4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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

Veterinary Feed Directive Regulation Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Draft revised guidance; availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for industry (GIF) #120 entitled "Veterinary Feed Directive Regulation Questions and Answers." The purpose of this document is to describe the current Veterinary Feed Directive (VFD) requirements for veterinarians, feed manufacturers and other distributors, animal producers, and other parties involved in the distribution or use of medicated feed containing a veterinary feed directive drug (VFD feed). This draft revised guidance reflects changes to the VFD requirements under the VFD final rule.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dragan Momcilovic, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6856, dragan.momcilovic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revised GFI #120 entitled "Veterinary Feed Directive Regulation Questions and Answers." The audience for this draft guidance is comprised of veterinarians issuing VFD orders, feed mills manufacturing VFD feeds and other distributors, animal producers who obtain VFD feeds for use in treating their animals, and others. This draft revised guidance reflects changes to the VFD requirements under the VFD final rule published elsewhere in this edition of the Federal Register.

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) to facilitate the approval and marketing of new animal drugs and medicated feeds. In passing the ADAA, Congress created a new regulatory category for certain animal drugs used in animal feed called veterinary feed directive (VFD) drugs. VFD drugs are new animal drugs intended for use in or

on animal feed which are limited to use under the professional supervision of a licensed veterinarian. FDA published final regulations implementing the VFD-related provisions of the ADAA in 2000.

Elsewhere in this edition of the Federal Register, FDA is publishing a VFD final rule that revises those VFD regulations and introduces clarifying changes to specified definitions. This draft revised guidance includes revisions that are consistent with the requirements in that final rule.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not establish any rights for or on any person and does is not binding on FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 558.6 have been approved under OMB control number 0910-0363.

IV. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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, and will be posted to the docket at http://www.regulations.gov.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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