List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ACE NE E2 McCook, NE

McCook Municipal Airport, NE
(Lat. 40°12′23″ N., long. 100°35′32″ W.)
McCook VOR/DME
(Lat. 40°12′14″ N., long. 100°35′39″ W.)

Within a 4.1-mile radius of McCook Municipal Airport and within 1.8 miles each side of the McCook VOR/DME 122° radial extending from the 4.1-mile radius of the airport to 7 miles southeast of the VOR/DME and within 1.8 miles each side of the McCook VOR/DME 326° radial extending from the 4.1-mile radius of the airport to 7 miles northwest of the VOR/DME. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Director.

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE NE E5 McCook, NE

McCook Municipal Airport, NE
(Lat. 40°12′23″ N., long. 100°35′32″ W.)

That airspace extending upward from 700 feet above the surface within a 7.6-mile radius of McCook Municipal Airport.

* * * * *

Issued in Kansas City, MO, on May 11, 2004.

Paul J. Sheridan,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–11894 Filed 5–26–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. 1993P–0174]

Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is changing the regulations for liquid medicated feed and free-choice medicated feed. By changing the regulations for liquid medicated feed, FDA is clarifying: What data are required to demonstrate chemical and physical stability of a drug in liquid feed, how such data may be submitted for use in the new animal drug approval process, and which liquid medicated feeds may be manufactured in a feed manufacturing facility that has not obtained a medicated feed mill license from FDA. By changing the regulations for free-choice medicated feed, FDA is ensuring that they are consistent with the requirements for liquid medicated feed, and that provisions for free-choice medicated feed and liquid medicated feed comply with the terms of the Animal Drug Availability Act (ADAA) of 1996.

DATES: This rule is effective June 28, 2004.

FOR FURTHER INFORMATION CONTACT: Dragan Momcilovic, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *dmomcilo@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 28, 2003 (68 FR 31645), FDA proposed changing regulations for liquid medicated feed and free-choice medicated feed and provided 90 days for comments on the proposed changes.

Several events led to the development of the proposed rule. First, an April 30, 1993, citizen petition requested that FDA amend § 558.5 (21 CFR 558.5) to clarify the information and data needed to demonstrate chemical and positional (physical) stability in liquid medicated feeds and describe circumstances under which a medicated feed application (MFA) will or will not be required. Second, our November 21, 1996 (61 FR 59209) advanced notice of proposed rulemaking, which we issued seeking comments concerning various issues for the development of regulations implementing provisions of ADAA, prompted the Animal Feed Industry Association to propose changes to the new animal drug requirements regarding free choice administration in feeds (§ 510.455 (21 CFR 510.455)).The proposed changes to § 510.455 would adopt the terms of feed mill licensing in accordance with ADAA and allow a feed manufacturer to submit a new animal drug application (NADA) for the approval of a Type A medicated article for use in the subsequent manufacture of a free-choice medicated feed. This document contains the liquid medicated feed and free-choice medicated feed final rules.

II. Summary of the Proposed Rule

A. Liquid Medicated Feed

The proposed rule had the following objectives: (1) Replaced the references to ''medicated feed application'' in the current rule with the term ''medicated feed mill license,'' (2) defined the types of liquid medicated feed covered by this regulation, (3) clarified the types of approvals required for liquid medicated feed, (4) explained that an approval is required for a drug intended for use in a liquid feed and clarifies the procedures and requirements for demonstrating chemical and physical stability of a drug in liquid feed, (5) permitted submission of the stability data through a master file (MF) for reference by a subsequent applicant, (6) explained what information will be included in the published approval of a drug for use in liquid feed, (7) identified the conditions under which an approved medicated feed mill license will be required for the manufacture of a liquid medicated feed, and (8) described the labeling provisions for several drugs approved for use in water but not in liquid feed. We invited comments on whether or not the waiver provision needs to continue to be available because no one has invoked the provision since its inception in 1973.

B. Free-Choice Medicated Feed

The proposed rule had the following objectives: (1) Modified the current rule

by providing a definition of free-choice medicated feed, (2) explained that one of three types of NADAs is required for a drug intended for use in a free-choice feed, (3) specified the data required for such applications and the procedures for their submission, (4) explained how such data must be submitted, (5) stated what information will be included in the published approval of a new animal drug intended for use in free-choice feed, and (6) explained the situations that will require a medicated feed mill license for the manufacture of a free-choice medicated feed.

III. Comments on the Proposed Rule

We received three letters commenting on the proposed rule: Two from trade associations and one from a feed manufacturer. The letters were supportive of the proposed rule. Issues addressed in the comments included waivers from labeling provisions, certified letters containing proprietary information, and the free-choice and liquid feed stability data requirements.

Following is our response to comments, grouped by issue:

A. Waiver From Labeling Provisions

(Comment 1) Two comments stated that the proposed rule should retain the labeling provisions allowing a waiver of warning statements on labels of dry medicated feeds containing bacitracin, oxytetracycline, and/or chlortetracycline, as specified in § 558.5(i). One of the two comments pointed out that the waiver option should be retained because it provides needed information to liquid feed manufacturers while granting appropriate labeling flexibility to new animal drug applicants. The other comment indicated that although the waiver has not been sought in the past, there are indications that several firms are considering to request such a waiver in the future.

We agree with the two comments and are retaining the waiver option in this final rule.

B. Providing a Certified Letter With the Formula and/or Specifications of a Free-Choice or a Liquid Medicated Feed Product

(Comment 2) Two comments expressed concern about our intention, expressed in the preamble of the proposed rule, to provide both the NADA and the MF holder with a certified letter setting forth the formula and/or specifications of a free-choice or a liquid medicated feed product, where the formula and/or specifications are not published in a regulation. The two comments argued that the certified letter, which contains proprietary information, should only be issued to the MF holder who owns that information, and not to the NADA holder.

We agree with these two comments and intend to provide a certified letter only to the owner of the proprietary formula and/or specifications, who is typically the MF holder.

(Comment 3) Two comments stated that currently there are many free-choice and liquid medicated feed products approved through an MF for which no such certified letters have been provided to the MF holders. In order to avoid possible confusion at feed mill inspections, where some products may have a certified letter and others may not, the two comments stated that FDA should either issue such certified letters to the MF holders of all such previously approved free-choice and liquid medicated feeds, or make it clear in this rule that the certified letter route applies only to free-choice and liquid feeds approved after a certain date.

We intend to provide a certified letter to the owner of the proprietary formula and/or specifications of those free-choice and liquid medicated feed products that are approved after the effective date of this rule. We do not intend to issue certified letters for feed products approved before the effective date of this rule. Firms that are making such feed products must be in compliance with existing requirements and regulations pertaining to the manufacture of those products.

C. The Free-Choice and Liquid Feed Stability Data Requirements

(Comment 4) Two comments stated that the agency should revisit the stability data requirements as well as the consumption data and manufacturing chemistry requirements articulated in the original April 30, 1993, citizen petition and revise the present liquid feed and free choice feed guidances regarding these topics.

This comment falls outside of the scope of this rulemaking. Comments pertaining to FDA guidance documents should be sent to the dockets for those documents. More information on how to submit comments to FDA guidance documents can be found at *http://www.fda.gov/cvm/guidance/guidance.html#purpose*.

IV. Final Rules

The final rules for liquid medicated feed and free-choice medicated feeds adopt the proposed rules without change. For both the liquid medicated feed and free-choice medicated feed final rules, FDA concluded that an approved medicated feed mill license should be required for facilities that manufacture free-choice or liquid medicated feeds with proprietary formulas and/or specifications. Where the formula and/or specifications are published, FDA has an assurance that medicated feed mills have access to the information necessary to manufacture the approved free-choice or liquid medicated feed. Where the formula and/or specifications are proprietary, medicated feed mills might attempt to manufacture the free choice or liquid medicated feed knowing only that the drug is approved for use in free-choice or liquid medicated feed, but not knowing the formula and/or specifications. Manufacture of such feeds without this crucial information could endanger animal health and public health. Section 510(h) of the act (21 U.S.C. 360(h)) requires that FDA inspect licensed medicated feed mills at least once every 2 years. During such inspections, FDA can ensure that medicated feed mills manufacturing free-choice or liquid medicated feed with proprietary formulas and/or specifications have the approved formula and/or specifications.

V. Environmental Impact

We have carefully considered the potential environmental impacts of this rule and determined under 21 CFR 25.30(h) 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 final rule merely clarifies existing regulations concerning liquid medicated feeds and free-choice medicated feeds.

VI. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts and equity). We believe that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866. We have also determined that the rule is not a significant regulatory action as defined

by the Executive order and so is not subject to review under the Executive order. Under the Regulatory Flexibility Act, if a regulation has a significant impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize the impact on small entities. FDA certifies in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) that this rule will not have a significant economic impact on a substantial number of small entities, and therefore, a regulatory flexibility analysis is not required.

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any regulation that may result in an expenditure by state, local and tribal governments in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule because the rule is not expected to result in any 1 year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is approximately $110 million.

The rule is intended to clarify, simplify, and elaborate on the current regulations concerning liquid medicated feeds and free-choice medicated feeds. This rule, which provides more precise and detailed provisions than the previous regulations, responds to requests submitted in citizen petitions and comments by an industry association. It also makes changes to the regulatory language for free-choice medicated feeds in order to be consistent with the ADAA provision that replaced the medicated feed application system with the medicated feed mill licensing system.

We did not receive any comments to the proposed rule that questioned the conclusions of the cost and benefit discussions. Further, changes made to the proposed rule as a result of other comments would not affect these conclusions. As such, we restate them for this final rule.

A. Liquid Medicated Feeds

The final rule for liquid medicated feeds clarifies the types of liquid medicated feeds for which a separate new animal drug approval is necessary and for which a medicated feed mill license is necessary. In particular, it fully elaborates on the procedures and requirements for demonstrating the chemical and physical stability of a drug in liquid feeds, as well as how the data from such a demonstration can be submitted to the agency.

The rule references requirements under 21 CFR 514.1 that are currently required for the approval of all new animal drugs. As these requirements do not represent a new burden, there is no cost associated with this aspect of the rule. Likewise, the rule adds to the current labeling provisions for certain drugs that are approved for use in animal feed or drinking water but not approved for use in certain liquid feeds. The rule describes the waiver process for the exclusion of certain products from these labeling requirements. Because this waiver process already exists under the current rule, it will not impose any additional cost to industry.

B. Free-Choice Medicated Feed

The revisions to § 510.455 concern free-choice medicated feed and very closely follow the liquid medicated feed proposal. Section 510.455 clarifies and elaborates on the NADA requirements for drugs intended for use in free-choice medicated feeds. In addition, it replaces the language that provided for the medicated feed application with language for the medicated feed mill licensing system that was created by ADAA. Because the estimated costs and benefits of the feed mill licensing system were prepared for the final regulations implementing that system, these costs and benefits are not considered to be effects of this rule. In total, the rule is not expected to impose any new compliance burdens on the industry and is not associated with any costs.

It is possible that the final rule will, in fact, result in some cost savings due to the provision that eliminates the requirement for a medicated feed mill license for the manufacture of some liquid and free-choice medicated feeds that contain a Category I drug. In recent years, we have received an average of 128 medicated feed mill license applications annually. Since the applications do not explicitly specify the types of medicated feed that would be manufactured, we are not able to estimate the size of the decrease in applications that would be expected as a result of the rule. However, we would expect there to be some decrease in applications as some feed mills would be exempted from this requirement in the future. We believe this could lead to a modest cost savings for these feed mills. Further, the increased clarity and simplification of §§ 510.455 and 558.5 would be expected to result in additional cost savings to industry in the preparation of new animal drug applications to the agency. We cannot precisely quantify such savings, but believe the impact to be modest.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

In this final rule, § 558.5 specifies procedures for obtaining a waiver from labeling requirements for certain drugs intended for use in animal feed or drinking water but not approved for use in liquid medicated feed. The following items must be included in a request for waiver: (1) A copy of the product label; (2) a description of the formulation; and (3) information to establish that the physical, chemical, or other properties of the product are such that diversion to use in liquid medicated feeds is unlikely. This information would be collected if the manufacturer or sponsor chose not to include the required warning ''FOR USE IN ____ONLY, NOT FOR USE IN LIQUID MEDICATED FEEDS'' on its product label. The sponsor or manufacturers would then need to satisfy the requirements of the waiver section of the regulation. The proposed burden estimate for this collection of information is 5 hours and will be included under the clearance for ''New Animal Drug Application,'' Office of Management and Budget (OMB) control number 0910–0032. All related data collections are already covered under OMB control number 0910–0032.

IX. Conforming Changes

FDA has made conforming changes in its regulations in 21 CFR 558.95, 558.305, 558.311, 558.342, 558.355, and 558.625 to remove references to the term ''medicated feed application.'' These conforming changes ensure the accuracy and consistency of the regulations.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling,

Reporting and recordkeeping requirements.

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, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.455 is revised to read as follows:

§ 510.455 Requirements for free-choice medicated feeds.

(a) *What is free-choice medicated feed*? For the purpose of this part, free-choice medicated feed is medicated feed that is placed in feeding or grazing areas and is not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Free-choice feeds include, but are not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements (''lick tank'' supplements) containing one or more new animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations in part 225 of this chapter for medicated feeds.

(b) *What types of approvals are required for new animal drugs intended for use in free-choice feed*? New animal drugs intended for use in free-choice feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(b)), as:

(1) An original new animal drug application (NADA),

(2) A supplemental NADA, or

(3) An abbreviated NADA.

(c) *What are the approval requirements for new animal drugs intended for use in free-choice feed*? (1) An approval under section 512 of the act is required for any new animal drug intended for use in a free-choice feed.

(2) An approved NADA for a Type A medicated article intended for use in free-choice feed must contain the following information:

(i) Data, or reference to data in a master file (MF), showing that the target animal consumes the new animal drug in the Type C free-choice feed in an amount that is safe and effective (consumption/effectiveness data); and

(ii) Data, or reference to data in a MF, showing the relevant ranges of conditions under which the drug will be chemically and physically stable in the Type C free-choice feed under field conditions.

(d) *How are consumption/effectiveness and/or stability data to be submitted*? The data must be submitted as follows:

(1) Directly in the NADA, by a sponsor; and/or

(2) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(e) *What will be stated in the published approval for a new animal drug intended for use in free-choice feed*? The approval of a new animal drug intended for use in free-choice feed, as published in this subchapter, will include:

(1) The formula and/or specifications of the free-choice medicated feed, where the owner of this information requests such publication, or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(f) *When is a medicated feed mill license required for the manufacture of a free-choice medicated feed*? An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All free-choice medicated feeds that contain a Category II drug, and

(2) Free-choice medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

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. Section 558.5 is revised to read as follows:

§ 558.5 Requirements for liquid medicated feed.

(a) *What types of liquid medicated feeds are covered by this section*? This section covers the following types of liquid medicated feed:

(1) Type B feed that is intended for further manufacture of other medicated feeds (§ 558.3(b)(3)) or:

(2) Type C feed that is intended for the following:

(i) Further manufacture of another Type C feed, or

(ii) Top-dressing (adding on top of the usual ration) (§ 558.3(b)(4)).

(b) *How is liquid free-choice medicated feed regulated*? Liquid free-choice medicated feed is covered by this section and by § 510.455.

(c) *What types of approvals are required for new animal drugs intended for use in liquid feed*? New animal drugs intended for use in liquid feed must be approved for such use under section 512 of the act, as:

(1) An original NADA,

(2) A supplemental NADA, or

(3) An abbreviated NADA.

(d) *What are the approval requirements for new animal drugs intended for use in liquid feed*? (1) An approval under section 512 of the act is required for any new animal drug intended for use in a liquid feed; and

(2) An approved new animal drug application (NADA) for a drug intended for use in liquid feed must contain the following information:

(i) Data, or a reference to data in a master file (MF), that shows the relevant ranges of conditions under which the drug will be chemically stable in liquid feed under field use conditions; and

(ii) Data, or a reference to data in an MF, that shows that the drug is physically stable in liquid feed under field conditions; or

(iii) Feed labeling with recirculation or agitation directions as follows:

(A) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(B) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *How are chemical and physical stability data to be submitted*? The data must be submitted as follows:

(1) Directly in the NADA,

(2) By a sponsor, or

(3) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(f) *What will be stated in the published approval for a new animal drug intended for use in liquid feed*? The approval of a new animal drug intended for use in liquid feed as published in this subchapter will include the following requirements:

(1) The formula and/or specifications of the liquid medicated feed, where the owner of this information requests such publication; and/or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(g) *When is a medicated feed mill license required for the manufacture of*

a liquid medicated feed? An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All liquid medicated feeds that contain a Category II drug, and

(2) Liquid medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

(h) *What measures are in place to prevent certain drugs, approved for use in animal feed or drinking water but not in liquid medicated feed, from being diverted to use in liquid feeds*? Any product containing any form of bacitracin, oxytetracycline, or chlortetracycline, intended for oral administration via animal feed and/or drinking water, and not approved for use in a liquid medicated feed must include in its labeling the following statement: ''FOR USE IN ____ONLY. NOT FOR USE IN LIQUID MEDICATED FEEDS.'' The blank may be filled in with the words: ''DRY FEEDS'', ''DRINKING WATER'', or ''DRY FEEDS AND DRINKING WATER''.

(i) *Can the labeling provisions of paragraph (h) of this section be waived, and how can I apply for a waiver*? (1) The labeling provisions of paragraph (h) of this section may be waived if there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

(2) To obtain a waiver, you must submit a letter requesting a waiver to the Office of New Animal Drug Evaluation (HFV–100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(3) The letter must include a copy of the product label; a description of the formulation; and information to establish that the physical, chemical, or other properties of the new animal drug are such that diversion to use in liquid medicated feed is unlikely.

(j) *What else do I need to know about the labeling provisions of paragraph (h) of this section*? The labeling provisions of paragraph (h) of this section may be implemented without prior approval as provided for in § 514.8(d) and (e) of this chapter.

§ 558.95 [Amended]

■ 5. Section 558.95 is amended in paragraph (d)(4)(iii)(*d*) by removing the last sentence.

§ 558.305 [Amended]

■ 6. Section 558.305 is amended in paragraphs (d)(1)(i) and (d)(1)(ii) by removing ''Type B'' wherever it appears.

■ 7. Section 558.311 is amended by revising paragraph (d); in paragraph (e)(2)(iv) by removing ''; each use of this Type C free-choice feed must be the subject of an approved FD–1900 as provided in § 510.455 of this chapter''; and in paragraph (e)(3)(iv) by removing the last sentence to read as follows:

§ 558.311 Lasalocid.

* * * * *

(d) *Special considerations.* (1) Type C cattle and sheep feeds may be manufactured from lasalocid liquid Type B feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable lasalocid liquid feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (d)(2) of this section, the manufacturer may secure approval of a positionally stable liquid feed by:

(i) Either filing a new animal drug application for the product or establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental new animal drug application to establish physical stability; and

(iii) Requesting the sponsor of an approved new animal drug application to file a supplement to provide for use of its lasalocid Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the supplemental new animal drug application will be approved. The approval will provide a basis for the individual liquid feed manufacturer to manufacture under a medicated feed license the liquid mediated feed described in the master file. A manufacturer who seeks to market a physically unstable lasalocid liquid feed with mixing directions different from the standard directions established in paragraph (d)(1) of this section may also follow this procedure.

(4) If adequate information is submitted to show that a particular liquid feed containing lasalocid is stable outside the pH of 4.0 to 8.0, the pH restriction described in paragraphs (d)(1) and (d)(2) of this section may be waived.

* * * * *

§ 558.342 [Amended]

■ 8. Section 558.342 is amended in paragraphs (d)(1)(i) and (d)(1)(ii) by removing the phrase ''Type B or C''; and in paragraph (d)(2) by removing ''positionally'' and by adding in its place ''physically.''

■ 9. Section 558.355 is amended by adding paragraph (d)(12); and by revising paragraphs (f)(3)(i)(*b*)(*1*), (f)(3)(i)(*b*)(*2*), (f)(3)(ix)(*b*), (f)(6)(i)(*b*)(*1*), and (f)(6)(i)(*b*)(*2*) to read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(12) Mixing directions for liquid feeds requiring recirculation or agitation:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

* * * * *

(f) *Conditions of use.* It is used as follows:

(3) *Cattle*—(i) *Amount per ton.* Monensin, 5–30 grams.

(*b*) *Limitations.* (*1*) Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 360 milligrams of monensin per head per day; as monensin sodium. Complete feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions as defined in paragraph (d)(12) of this section. The liquid feed must bear caution statement as follows: Inadequate mixing, (recirculation or agitation), of liquid feeds has resulted in increased

monensin concentration which has been fatal to cattle.

(*2*) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)(12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(*i*) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(*ii*) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(*iii*) Requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

* * * * *

(ix) *Amount.* * * *

* * * * *

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously at the rate of 8.2 to 10.2 kilograms (18 to 22.5 pounds) of Type C medicated feed per head per day to supply 240 milligrams of monensin and 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate. Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by equines has been fatal. Safe use in unapproved species and breeding cattle has not been established. The liquid medicated feed must bear expiration date of 14 days after date of manufacture. The mixing directions for this liquid medicated feed stored in recirculation or agitation tank systems are as defined in paragraph (d)(12) of this section.

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(6) *Goats*—(i) *Amount per ton.* Monensin, 20 grams.

* * * * *

(*b*) *Limitations.* (*1*) Feed only to goats being fed in confinement. Do not feed to lactating goats. Feed continuously in Type C feed as monensin sodium. Type C feed may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions, as defined in paragraph (d)(12) of this section. The liquid feed must bear caution statement as follows: Inadequate mixing, (recirculation or agitation), of liquid feeds has resulted in increased monensin concentration which could be fatal to goats.

(*2*) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(*i*) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(*ii*) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(*iii*) Requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

§ 558.625 [Amended]

■ 10. Section 558.625 is amended in paragraphs (c)(1)(i) and (c)(1)(ii) by removing ''Type B'' and by removing the phrase ''no fewer than 10 minutes'' and adding in its place the phrase ''not less than 10 minutes''.

Dated: May 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11943 Filed 5–26–04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–04–057]

RIN 1625–AA00

Security Zone; Potomac River, Washington, DC, and Arlington and Fairfax Counties, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone, May 27 through May 30, 2004, encompassing the waters of the Potomac River in order to safeguard a large number of high-ranking officials and spectators attending the dedication of the National World War II Memorial from terrorist acts and incidents. This action is necessary to ensure the safety of persons and property, and prevent terrorist acts or incidents. This rule prohibits vessels and people from entering the security zone and requires vessels and persons in the security zone to depart the security zone, unless specifically exempt under the provisions in this rule or granted specific permission from the Coast Guard Captain of the Port Baltimore.

DATES: This rule is effective from 4 a.m. local time on May 27, 2004, through 10 p.m. local time on May 30, 2004.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD05–04–057] and are available for inspection or copying at The Ports and Waterways Department of Coast Guard Activities Baltimore between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Ronald L. Houck, at Coast Guard Activities Baltimore, Waterways Management Branch, at telephone number (410) 576–2674.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On May 4, 2004, we published a notice of proposed rulemaking (NPRM) entitled ''Security Zone; Potomac River, Washington, DC and Arlington and Fairfax Counties, VA'' in the **Federal Register** (69 FR 24552). We received no letters commenting on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for