

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 Pennfield Oil Co. The supplemental ANADA provides for a zero-day preslaughter withdrawal time for use of oxytetracycline hydrochloride (HCl) soluble powder in the drinking water of swine.

DATES: This rule is effective August 7, 2002.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed a supplement to ANADA 200-026 that provides for use of PENNOX 343 (oxytetracycline HCl) soluble powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a zero-day preslaughter withdrawal time after the use of the product in the drinking water of swine. The supplemental ANADA is approved as of April 10, 2002, and 21 CFR 520.1660d is amended 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 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 Dockets Management Branch (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.

The agency had 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 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. Section 520.1660d is amended by revising the last sentence in paragraph (d)(1)(iii)(C) to read as follows:

**§ 520.1660d Oxytetracycline hydrochloride
soluble powder.**

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(C) * * * Administer up to 5 days; do not use for more than 5 consecutive days; withdraw zero days prior to slaughter those products sponsored by Nos. 046573, 053389, 057561, and 061133.

* * * * *

Dated: July 17, 2002.

Alan Rudman,

*Acting Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.*
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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

21 CFR Part 558

**New Animal Drugs for Use in Animal
Feeds; Oxytetracycline**

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 two supplemental new animal drug applications (NADAs) filed by Phibro Animal Health, Inc., which provide for a zero-day preslaughter withdrawal time for use of oxytetracycline in swine feed.

DATES: This rule is effective August 7, 2002.

FOR FURTHER INFORMATION CONTACT:

Steven D. Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7580, e-mail: svaughn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 710 Rte. 46 East, suite 401, Fairfield, NJ 07004, filed

supplements to NADA 8-804 for TM-50, TM-50D, TM-100, and TM-100D (oxytetracycline) Type A medicated articles and NADA 95-143 for OXTC (oxytetracycline) Type A medicated articles used for making medicated feeds for the treatment of various bacterial diseases of livestock. The supplemental NADAs provide for a zero-day withdrawal time prior to slaughter when Type C medicated feeds containing oxytetracycline are fed continuously to swine at a dosage of 10 milligrams per pound (mg/lb) of body weight for up to 14 days. The supplemental NADAs are approved as of April 29, 2002, and the regulations are amended in 21 CFR 558.450 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (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.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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 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 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.

§ 558.450 [Amended]

2. Section 558.450 *Oxytetracycline* is amended in the table in paragraph (d)(1)(ix), in entries 4 and 5, under the "Limitations" column, by removing

“withdraw 5 d before slaughter” and by adding in its place “for No. 053389, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal”.

Dated: July 17, 2002.

Alan Rudman,

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

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 6 and 125

[USCG-2002-12917]

Maritime Identification Credentials

AGENCY: Coast Guard, DOT.

ACTION: Clarification of regulation.

SUMMARY: The Coast Guard brings to the public's attention, clarification of the identification credentials that would be acceptable to the Commandant under 33 CFR 125.09(f), for access to waterfront facilities and to port and harbor areas, including the vessels and harbor craft in them. The Coast Guard has authority and the rules in place for this measure. As specified in 33 CFR 6.10-5, 125.15, and 125.53, such credentials—in addition to those acceptable under 33 CFR 125.09(a)-(e)—can, at a minimum, be laminated (or otherwise secured against tampering), contain the full name and a current photograph of the person, and bear the name of the issuing authority.

DATES: This clarification is effective on September 6, 2002.

FOR FURTHER INFORMATION CONTACT: For questions on this notice, call Mr. Gerald Miente, Program Manager, Maritime Personnel Qualification Division, Coast Guard Headquarters, at (202) 267-0229. For questions on viewing materials already in the docket, call Ms. Dorothy Beard, Chief, Dockets, Department of Transportation, at 202-366-5149.

SUPPLEMENTARY INFORMATION:

Public Meetings

A public meeting concerning initiatives toward international maritime security was held on January 3, 2002 (see **Federal Register** of December 14, 2001 [66 FR 64898]), at Coast Guard Headquarters, Washington, DC. A workshop concerning National Maritime Security was held on January 28-29, 2002 (see **Federal Register** of January 16, 2002 [66 FR 2271]), in Washington, DC, to discuss issues of domestic maritime security.

We are not receiving comments in response to this document because it simply clarifies existing requirements. You may see materials from the meeting and workshop, including our responses to comments we did receive, on the Internet at <http://dms.dot.gov> under docket number USCG-2002-11137.

Background

On September 11, 2001, acts of terrorism were committed against the United States in New York, Virginia, and Pennsylvania. In light of these attacks, the security of all modes of transportation is being reevaluated. Under the provisions of Title 33, Code of Federal Regulations (33 CFR), parts 6 and 125, the Coast Guard has the authority and the rules in place to require identification credentials for access to waterfront facilities and to port and harbor areas, including vessels and harbor craft in them. This notice serves to announce a clarification of these rules and serves to direct the public's attention to 33 CFR 125.09(f) authorizing the Commandant of the Coast Guard to require approved identification credentials.

In the week after September 11, the Secretary of the Department of Transportation (SEC DOT) established the National Infrastructure Security Committee (NISC) to evaluate security in the surface modes of transportation and to provide recommendations for improvement. To reach that goal, the NISC created six “Direct-Action Groups” (DAGs) to generally examine each mode of transportation; and, pursuant to their initial studies, it established a seventh DAG, the Credentialing Direct Action Group (CDAG), to study the issue of a National Transportation Workers' Identification Card (TWIC) for all transportation workers and other persons who require access to secure areas at transportation facilities. Pending legislation has pointed to a need for such a card. Further, the Transportation Security Administration (TSA), newly formed within the Department of Transportation (DOT) itself, formed “Go-Teams”—short-term, highly focused working groups that are concentrating on various specific technologies and credentialing issues, such as card architecture, biometrics, and “smart cards.” More information about credentialing is available on the website of TSA at <http://www.tsa.gov/>.

The goal of the CDAG is to fashion a nationwide solution to the problem of identifying workers that verifies their identity, validates their background information, assists transportation facilities in managing their security

risks, and accounts for access of authorized personnel to transportation facilities and activities. The CDAG is seeking to identify a solution that would—

- Be fully inter-modal;
- Be built on existing technology, as well as on governmental and commercial business processes and infrastructure, as much as possible;
- Minimize the need for workers and other people to carry multiple ID cards;
- Ensure due protection of a card holder's privacy;
- Meet Congressional mandates as both expressed in current legislation and supported in pending legislation;
- Meet standards of the International Maritime Organization (IMO); and
- Be scalable and expandable to address future access-enabling technologies.

In terms developed by the workshop, the solution would be Secure, Acceptable, Reliable, and Uniform.

The events of September 11 heightened awareness of waterfront vulnerability and the need for better control. This is a very dynamic area in which new risks are perceived and new technologies are available to address them. The Coast Guard intends to address those risks initially by resuming enforcement of existing rules, such as 33 CFR Parts 6 and 125, until DOT, Congress, and the CDAG provide new guidance and direction for incorporating more effective, commerce-friendly technology.

The Coast Guard is continually participating in the CDAG's efforts and awaits its recommendations, as well as DOT's decision on the TWIC, to avoid proceeding in any direction that may be in conflict with the decision ultimately chosen by the Department. We recognize the necessity of gathering information so that we will be prepared to carry out our commitment to enhance maritime security in a timely manner. We also recognize the imperative of controlling access while we achieve a longer-term, comprehensive means of security. At this time we are not requesting that comments be submitted addressing this notice or its subject. However, before any new rulemaking the public will have the opportunity to comment.

Purpose

This document serves to bring to the attention of the public clarification of the identification credentials deemed acceptable to the Commandant under 33 CFR 125.09(f). Furthermore, as stated in 33 CFR 6.10-5, and in 33 CFR 125.09, 125.15, and 125.53, the Coast Guard may, from time to time, prevent