pressure indicator at the end of the discharge line to confirm that the container has not discharged.

(2) *The discharge line terminates inside the airplane.* As part of a pre-departure check, visually inspect the pressure indicator for the container for loss of pressure within the container.

(b) The certificate holder also must ensure that only non-corrosive extinguishing agents are used in systems where the pressure discharge line terminates inside the airplane.

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 3. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 41706, 44113, 44101, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722.

■ 4. Amend § 135.169 by revising paragraph (a) to read as follows:

§ 135.169 Additional airworthiness requirements.

(a) Except for commuter category airplanes, no person may operate a large airplane unless it meets the additional airworthiness requirements of §§ 121.215 through 121.283 and 121.307 of this chapter.

* * * * *

Marion C. Blakey,

Administrator.

[FR Doc. 07–1937 Filed 4–19–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clindamycin Solution

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 an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for the veterinary prescription use of clindamycin hydrochloride oral solution in dogs and cats for the treatment of various infections due to susceptible bacterial pathogens.

DATES: This rule is effective April 20, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–398 for the veterinary prescription use of Clindamycin Hydrochloride Oral Drops in dogs and cats for the treatment of various infections due to susceptible bacterial pathogens. First Priority, Inc.'s Clindamycin Hydrochloride Oral Drops is approved as a generic copy of ANTIROBE AQUADROPS Liquid, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 135–940. The ANADA is approved as of March 19, 2007, and 21 CFR 520.447 is amended to reflect the approval.

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.

FDA 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 520

Animal drugs.

■ 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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.447 revise paragraph (b) to read as follows:

§ 520.447 Clindamycin Solution.

* * * * *

(b) *Sponsors.* See Nos. 000009, 051311, 058829, and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: April 9, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–7472 Filed 4–19–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Oral Dosage Form New Animal Drugs; Dexmedetomidine; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a final rule that appeared in the **Federal Register** of January 4, 2007 (72 FR 263), revising the animal drug regulations to reflect approval of an original new animal drug application (NADA). The document incorrectly listed the amount of drug per milliliter of dexmedetomidine hydrochloride injectable solution. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective April 20, 2007.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–267–9019, e-mail: *george.haibel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA has discovered that an error has been incorporated into the agency's regulations for 21 CFR part 522. This document corrects that error. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

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 AQUAFLOR (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