DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2003–N–0446 (formerly 2003N–0324)]

New Animal Drugs for Use in Animal Feeds; Removal of Obsolete and Redundant Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing regulations that required sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofuran, and sulfonamide drugs administered in animal feed as these regulations have been determined to be obsolete. FDA has other strategies for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern, and the only remaining animal drug use listed in these regulations is now listed elsewhere in the new animal drug regulations.

DATES: This rule is effective April 6, 2016.

ADDRESSES: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–1), 7519 Standish Pl., Rockville, MD 20855, 240–402–5704, email: *william.flynn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 8, 2003 (68 FR 47272), FDA published a notice of proposed rulemaking to remove 21 CFR 558.15, *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* (§ 558.15), on the grounds that these regulations were obsolete or redundant. The proposed rule explained the nature and purpose of § 558.15, and noted that most of the products and use combinations subject to the listings in that section had approvals that were already codified in part 558, subpart B of this chapter.

In the same issue of the **Federal Register** as the proposed rule, FDA's Center for Veterinary Medicine (CVM) published a Notice of Opportunity for Hearing (NOOH), which announced CVM's findings of effectiveness for nine products and use combinations that were listed in § 558.15, but which were subject to the Drug Efficacy Study Implementation (DESI) program (68 FR 47332). CVM proposed to withdraw the new animal drug applications (NADAs) for those nine products and use combinations lacking substantial evidence of effectiveness, following an opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. For applications proposed to be withdrawn, the Agency provided an opportunity for hearing.

The Agency received only one set of comments on the 2003 proposed rule, from Pennfield Oil Co. (Pennfield). At that time, Pennfield was the sponsor of NADA 141–137, a bacitracin methylene disalicylate (BMD) Type A medicated article that is listed in the table in § 558.15(g)(1). In the table, the listing is under Fermenta Animal Health Co., which was a predecessor in interest to Pennfield. In response to the NOOH, Pennfield submitted a hearing request regarding this product. In its comments on the 2003 proposed rule, Pennfield objected to the removal of § 558.15 until the issues in the NOOH were addressed. It argued that the BMD listing in § 558.15 provides evidence of Pennfield's approval, and that removal of that section, without updating the BMD listing in part 558, subpart B, would result in a lack of recognition in the regulations of the approval that Pennfield currently has. Pharmgate LLC (Pharmgate) is the current sponsor of NADA 141–137 (80 FR 13226, March 13, 2015).

For the eight other products and use combinations subject to the NOOH, FDA received supplemental applications with labeling conforming to the relevant findings of effectiveness. FDA approved those applications in 2006 and 2009 and amended part 558 subpart B to reflect those approvals (71 FR 16222 (March 31, 2006); 71 FR 16223 (March 31, 2006); and 74 FR 40723 (August 13, 2009)). Subsequent to those approvals, FDA finalized portions of the 2003 proposed rule by removing from the tables in § 558.15(g) the products and use combinations that were not approved, and the products and use combinations whose approval was reflected in part 558, subpart B (71 FR 16219 (March 31, 2006) and 75 FR 16001 (March 31, 2010)). FDA retained only the listing in the table in § 558.15(g)(1) relating to NADA 141–137 as well as § 558.15(a) through (f). In both the 2006 and 2010 final rules, FDA stated it intended to continue to finalize the proposed rule to remove all of § 558.15.

Recently, Pharmgate filed a supplemental application to NADA 141–137 which provided labeling conforming to the relevant findings of effectiveness announced in the NOOH. FDA approved this supplement on October 6, 2015. Also on October 6, 2015, Pharmgate withdrew the hearing request relating to NADA 141–137. FDA has since published in the **Federal Register** a notice amending § 558.76 of subpart B to reflect this supplemental approval (80 FR 79474, December 22, 2015).

Because the approval of NADA 141–137 is now listed in § 558.76 of subpart B, FDA is removing its associated listing in § 558.15(g)(1) as obsolete. In addition, FDA is finalizing the proposed rule by removing all of the other remaining portions of § 558.15 because they are also obsolete. A conforming change is made in § 558.4.

II. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–602), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options to minimize any significant impact on a substantial number of small entities. We have determined that this final rule does not impose compliance costs on the sponsors of any products that are currently marketed. Further, it does not cause any drugs that are currently marketed to lose their marketing ability. Therefore, FDA certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that may result in an annual expenditure by State, local and tribal

governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in any 1-year expenditure that meets or exceeds this amount.

FDA proposed the removal of § 558.15 on August 8, 2003, because it was obsolete or redundant. The original purpose of § 558.15 was to require the submission of the results of studies on the long-term administration of then-marketed antimicrobial drugs in animal feed on the occurrence of multiple drug-resistant bacteria associated with these animals. FDA determined that this section was obsolete as FDA had a new strategy and concept for assessing the safety of antimicrobial new animal drugs, including subtherapeutic use of antimicrobials in animal feed, with regard to their microbiological effects on bacteria of human health concern. This final rule removes the only remaining animal drug use listed in § 558.15(g), which is obsolete since approval of its NADA is now listed elsewhere in part 558.

Only one set of comments to the proposal was received by FDA. Since these comments did not question the benefits as described in the proposed rule, we retain the benefits for the final rule. This final rule is expected to provide greater clarity in the regulations for new animal drugs for use in animal feeds by deleting obsolete provisions in § 558.15. We do not expect this final rule to result in any direct human or animal health benefit. Rather, this final rule would remove regulations that are no longer necessary.

We do not expect the final rule that revokes the remaining portions of § 558.15 to have a substantive effect on any approved new animal drug or to cause any approved new animal drug to lose its marketing ability or experience a loss of sales.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) 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.

IV. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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, 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.

§ 558.4 [Amended]

■ 2. In paragraph (c) of § 558.4, remove ''and in § 558.15 of this chapter''.

§ 558.15 [Removed]

■ 3. Remove § 558.15.

Dated: March 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04945 Filed 3–4–16; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2014–HA–0133]

RIN 0720–AB62

TRICARE; Revision of Nonparticipating Providers Reimbursement Rate; Removal of Cost Share for Dental Sealants; TRICARE Dental Program

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule revises the benefit payment provision for nonparticipating providers to more closely mirror industry practices by requiring TDP nonparticipating providers to be reimbursed (minus the appropriate cost-share) at the lesser of billed charges or the network maximum allowable charge for similar services in that same locality (region) or state. This rule also updates the regulatory provisions regarding dental sealants to clearly categorize them as a preventive service and, consequently, eliminate the current 20 percent cost-share applicable to sealants to conform with the language in the regulation to the statute.

DATES:

Effective date: The final rule is effective April 6, 2016.

Applicability date: The programmatic improvements in this final rule are scheduled to take effect as soon as the Director, Defense Health Agency can effectively and efficiently implement through award of a new TRICARE Dental Program contract. No change will be negotiated for existing contracts to implement this rule. Implementation through the new contract will be effective with the start of care delivery under the new contract (currently anticipated to start February 1, 2017).

FOR FURTHER INFORMATION CONTACT: Col James Honey, Defense Health Agency, telephone (703) 681–0039.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

1. Purpose of Regulatory Actions

a. Need for Regulatory Actions

(1) Revision of Nonparticipating Providers' Reimbursement Rate

Prior to 2006, TRICARE Dental Program (TDP) participating and nonparticipating providers were reimbursed at the equivalent of not less than the 50th percentile of prevailing charges made for similar services in the same locality (region) or state, or the provider's actual charge, whichever is lower, less any cost-share amount due for authorized services. This provision was included in the regulation to constitute a significant financial incentive for participation of providers in the contractor's network and to ensure a network of quality providers through use of a higher reimbursement rate. Over time, the Department discovered that this provision placed an unnecessary burden on contractors with already established, high quality provider networks with reimbursement rates below the 50th percentile that were of sufficient size to meet the access requirements of the TDP. Consequently, the Department of Defense published a final rule in the **Federal Register** on January 11, 2006 (71 FR 1695), revising the participating provider's reimbursement rate for the TDP that has resulted in significant cost savings to the TDP enrollees and the Government. Since over 80 percent of all TDP care was provided by network dentists, the need to also change the reimbursement rate for nonparticipating dentists was overlooked and not included in the 2006 rule change. However, over the past eight years this has created an incentive for some network providers to leave the TDP network and for other providers not to become network providers. As the rule is currently written, depending on the geographic location, some non-network providers