4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA-2025-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 Address; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment; correcting amendment.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the final rule that published in the *Federal Register* of April 16, 2026. That final rule updated regulations to reflect application-related actions for new animal drug applications and abbreviated new animal drug applications during October, November, and December of 2025. The final rule published with some inadvertent errors in the instructions for technical amendments. This document corrects those errors.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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SUPPLEMENTARY INFORMATION: In the *Federal Register* of April 16, 2026 (91 FR 20337), FDA published the final rule "New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Address" with errors. On page 20340, amendatory language in instruction 9 for § 520.1263b Lincomycin hydrochloride soluble powder, did not properly provide instructions to revise paragraphs (d)(1), (d)(2) heading, (d)(2)(i), (d)(2)(iii), and (d)(3). On page 20343,

amendatory language in instruction 30 for § 558.305 Laidlomycin propionate potassium, did not properly provide instructions to revise paragraphs (d)(1) introductory text, (d)(2), (d)(3) introductory text, and (e) introductory text including table headings. On page 20346, amendatory language in instruction 33 for § 558.500 Ractopamine, did not include instructions to revise paragraph (d)(2) introductory text. This document corrects these errors.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Accordingly, 21 CFR parts 520 and 558 are corrected by making the following correcting amendments:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. In § 520.1263b, revise paragraphs (d)(1), (d)(2) heading, (d)(2)(i) and (iii), and (d)(3)(i) and (ii) to read as follows:

§ 520.1263b Lincomycin hydrochloride soluble powder.

* * * * *

(d) * * *

(1) *Swine*—(i) *Amount*. Administer at a dose rate of 250 milligrams (mg) of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day. The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin Type A medicated article at 100 grams

lincomycin per ton of complete feed as the sole ration according to label directions. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lb of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioner to deliver 1 ounce of stock solution per gallon of drinking water. After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin Type A medicated article at 40 grams lincomycin per ton of complete feed as the sole ration.

(ii) *Indications for use*. For the treatment of swine dysentery (bloody scours) in swine. Not for use in pregnant swine or swine intended for breeding.

(iii) *Limitations*. Discard medicated drinking water if not used within 2 days. Fresh stock should be prepared daily. Do not use the water treatment and the feed treatment simultaneously. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. If clinical signs of bloody scours (watery, mucoid, or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. On rare occasions, some pigs may show reddening of the skin, swelling of the anus, and irritable behavior. These conditions have been self-correcting within five to seven days without discontinuing the lincomycin treatment. The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Broiler chickens*—(i) *Amount*. Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water. Start medication as soon as the diagnosis of necrotic enteritis is determined. The drug should be administered for 7 consecutive days. After water medication is

discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin Type A medicated article at 2 grams lincomycin per ton of complete feed.

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(iii) *Limitations*. Not for use in laying hens or breeder chickens. Discard medicated drinking water if not used within 2 days. Fresh stock should be prepared daily. Do not use the water treatment and the feed treatment simultaneously. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) * * *

(i) *Amount*. Administer 100 mg lincomycin per hive once weekly for 3 weeks. Mix 250 mg LINCOMIX Soluble Powder (100 mg lincomycin) with 20 g confectioners'/powder sugar and dust over the top bars of the brood chamber.

(ii) *Indications for use*. For the control of American foulbrood (*Paenibacillus larvae*) in honey bees.

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PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

4. In § 558.305, revise paragraphs (d)(1) introductory text, (d)(2), (d)(3) introductory text, (e) introductory text, and the column headings for the table in paragraph (e) to read as follows:

§ 558.305 Laidlomycin propionate potassium.

* * * * *

(d) * * *

(1) Laidlomycin propionate potassium Type B liquid medicated feeds may be manufactured from dry laidlomycin propionate potassium Type A medicated articles. The Type

B liquid medicated feeds must have a pH of 6.0 to 8.0, dry matter of 62 to 75 percent, and bear appropriate mixing directions as follows:

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(2) The expiration date of the Type B liquid medicated feed is 21 days after date of manufacture. The expiration date for the dry Type C medicated feed made from the Type B liquid medicated feed is 7 days after date of manufacture.

(3) Labeling for all Type B medicated feeds (liquid and dry) and Type C medicated feeds containing laidlomycin propionate potassium shall bear the following statements:

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(e) *Conditions of use*. It is used in growing beef steers and heifers fed in confinement for slaughter as follows:

Laidlomycin propionate potassium in grams per ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
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5. In § 558.500, revise paragraph (d)(2) introductory text to read as follows:

§ 558.500 Ractopamine.

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(d) * * *

(2) Labeling of Type A medicated articles and Type B and Type C medicated feeds intended for swine shall bear the following:

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Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-11104 Filed: 6/2/2026 8:45 am; Publication Date: 6/3/2026]