>
<td>Beef steers and heifers fed in confinement for slaughter: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever, and for increased rate of weight gain.</td>
<td>Feed continuously for 28 days to provide 350 mg chlortetracycline, 350 mg sulfamethazine, and 250 to 300 mg lasalocid per head per day. Do not allow horses or other equines access to Type C feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established. Withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.</td>
<td>054771</td>
<td></td>
</tr>
<tr>
<td>(iv) 35 to 700 g/ton, each. Lasalocid, 30 to 181.8.</td>
<td>Beef cattle up to 800 lb: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever, and for control of coccidiosis caused by <em>Eimeria bovis</em> and <em>E. zuernii</em>.</td>
<td>Hand feed continuously for 28 days to provide 350 mg chlortetracycline, 350 mg sulfamethazine, and 1 mg lasalocid per 2.2 lb body weight per day up to a maximum of 350 mg lasalocid per head per day. Do not allow horses or other equines access to Type C feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established. Withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.</td>
<td>054771</td>
<td></td>
</tr>
</tbody>
</table>

**§ 558.311 Lasalocid.**

<table>
<thead>
<tr>
<th>Melengestrol acetate in mg/head/day</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 0.25 to 0.5</td>
<td>Halters fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat). Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day.</td>
<td>* * * *</td>
<td>016592 054771 058198</td>
<td></td>
</tr>
</tbody>
</table>

**§ 558.342 Melengestrol.**

<table>
<thead>
<tr>
<th>Melengestrol acetate in mg/head/day</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) 0.25 to 24.6</td>
<td>Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed</td>
<td>Feed continuously as sole ration during the last 28 to 42 days on feed.</td>
<td>016592 054771 058198</td>
<td></td>
</tr>
</tbody>
</table>
DEPARTMENT OF THE TREASURY
Internal Revenue Service
26 CFR Part 1
[TD 9926]
RIN 1545–BO60
Title: Withholding of Tax and Information Reporting With Respect to Interests in Partnerships Engaged in a U.S. Trade or Business; Correcting Amendment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (Treasury Decision 9926) that were published in the Federal Register on Monday, November 30, 2020. The final regulations provide guidance related to the withholding of tax and information reporting with respect to certain dispositions of interests in partnerships engaged in a trade or business within the United States.

DATES: This correction is effective on March 8, 2021 and applies to partnership taxable years beginning on or after November 30, 2020. See § 1.1446–7.

FOR FURTHER INFORMATION CONTACT: Chadwick Rowland or Ronald M. Gootzeit (202) 317–6937 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9926) that are the subject of this correction are issued under section 1446 of the Code.

Need for Correction

As published, November 30, 2020 (85 FR 70910), the final regulations (TD 9926) contain an error that needs to be corrected.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following corrective amendments:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Amend § 1.1446–4, by revising the last seven sentences of paragraph (f)(1).”

§ 1.1446–4 Publicly traded partnerships. * * * * *(f) * * * (1) * * * * LTP makes a distribution subject to section 1446 of $100 to UTP during its taxable year beginning January 1, 2020, and withholds 37 percent (the highest rate in section 1) (37) of that distribution under section 1446. UTP receives a net distribution of $63 which it immediately redistributes to its partners. UTP has a liability to pay 37 percent of the total actual and deemed distribution it makes to its foreign partners as a section 1446 withholding tax. UTP may credit the $37 withheld by LTP against this liability as if it were paid by UTP. See §§ 1.1446–1(b) and 1.1446–5(b)(1). When UTP distributes the $63 it actually receives from LTP to its partners, UTP is treated for purposes of section 1446 as if it made a distribution of $100 to its partners ($63 actual distribution and $37 deemed distribution). UTP’s partners (U.S. and foreign) may claim a credit against their U.S. income tax liability for their allocable share of the $37 of 1446 tax paid on their behalf.

Crystal Pemberton, Senior Federal Register Liaison, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by Georgia, through the Georgia Environmental Protection Division (GA EPD), on September 16, 2019, for the purpose of removing certain transportation control measures (TCMs) from the SIP for the thirteen counties in the Atlanta, Georgia, area.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

Air Plan Approval; GA: Non-Interference Demonstration and Maintenance Plan Revision for the Removal of Transportation Control Measures in the Atlanta Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by Georgia, through the Georgia Environmental Protection Division (GA EPD), on September 16, 2019, for the purpose of removing certain transportation control measures (TCMs) from the SIP for the thirteen counties in the Atlanta, Georgia, area.

EPA is also approving Georgia’s update to the 2008 6-hour ozone maintenance plan that was submitted in the September 16, 2019, SIP revision. Specifically, EPA is approving the updated mobile emissions inventory,