FDA finds that the effective date of the final rule that published in the **Federal Register** of July 28, 2004, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (1410.10 of the FDA Staff Manual Guide), notice is given that no objections or requests for a hearing were filed in response to the July 28, 2004, final rule. Accordingly, the amendments issued thereby became effective August 30, 2004.

Dated: September 30, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22605 Filed 10–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

New Animal Drugs; Flunixin

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 Schering-Plough Animal Health Corp. The supplemental NADA provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection in lactating dairy cattle for control of pyrexia associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. It also provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection for control of pyrexia associated with acute bovine mastitis and for the establishment of a tolerance for residues of flunixin in milk.

DATES: This rule is effective October 8, 2004.

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., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 101–479 that provides for the veterinary prescription use of BANAMINE (flunixin meglumine) Injectable Solution by intravenous injection in lactating dairy cattle for control of pyrexia associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. It also provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection for control of pyrexia associated with acute bovine mastitis and for the establishment of a tolerance for residues of flunixin in milk. The supplemental NADA is approved as of August 19, 2004, and the regulations are amended in 21 CFR 522.970 and 556.286 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act the act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 19, 2004. The 3 years of marketing exclusivity applies only to the new indication of control of pyrexia associated with acute bovine mastitis.

The agency has determined under 21 CFR 25.33(d)(5) 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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 522 and 556 are 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. Section 522.970 is amended by revising the section heading; by revising paragraph (b)(1); by redesignating paragraph (b)(2) as paragraph (b)(3); by adding new paragraph (b)(2); and by revising paragraphs (e)(2) introductory text, (e)(2)(i), (e)(2)(ii), and (e)(2)(iii) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(1) See No. 000061 for use as in paragraph (e) of this section.

(2) See Nos. 055529, 057561, and 059130 for use as in paragraphs (e)(1), (e)(2)(i)(A), (e)(2)(ii)(A), and (e)(2)(iii), of this section.

* * * * *

(e) * * *

* * * * *

(2) *Cattle*—(i) *Amount.* (A) 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day, as a single dose or divided into two doses administered at 12-hour intervals, intravenously, for up to 3 days.

(B) 2.2 mg/kg (1.0 mg/lb) of body weight given once by intravenous administration.

(ii) *Indications for use.* (A) For control of pyrexia associated with bovine respiratory disease and endotoxemia. Also indicated for control of inflammation in endotoxemia.

(B) For control of pyrexia associated with acute bovine mastitis.

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. For No. 000061: Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For Nos. 055529, 057561, and 059130: Not for use in lactating or dry dairy cows.

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

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

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

■ 4. Section 556.286 is amended by revising the section heading; by revising paragraph (b); and by adding paragraph (c) to read as follows:

§ 556.286 Flunixin.

* * * * *

(b) *Tolerances*—(1) *Cattle*. The tolerance for flunixin free acid (the marker residue) is:

(i) *Liver (the target tissue*). 125 parts per billion (ppb).

(ii) *Muscle*. 25 ppb.

(iii) *Milk*. 2 ppb.

(2) [Reserved]

(c) *Related conditions of use*. See § 522.970 of this chapter.

Dated: September 27, 2004.

Stephen D. Vaughn,

Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–22606 Filed 10–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[USCG–2002–14273]

RIN 1625–AA52

Mandatory Ballast Water Management Program for U.S. Waters; Corrections

AGENCY: Coast Guard, DHS.

ACTION: Correcting amendments.

SUMMARY: The Coast Guard is correcting a final rule that appeared in the **Federal Register** of July 28, 2004 (69 FR 44952). The final rule requires mandatory ballast water management practices for all vessels equipped with ballast water tanks bound for ports or places within the U.S. or entering U.S. waters. These grammatical corrections clarify the final rule.

DATES: This correction is effective on July 28, 2004.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Bivan Patnaik, Project Manager, Environmental Standards Division, Coast Guard, telephone 202–267–1744, email: *bpatnaik@comdt.uscg.mil.* If you have questions on viewing the docket, call Ms. Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202–366–0271.

SUPPLEMENTARY INFORMATION:

Need for Correction

As published, the final rule contain errors which may prove to be misleading and therefore need to be clarified.

List of Subjects in 33 CFR Part 151

Administrative practice and procedure, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

■ Accordingly, 33 CFR part 151 is corrected by making the following correcting amendments:

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE, MUNICIPAL OR COMMERCIAL WASTE, AND BALLAST WATER

Subpart D—Ballast Water Management for Control of Nonindigenous Species in Waters of the United States

■ 1. The authority citation for subpart D continues to read as follows:

Authority: 16 U.S.C. 4711; Department of Homeland Security Delegation No. 0170.1.

§ 151.2035 [Corrected]

■ 2. In § 151.2035(b)(2), add the word ''or'' after the semicolon. In paragraph (b)(3), replace the semi-colon with a period.

Dated: September 28, 2004.

Joseph J. Angelo,

Director of Standards, Marine Safety, Security & Environmental Protection.

[FR Doc. 04–22721 Filed 10–7–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket No. FEMA–7849]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program(NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

DATES: The effective date of each community's suspension is the third date (''Susp.'') listed in the third column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA RegionalOffice or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Mike Grimm, Mitigation Division, 500 C Street, SW.; Room 412, Washington, DC 20472, (202) 646–2878.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.;* unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of