

of Food and Drugs, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. In § 522.558, paragraph (a) is revised to read as follows:

§ 522.558 Dexmedetomidine.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligram (mg) of dexmedetomidine hydrochloride.

* * * * *

Dated: April 13, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7-7594 Filed 4-19-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs; Florfenicol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for the use of florfenicol by veterinary feed directive (VFD) for the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum*.

DATES: This rule is effective April 20, 2007.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed a supplement to NADA 141-246 that provides for use of AQUAFLO (florfenicol), a type A medicated article, by VFD to formulate type C medicated feed for the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *F. psychrophilum*. The supplemental application is approved as of March 19, 2007, and the regulations are amended in 21 CFR 556.283, 558.4, and 558.261 to reflect the approval.

The single VFD order form for florfenicol includes both catfish and freshwater-reared salmonid indications because each comprises multiple species and is approved in each for use under similar directions and conditions of use.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc-2), this supplemental approval qualifies for 7 years of exclusive marketing rights beginning March 19, 2007, because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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

21 CFR Part 556

Animal drugs, Foods.

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 parts 556 and 558 are amended as follows:

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

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 2. In § 556.283, add paragraph (b)(4) to read as follows:

§ 556.283 Florfenicol.

* * * * *

(b) * * *

(4) *Salmonids.* The tolerance for florfenicol amine (the marker residue) in muscle/skin (the target tissues) is 1 ppm.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 360b, 371.

■ 4. In paragraph (d) of § 558.4, in the "Category II" table, revise the entry in alphabetical order for "Florfenicol" to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent ¹ Type A	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
* * * * *	* * * * *	* * * * *	* * * * *
Florfenicol	90-110	Swine feed: n/a Catfish feed: n/a Salmonid feed: n/a	Swine feed: 85-115 Catfish feed: 80-110 Salmonid feed: 80-110

CATEGORY II—Continued

Drug	Assay limits percent ¹ Type A	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
*	*	*	*

¹ Percent of labeled amount.

² Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

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■ 5. In § 558.261, revise paragraph (a)(2), paragraph (c)(2)(i), and the first two sentences of paragraph (e)(2)(iii); and add new paragraph (e)(3) to read as follows:

§ 558.261 Florfenicol.

(a) * * *

(2) 500 grams per kilogram for use as in paragraphs (e)(2) and (e)(3) of this section.

* * * * *

(c) * * *

(2) * * *

(i) For catfish and freshwater-reared salmonids, must not exceed 15 days from the date of issuance;

* * * * *

(e) * * *

(2) * * *

(iii) * * * Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. * * *

(3) *Freshwater-reared salmonids*—(i) *Amount.* 10 milligrams florfenicol per kilogram of fish daily for 10 consecutive days.

(ii) *Indications for use.* For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum*.

(iii) *Limitations.* Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Dated: April 9, 2007.

Bernadette Dunham,
Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7-7475 Filed 4-19-07; 8:45 am]

BILLING CODE 4160-01-S

BROADCASTING BOARD OF GOVERNORS

22 CFR Part 504

Testimony by BBG Employees, Production of Official Records, and Disclosure of Official Information In Legal Proceedings

AGENCY: Broadcasting Board of Governors.

ACTION: Final rule.

SUMMARY: The Broadcasting Board of Governors (BBG) is publishing as a final rule a regulation governing access to BBG information and records in connection with legal proceedings in which neither the United States nor the BBG is a party. The proposed rule was published for comment in 72 FR 10954 dated March 12, 2007. The BBG received no responses to the proposed rule. The final rule and corresponding regulation establishes guidelines for use in determining whether BBG employees are permitted to testify or to provide records relating to their official duties and procedures that requesters must follow when making demands on, or requests to, a BBG employee for official documents or to provide testimony.

DATES: The effective date of the regulation is April 23, 2007.

FOR FURTHER INFORMATION CONTACT: Christopher Veith, Assistant General Counsel, Broadcasting Board of Governors, 330 Independence Ave., SW., Washington, DC 20237, phone: (202) 203-4550 or fax at (202) 203-4585.

SUPPLEMENTARY INFORMATION: Briefly, the final rule prohibits disclosure of nonpublic official records or testimony by the BBG's employees, as defined in Part 504.4, unless there is compliance with the rule. The final rule sets out the information that requesters must provide and the factors that the BBG will consider in making determinations in response to requests for testimony or the production of documents.

The final rule applies to a range of matters in any legal proceeding in which the BBG is not a named party and applies to current and former BBG employees. The final rule will ensure a more efficient use of the BBG's

resources, minimize the possibility of involving the BBG in issues unrelated to its responsibilities, promote uniformity in responding to subpoenas and like requests, and maintain the impartiality of the BBG in matters that are in dispute between other parties. It will also serve the BBG's interest in protecting sensitive, confidential, and privileged information and records that are generated in fulfillment of the BBG's statutory responsibilities.

The final rule is internal and procedural rather than substantive. It does not create a right to obtain official records or the official testimony of a BBG employee nor does it create any additional right or privilege not already available to the BBG to deny any demand or request for testimony or documents. Failure to comply with the procedures set out in these regulations would be a basis for denying a demand or request submitted to the BBG.

List of Subjects in 22 CFR Part 504

Administrative practice and procedure.

■ For the reasons stated in the preamble, the Broadcasting Board of Governors amends 22 CFR, Chapter V, by adding part 504, as follows:

PART 504—TESTIMONY BY BBG EMPLOYEES, PRODUCTION OF OFFICIAL RECORDS, AND DISCLOSURE OF OFFICIAL INFORMATION IN LEGAL PROCEEDINGS

Subpart A—General Provisions

- Sec.
- 504.1 Scope and purpose.
- 504.2 Applicability.
- 504.3 Definitions.

Subpart B—Demands or Requests for Testimony and Production of Documents

- 504.4 General prohibition.
- 504.5 Factors the BBG will consider.
- 504.6 Filing requirements for litigants seeking documents or testimony.
- 504.7 Service of requests or demands.
- 504.8 Processing requests or demands.
- 504.9 Final determinations.
- 504.10 Restrictions that apply to testimony.
- 504.11 Restrictions that apply to released records.