

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2010-N-0155]

Veterinary Feed Directive; Draft Text for Proposed Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; draft text for proposed regulation.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft text for a proposed regulation intended to improve the efficiency of FDA's Veterinary Feed Directive (VFD) program. The Agency is making this draft text for a proposal available because of the complex scientific and regulatory issues involved, and because of the potential impact that changes to the VFD regulations may have on stakeholders. The Agency invites the public to submit comments with questions and concerns about the draft text for a proposed regulation.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2010-N-0155, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2010-N-0155 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

This document is related to two other documents published elsewhere in this issue of the Federal Register, wherein FDA is announcing: (1) The availability of a guidance document entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (GFI #209) and (2) the availability of a draft guidance document entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209" (draft GFI #213).

In the Federal Register of March 29, 2010 (75 FR 15387), FDA published an advance notice of proposed rulemaking (ANPRM) with a 90-day comment period requesting comments on all aspects of the VFD regulations. FDA published a subsequent document in the Federal Register of June 28, 2010 (75 FR 36588), extending the ANPRM comment period for an additional 60 days.

While FDA encouraged comments on all aspects of the VFD regulations, the Agency requested input specifically on whether efficiency improvements need to be made to the current VFD regulations. The Agency received considerable comments from stakeholders suggesting that efficiency improvements are needed for the VFD regulations. FDA reviewed comments to the docket and, based on its review of those comments, developed draft text of regulatory language intended to implement specified changes to the existing regulations in part 558 (21 CFR part 558).

Comments to the docket confirmed that this is a very complex issue that potentially affects many different stakeholder interests. Having carefully considered the comments and

other relevant information, the Agency has prepared draft text for revisions to the existing regulatory language in part 558. Because stakeholders' interests are varied, striking the proper regulatory balance between sufficient veterinary oversight for VFD drugs and increased efficiency of the VFD process is a challenging proposition. Given the number and the nature of the comments received, and given the considerable impact proposed revisions potentially could have on stakeholders, FDA believes it is appropriate, before publishing an additional proposed rule, to offer stakeholders an opportunity to review and comment on our draft text of proposed revisions to the codified language in part 558.

For that reason, as provided for in §§ 10.40(f)(4) and 10.80(b)(2) (21 CFR 10.40(f)(4) and 21 CFR 10.80(b)(2)), FDA has decided to publish the draft text of proposed revisions to the codified language that the Agency has developed in response to public comments on this issue. FDA believes that, by making this document available under the provisions of §§ 10.40(f)(4) and 10.80(b)(2) and allowing an additional public comment period prior to publishing an additional proposed rule under the provisions of 21 CFR 10.40(b), the Agency will be able to develop a more informed proposal. When FDA publishes the proposed rule, the Agency will provide a detailed discussion of proposed changes to existing regulations.

The proposed revisions announced in this document were developed in conjunction with other initiatives designed to transition certain new animal drug products containing medically important antimicrobial drugs from an over-the-counter (OTC) status to a status that requires veterinary oversight. Specifically, the draft text of proposed revisions to part 558 reflect principles expressed in FDA's guidance document entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (GFI #209). Further, this draft text of proposed revisions is also consistent with the specific recommendations described in FDA's

draft guidance document entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209" (draft GFI #213). The notices of availability for GFI #209 and draft GFI #213 are both published elsewhere in this issue of the Federal Register.

FDA acknowledges that in order to facilitate the transition of certain new animal drug products from an OTC status to a status that requires veterinary oversight, existing requirements related to the distribution and use of VFD drugs must be updated and streamlined. As reflected in the draft text of proposed revisions to part 558 in this document, some of the key changes being considered include (1) providing for alignment between the criteria for appropriate veterinary supervision or oversight and those established as part of veterinary licensing and practice requirements, (2) providing veterinarians greater flexibility to exercise their professional discretion to authorize producer access to appropriate VFD drugs, and (3) streamlining administrative procedures. To facilitate the transition from OTC to VFD status, FDA believes it is critically important that changes such as these be implemented to minimize impacts on veterinarians, the animal feed industry, and animal producers.

FDA is requesting comments on the draft text of proposed revisions to part 558 as well as comments on any other aspect of the VFD regulations, including aspects of the regulations not specifically addressed in the draft text of the proposal. FDA recognizes that it is critically important that the Agency work with the veterinary and animal producer communities, the end users of the affected products, to ensure that their concerns are taken into consideration as these changes are implemented. With this in mind, FDA is very interested in receiving comments on the practical implications of these changes for animal producers, particularly those with smaller

operations in remote locations. The Agency is also interested in receiving input on how impacts or disruption to animal producers could be minimized.

FDA acknowledges that one issue of concern is the ability of producers, particularly those with smaller operations in remote locations, to have adequate access to veterinary services. Therefore, as steps are taken to phase in the changes discussed in this document, FDA recognizes the need to concurrently engage key stakeholders on this broader issue. Therefore, FDA intends to work collaboratively with U. S. Department of Agriculture (USDA) to engage the veterinary community and other stakeholders to explore strategic approaches (e.g., new models, pilot programs) to address this issue.

FDA encourages the submission of comments on the draft text of this proposed regulation so that practical implementation concerns are adequately considered and addressed. However, FDA is also exploring other venues for seeking and obtaining input, particularly from animal producers, such as through listening sessions held in various parts of the country. FDA is working closely with the USDA to identify mechanisms for obtaining this critical input.

The draft text of the proposed regulation is provided in this document and in the docket (refer to the docket number in brackets in the heading of this document). The Agency emphasizes that the draft text of the proposed revisions does not represent final Agency action or the Agency's final decision on this regulation.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments on this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the

heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Accordingly, 21 CFR part 558 is proposed to be 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.

2. In § 558.3, republish the introductory text of paragraph (b), and revise paragraphs (b)(1) and (b)(7) to read as follows:

§ 558.3 Definitions and general considerations applicable to this part.

* * * * *

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I--These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) Category II--These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a “no-residue” basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required.

* * * * *

(7) A "veterinary feed directive" is a written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client's animals only in accordance with the directions for use approved, conditionally approved, or indexed by the Food and Drug Administration (FDA).

* * * * *

3. Revise § 558.6 to read as follows:

§ 558.6 Veterinary feed directive drugs.

(a) General requirements related to veterinary feed directives (VFD):

(1) A feed containing a VFD drug (a VFD feed) shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian's professional practice.

(2) VFDs may not be filled after the expiration date on the VFD.

(3) Use and labeling of a VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. Extralabel use (i.e., actual or intended use other than as directed on the labeling) is not permitted.

(4) All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD and any other required records for 1 year.

(5) All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA.

(6) All labeling and advertising for VFD drugs and feeds containing VFD drugs must prominently and conspicuously display the following cautionary statement: "Caution: Federal

law restricts medicated feed containing this VFD drug to use by or on the order of a licensed veterinarian."

(b) Responsibilities of the veterinarian issuing the VFD:

(1) The veterinarian may only issue a VFD for use in animals under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements.

(2) The veterinarian must fully and accurately enter the following information on the VFD:

(i) The veterinarian's name, address, and telephone number;

(ii) The client's name, telephone number, and business or home address;

(iii) The premises at which the animals specified in the VFD are located;

(iv) The date of VFD issuance;

(v) The expiration date of the VFD. This date cannot extend beyond the expiration date specified in the approval, conditional approval, or index listing, if such date is specified. In cases where the expiration date is not specified in the approval, conditional approval, or index listing, the expiration date of the VFD cannot exceed 6 months after the date of issuance;

(vi) The name of the animal drug;

(vii) The species and production class of animals to be fed the medicated feed;

(viii) The approximate number of animals to be fed the medicated feed prior to the expiration date on the VFD;

(ix) The indication for which the VFD is issued;

(x) The level of drug in the feed and duration of use;

(xi) The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;

(xii) The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing;

(xiii) The statement: "Extralabel use (i.e., use of this VFD feed in a manner other than as directed on the labeling) is not permitted"; and

(xiv) The veterinarian's electronic or written signature.

(3) The veterinarian may, at his or her discretion, enter the following information on the VFD to more specifically identify the animals authorized to be treated/fed the medicated feed:

(i) A more specific description of the location of animals (e.g., by site, pen, barn, stall, tank, or other descriptor that the veterinarian deems appropriate);

(ii) The approximate age range of the animals;

(iii) The approximate weight range of the animals; and

(iv) Any other information the veterinarian deems appropriate to identify the animals specified in the VFD.

(4) The veterinarian must send the VFD to the feed distributor via hardcopy, fax, or electronically. If in hardcopy, the veterinarian may send the VFD to the distributor either directly or through the client.

(5) The veterinarian must provide a copy of the VFD to the client.

(6) The veterinarian may not transmit a VFD by phone.

(c) Responsibilities of any person who distributes an animal feed containing a VFD drug:

(1) The distributor may only fill a VFD if the VFD contains the information required in § 558.6(b)(2).

(2) The distributor may only distribute an animal feed containing a VFD drug that complies with the terms of the VFD.

(3) A distributor of animal feed containing VFD drugs must notify FDA at the time it first distributes animal feed containing VFD drugs. The notification is required one time per distributor and must include the following information:

- (i) The distributor's complete name and business address;
- (ii) The distributor's signature or the signature of the distributor's authorized agent; and
- (iii) The date the notification was signed;

(4) A distributor must submit the notification by letter or facsimile to the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 7519 Standish Pl., Rockville, MD 20855, prior to beginning its first distribution.

(5) A distributor must notify the Center for Veterinary Medicine within 30 days of any change in ownership, business name, or business address.

(6) A distributor may only distribute a VFD feed to another person for further distribution if the distributor first obtains a written acknowledgment from the person to whom the feed is shipped stating that that person must not ship or move such feed to an animal production facility without a VFD, or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to the distributor's immediate supplier.

Dated: April 5, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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