2d 299 (5th Cir. 1976), and the job benefits extended to any U.S. workers shall be at least those extended to the alien workers.

(b) *Subparts D and E.* Subparts D and E of this part set forth the process by which health care facilities can file attestations with the Department of Labor for the purpose of employing or otherwise using nonimmigrant registered nurses under H–1A visas.

(c) *Subparts F and G.* Subparts F and G of this part set forth the process by which employers can file attestations with the Department of Labor for the purpose of employing alien crewmembers in longshore work under D-visas and enforcement provisions relating thereto.

(d) *Subparts H and I of this part.* Subpart H of this part sets forth the process by which employers can file labor condition applications (LCAs) with, and the requirements for obtaining approval from, the Department of Labor to temporarily employ the following three categories of nonimmigrants in the United States: (1) H–1B visas for temporary employment in specialty occupations or as fashion models of distinguished merit and ability; (2) H–1B1 visas for temporary employment in specialty occupations of nonimmigrant professionals from countries with which the United States has entered into certain agreements identified in section 214(g)(8)(A) of the INA; and (3) E–3 visas for nationals of the Commonwealth of Australia for temporary employment in specialty occupations. Subpart I of this part establishes the enforcement provisions that apply to the H–1B, H–1B1, and E–3 visa programs.

(e) *Subparts J and K of this part.* Subparts J and K of this part set forth the process by which employers can file attestations with the Department of Labor for the purpose of employing nonimmigrant alien students on F-visas in off-campus employment and enforcement provisions relating thereto.

[43 FR 10312, Mar. 10, 1978, as amended at 52 FR 20507, June 1, 1987; 55 FR 50510, Dec. 6, 1990; 56 FR 24667, May 30, 1991; 56 FR 54738, Oct. 22, 1991; 56 FR 56875, Nov. 6, 1991; 57 FR 1337, Jan. 13, 1992; 57 FR 40989, Sept. 8, 1992; 69 FR 68226, Nov. 23, 2004; 73 FR 19947, Apr. 11, 2008]

[FR Doc. 2010–7380 Filed 3–30–10; 8:45 am]

BILLING CODE 1505–01–D

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 558

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

## New Animal Drugs; Removal of Obsolete and Redundant Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is removing portions of a regulation 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 or redundant. The portions of the regulation being removed are provisions listing certain feed use combinations for oxytetracycline and neomycin in the tables contained in that regulation. This rule does not finalize the provisions of the proposed rule regarding removing the remainder of the regulation.

**DATES:** This rule is effective April 30, 2010.

**FOR FURTHER INFORMATION CONTACT:** William T. Flynn, Center for Veterinary Medicine (HFV–50), 7519 Standish Pl., Rockville, MD 20855, 240–276–9090, e-mail: *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 (21 CFR 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 (21 CFR part 558, subpart B).

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.

FDA received hearing requests regarding two products owned by Pennfield Oil Co. (Pennfield). One is a bacitracin methylene disalicylate (BMD) Type A medicated article, NADA 141–137, that is listed in the table in § 558.15(g)(1). This listing is under Fermenta Animal Health Co., which is a predecessor in interest to Pennfield. The other is a two-way, fixed-combination Type A medicated article containing oxytetracycline and neomycin sulfate, NADA 138–939, that is listed in the table in § 558.15(g)(2).

The agency received only one set of comments on the 2003 proposed rule, from Pennfield. The comment objected to the removal of § 558.15 until the issues in the NOOH are 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.

In 2006, FDA finalized portions of the 2003 proposed rule. In that final rule (71 FR 16219, March 31, 2006), FDA removed from the tables in § 558.15(g) products and use combinations that were not approved, and products and use combinations whose approval was reflected in part 558, subpart B. FDA retained only the listings for NADA 141–137 and NADA 138–939 in those tables. In addition, FDA retained § 558.15(a) through (f). FDA stated it intended to finalize the proposed rule to remove all of § 558.15 once, as part of the DESI program, either the approvals for NADA 141–137 and NADA 138–939 have been withdrawn or part 558, subpart B has been amended to reflect their approvals.

Subsequently, Pennfield filed a supplement to NADA 138–939 for its fixed-combination oxytetracycline/neomycin Type A medicated articles. The supplemental NADA, which provided labeling conforming to the relevant findings of effectiveness announced in the NOOH, was approved on July 2, 2009, and the regulations were amended in § 558.455 of subpart B to reflect that approval (74 FR 40723, August 13, 2009).

This oxytetracycline/neomycin use combination is listed in the table in § 558.15(g)(2) and is the only use combination listed in this provision. Because this use combination's approval is now reflected in § 558.455, FDA is removing § 558.15(g)(2) as obsolete or redundant. As in the 2006 final rule, FDA is retaining the sole listing in the table in § 558.15(g)(1) for NADA 141–137 as well as § 558.15(a) through (f), and intends to continue to finalize the proposed rule to remove all of § 558.15.

**II. Environmental Impact**

The agency has 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.

**III. Analysis of Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–602), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies 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). The agency believes that this final rule is not a significant regulatory action under the Executive order.

FDA proposed the removal of § 558.15 on August 8, 2003, because it was obsolete or redundant. The original purpose of § 558.15, requiring 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, 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 would delete the only animal drug use combination listed in § 558.15(g)(2) which is redundant because its approved conditions of use are now listed in § 558.455.

*A. Benefits*

Only one set of comments on the proposal was received by FDA. Because 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.

*B. Compliance Costs*

We do not expect the final rule that revokes § 558.15(g)(2) to have a substantive effect on any approved new animal drugs, or to cause any approved new animal drug to lose its marketing ability or experience a loss of sales.

*C. Regulatory Flexibility Analysis*

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA has 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. We therefore certify that this final rule would not have a significant economic effect on a substantial number of small entities.

*D. Unfunded Mandates Reform Act*

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

**IV. Paperwork Reduction Act of 1995**

FDA concludes that this rule does not have information collection requirements.

**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. 360b, 371.

**§ 558.15 [Amended]**

■ 2. In § 558.15, remove and reserve paragraph (g)(2).

Dated: March 18, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–7108 Filed 3–30–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

**[Docket No. USCG–2009–0959]**

**RIN 1625–AA09**

## Drawbridge Operation Regulation; Chehalis River, Aberdeen, WA, Schedule Change

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is changing the regulations that govern the operation of the U.S. Highway 101 bascule bridge across the Chehalis River, mile 0.1, at Aberdeen, Washington. At least one-hour notice by telephone will be required at all times for draw openings. The change is necessary to allow the bridge owner to reduce the staffing requirements of the bridge in light of the infrequent openings requested for the bridge.

**DATES:** This rule is effective April 30, 2010.

**ADDRESSES:** Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2009–0959 and are available online by going to *http://www.regulations.gov.*, inserting USCG–2009–0959 in the "Keyword" box, and then clicking "Search". This material is also available for inspection or copying at the Docket Management Facility (M–60), U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or