DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs for Use in Animal Feeds; Bacitracin Methylenedisalicylate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmgate LLC for the use of a Type A medicated article containing bacitracin methylenedisalicylate to manufacture Type B and Type C medicated feeds for chickens, turkeys, pheasants, quail, and feedlot cattle. This supplemental approval reflects FDA's effectiveness conclusions that relied on the National Academy of Sciences/National Research Council Drug Efficacy Study Group's evaluation of the effectiveness of this drug as well indications for use not subject to this review.

DATES: This rule is effective December 22, 2015.

FOR FURTHER INFORMATION CONTACT: Matthew Lucia, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0589, email: *matthew.lucia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 8, 2003 (68 FR 47332), as corrected October 7, 2003 (68 FR 57911), as part of the Drug Efficacy Study Implementation (DESI) program, the Center for Veterinary Medicine (CVM) announced the effective conditions of use for several drug products and use combinations that were listed in 21 CFR 558.15. CVM proposed to withdraw the NADAs for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness.

In response to that notice of opportunity for a hearing (NOOH), Pennfield Oil Co. (Pennfield), 14040 Industrial Rd., Omaha, NE 68144, filed a hearing request for its approved, non-DESI finalized NADA 141–137 for a bacitracin methylenedisalicylate Type A medicated article.

In March 2015, Pennfield transferred sponsorship of NADA 141–137 to Pharmgate LLC, 1015 Ashes Dr., Suite 102, Wilmington, NC 28405 (Pharmgate) (80 FR 13226, March 13, 2015). Subsequently, Pharmgate filed a supplement to NADA 141–137 for PENNITRACIN MD 50G (bacitracin Type A medicated article) with labeling conforming to the findings of effectiveness in the 2003 NOOH. In addition, the submitted labeling included indications for use approved by FDA that were not subject to DESI findings of effectiveness (34 FR 7906, May 20, 1969).

The supplemental NADA provides for use of a Type A medicated article containing bacitracin methylenedisalicylate to manufacture Type B and Type C medicated feeds for several production and therapeutic indications in broiler and replacement chickens, growing turkeys, growing pheasants, growing quail, and beef steers and heifers fed in confinement for slaughter. The supplemental NADA is approved as of October 6, 2015, and the regulations are amended in 21 CFR 558.76 to reflect the approval. Pharmgate, as successor to Pennfield, has since withdrawn the hearing request for NADA 141–137.

Approval of this supplemental NADA did not require review of any new safety or effectiveness data. Therefore, a freedom of information summary was not prepared.

The DESI evaluation was concerned only with the effectiveness of the drug products and use combinations. Nothing in this document constitutes a bar to further proceedings with respect to questions of safety of the subject drugs in treated animals or of the drugs or their metabolites in food products derived from treated animals.

Products that comply with FDA's findings of effectiveness are eligible for copying, as described in the ''Generic Animal Drug and Patent Term Restoration Act; Eighth Policy Letter,'' August 21, 1991 (56 FR 41561). Accordingly, sponsors may now obtain approval of abbreviated NADAs for this Type A medicated article.

The Agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule 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.

List of Subjects in 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 and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

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

■ 2. Amend § 558.76 as follows:
■ a. Revise the section heading and paragraph (a);
■ b. Redesignate paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e);
■ c. Add new paragraph (b); and
■ d. Revise newly redesignated paragraph (e)(1).

The revisions and addition read as follows:

§ 558.76 Bacitracin methylenedisalicylate.

(a) *Specifications.* (1) Type A medicated articles containing 10, 25, 30, 40, 50, 60, or 75 grams bacitracin methylenedisalicylate per pound.

(2) Type A medicated article containing 50 grams bacitracin methylenedisalicylate per pound.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 054771 for use of products in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(iii), (e)(1)(v) through (xiii), and (e)(1)(xv) of this section.

(2) No. 069254 for use of products in paragraph (a)(2) of this section as in paragraphs (e)(1)(ii), (e)(1)(iv), (e)(1)(xiv), and (e)(1)(xvi) of this section.

* * * * *

(e) * * *

(1) It is used as follows:

Bacitracin methylenedisalicylate amount	Combination in grams per ton (g/ton)	Indications for use	Limitations	Sponsor
(i) 4 to 50 g/ton		Chickens, turkeys, and pheasants: For increased rate of weight gain and improved feed efficiency.		054771
(ii) 4 to 50 g/ton		Broiler and replacement chickens, growing turkeys, and growing pheasants: For increased rate of weight gain and improved feed efficiency.		069254
(iii) 5 to 20 g/ton		Quail not over 5 weeks of age: For increased rate of weight gain and improved feed efficiency.		054771
(iv) 5 to 20 g/ton		Growing quail: For increased rate of weight gain and improved feed efficiency.	For use in quail not over 5 weeks of age.	069254
(v) 10 to 25 g/ton		Chickens: For increased egg production and improved feed efficiency for egg production.	For first 7 months of production	054771
(vi) 10 to 30 g/ton		Swine: For increased rate of weight gain and improved feed efficiency.	For growing and finishing swine	054771
(vii) 10 to 30 g/ton	Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams (mg) per pound of body weight per day.	Swine: For increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed for not more than 14 days; bacitracin methylenedisalicylate provided by No. 054771; chlortetracycline provided by Nos. 054771 and 069254 in § 510.600(c) of this chapter.	054771 069254
(viii) 10 to 30 g/ton		Swine: For control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed for not more than 14 days; chlortetracycline and bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(ix) 50 g/ton		Broiler chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. Replacement chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration	054771
(x) 100 to 200 g/ton		Broiler chickens: As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. Replacement chickens: As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/ton).	054771
(xi) 200 g/ton		Turkeys: As an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylenedisalicylate. Quail: For the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylenedisalicylate.	Feed continuously as the sole ration	054771
(xii) 250 g/ton		1. Growing/finishing swine: For control of swine dysentery *Treponema hyodysenteriae* on premises with history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition.	As the sole ration. Not for use in swine weighing more than 250 pounds. Diagnosis should be confirmed by a veterinarian a when results are not satisfactory.	054771

Bacitracin methylenedisalicylate amount	Combination in grams per ton (g/ton)	Indications for use	Limitations	Sponsor
		2. Pregnant sows: For control of clostridial enteritis caused by *C. perfringens* in suckling piglets.	As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by veterinarian when results are not satisfactory.	
(xiii) To provide 70 mg per head per day.	.....	Feedlot beef cattle: For reduction in the number of liver condemnations due to abscesses.	Administer continuously throughout the feeding period.	054771
(xiv) To provide 70 mg per head per day.	.....	Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses.	Administer continuously throughout the feeding period.	069254
(xv) To provide 250 mg per head per day.	.....	Feedlot beef cattle: For reduction in the number of liver condemnations due to abscesses.	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	054771
(xvi) To provide 250 mg per head per day.	.....	Beef steers and heifers fed in confinement for slaughter: For reduction in the number of liver condemnations due to abscesses.	Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.	069254

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Dated: December 16, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–32000 Filed 12–21–15; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under the asset allocation regulation for valuation dates in the first quarter of 2016. The interest assumptions are used for valuing benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC. As discussed below, PBGC has published a separate final rule document dealing with interest assumptions under its regulation on Benefits Payable in Terminated Single-Employer Plans for January 2016.

DATES: Effective January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@PBGC.gov*), Assistant General Counsel for Regulatory Affairs, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions—including interest assumptions—for valuing plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

The interest assumptions in Appendix B to Part 4044 are used to value benefits for allocation purposes under ERISA section 4044. Assumptions under the asset allocation regulation are updated quarterly and are intended to reflect current conditions in the financial and annuity markets. This final rule updates the asset allocation interest assumptions for the first quarter (January through March) of 2016.

The first quarter 2016 interest assumptions under the allocation regulation will be 2.82 percent for the first 20 years following the valuation date and 2.95 percent thereafter. In comparison with the interest assumptions in effect for the fourth quarter of 2015, these interest assumptions represent no change in the select period (the period during which the select rate (the initial rate) applies), an increase of 0.36 percent in the select rate, and a decrease of 0.03 percent in the ultimate rate (the final rate).

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation of benefits under plans with valuation dates during the first quarter of 2016, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4044 continues to read as follows: