

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The supplemental ANADA provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection in dairy cattle for control of pyrexia associated with acute bovine mastitis.

DATES: This rule is effective February 12, 2009.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed supplemental ANADA 200-387 that provides for veterinary prescription use of FLUNAZINE (flunixin meglumine) Injectable Solution intravenously in dairy cattle for control of pyrexia associated with acute bovine mastitis. The supplemental ANADA is approved as of December 18, 2008, and the regulations are amended in 21 CFR 522.970 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 Subject 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 and redelegated to

the Center for Veterinary Medicine, 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 § 522.970, revise paragraphs (b)(2) and (b)(4) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(2) See No. 057561 for use as in paragraphs (e)(1), (e)(2)(i)(A), (e)(2)(ii)(A), and (e)(2)(iii) of this section.

* * * * *

(4) See Nos. 055529, 059130, and 061623 for use as in paragraphs (e)(1) and (e)(2) of this section.

* * * * *

Dated: February 3, 2009.

Steven D. Vaughn,

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

[FR Doc. E9-2941 Filed 2-11-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 105

[Docket Nos. TSA-2006-24191; USCG-2006-24196]

Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License

AGENCY: United States Coast Guard; DHS.

ACTION: Notice of extension of compliance date, American Samoa, Captain of the Port Zone Honolulu.

SUMMARY: This document informs owners and operators of facilities located on the island of American Samoa within Captain of the Port Zone Honolulu that the date by which they must implement access control procedures utilizing TWIC has been extended to no later than April 14, 2009. This extension is due to the fact that a large percentage of the maritime workforce in American Samoa is not native to the island, and do not need to comply with United States immigration laws.

DATES: The new compliance date for the TWIC regulations found in 33 CFR part 105 for the island of American Samoa in Captain of the Port Zone Honolulu is April 14, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this document as being available in the docket, are part of dockets TSA-2006-24191 and USCG-2006-24196, and are available for inspection or copying at the Docket Management Facility, 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. You may also find this docket on the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call LCDR Jonathan Maiorine, telephone 1-877-687-2243. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-493-0402.

SUPPLEMENTARY INFORMATION:

I. Regulatory History

On May 22, 2006, the Department of Homeland Security (DHS), through the United States Coast Guard (Coast Guard) and the Transportation Security Administration (TSA), published a joint notice of proposed rulemaking entitled "Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License" in the **Federal Register** (71 FR 29396). This was followed by a 45-day comment period and four public meetings. The Coast Guard and TSA issued a joint final rule, under the same title, on January 25, 2007 (72 FR 3492) (hereinafter referred to as the original TWIC final rule). The preamble to that final rule contains a discussion of all the comments received on the NPRM, as well as a discussion of the provisions found in the original TWIC final rule, which became effective on March 26, 2007.

On May 7, 2008, the Coast Guard and TSA issued a final rule to realign the compliance date for implementation of the Transportation Worker Identification Credential (73 FR 25562). The date by which mariners need to obtain a TWIC, and by which owners and operators of vessels and outer continental shelf facilities must implement access control procedures utilizing TWIC, is April 15, 2009. Owners and operators of facilities that

must comply with 33 CFR part 105 are subject to earlier, rolling compliance dates, as set forth in 33 CFR 105.115(e). The Coast Guard announced the rolling compliance dates, as provided in 33 CFR 105.115(e), at least 90 days in advance via notices published in the **Federal Register**. The final compliance date for all COTP Zones will not be later than April 15, 2009.

On September 30, 2008, we announced the compliance date for COTP Zone Honolulu would be February 12, 2009 (73 FR 56730).

II. Notice of Facility Compliance Date—American Samoa, COTP Zone Honolulu

Title 33 CFR 105.115(e) currently states that “[f]acility owners and operators must be operating in accordance with the TWIC provisions in this part by the date set by the Coast Guard in a Notice to be published in the **Federal Register**.” Through this Notice, the Coast Guard informs the owners and operators of facilities subject to 33 CFR 105.115(e) located on American Samoa within COTP Zone Honolulu that the deadline for their compliance with Coast Guard and TSA TWIC requirements has been extended until April 14, 2009.

This extension is being granted due to the fact that approximately 87% of the maritime workers that require TWICs in American Samoa are not native to the island, and do not need to comply with United States immigration laws. They are not issued a visa by the U.S. Department of State (DOS), and therefore they do not meet the immigration standards required for a TWIC, found in 49 CFR 1572.105. This new date provides sufficient time for the Coast Guard, in consultation with TSA, DHS, and DOS, to determine whether there is an equivalent visa category that these workers can use to qualify for a TWIC, or whether the TWIC requirement for facilities in American Samoa needs to be reconsidered, as it was for facilities located in the Commonwealth of the Northern Marianas Islands (72 FR 55043).

We note that this compliance delay ONLY applies to facilities located on the island of American Samoa; facilities subject to 33 CFR part 105 in the remainder of COTP Zone Honolulu must continue to comply with the TWIC requirements beginning February 12, 2009.

You may visit our Web site at homeport.uscg.mil/twic for a listing of all compliance dates by COTP Zone. This list is subject to change; any changes in compliance dates will appear on that Web site and be announced in the **Federal Register**.

Dated: February 9, 2009.

Mark P. O'Malley,

Captain, U.S. Coast Guard, Chief, Ports and Facilities Activities.

[FR Doc. E9-3119 Filed 2-10-09; 1:00 pm]

BILLING CODE 4910-15-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 209

[FRA-2007-28573]

RIN 2130-AB87

Railroad Safety Enforcement Procedures; Enforcement, Appeal and Hearing Procedures for Rail Routing Decisions

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule; clarification.

SUMMARY: On November 26, 2008, FRA published the final rule in this docket that established procedures to enable railroad carriers to challenge rail routing decisions made by FRA's Associate Administrator for Safety. The final rule was published with an immediate effective date. Under applicable federal statutes, this document did not qualify for an immediate effective date.

DATES: The applicability date for the final rule published at 73 FR 72194 was January 15, 2009.

FOR FURTHER INFORMATION CONTACT:

Lucinda Henriksen, Office of Chief Counsel, Federal Railroad Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590 (telephone 202-493-1345).

SUPPLEMENTARY INFORMATION: The final rule in this proceeding, published on November 26, 2008, indicated that it would be effective upon publication. See 73 FR 72194. Pursuant to Section 553 of the Administrative Procedure Act (APA), codified at 5 U.S.C. 553, with certain exceptions, substantive rules cannot take effect less than 30 days after publication, unless the agency finds good cause for doing so and provides a written explanation of any good cause found when the rule is published. FRA provided no justification for the immediate effective date in the published rule document and, in fact, FRA did not intend to avail itself of the good cause exception of 5 U.S.C. 553.

In addition, in accordance with the Congressional Review Act (CRA), at 5 U.S.C. 801(a)(4), a final rule cannot take effect until the rule is submitted to

Congress in accordance with 5 U.S.C. 801(a)(1). The rule was submitted to Congress on January 15, 2009.

According to the procedures established by the Administrative Committee of the **Federal Register** under the **Federal Register** Act (44 U.S.C. Chapter 15), the amendments to the Code of Federal Regulations (CFR) set out in this final rule were incorporated into the CFR on November 26, 2008, the effective date of the rule. However, because of the issues with the APA and the CRA, this rule could not become applicable or enforceable until January 15, 2009.

Accordingly, FRA acknowledges that the rule was not effective and enforceable until January 15, 2009. FRA further notes that because the rule establishes procedures that have not yet been utilized, neither the public, nor any regulated entities, were harmed in the interim period between publication of the rule and January 15, 2009.

Issued in Washington, DC, on February 6, 2009.

Jo Strang,

Acting Deputy Administrator.

[FR Doc. E9-3073 Filed 2-11-09; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

RIN 0648-XM03

Fraser River Sockeye Salmon Fisheries; Inseason Orders

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary orders; inseason orders; request for comments.

SUMMARY: NMFS publishes Fraser River salmon inseason orders to regulate salmon fisheries in U.S. waters. The orders were issued by the Fraser River Panel (Panel) of the Pacific Salmon Commission (Commission) and subsequently approved and issued by NMFS during the 2008 salmon fisheries within the U.S. Fraser River Panel Area. These orders established fishing dates, times, and areas for the gear types of U.S. treaty Indian and all citizen fisheries during the period the Panel exercised jurisdiction over these fisheries.

DATES: The effective dates for the inseason orders are set out in this