4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3056]

Distributor Labeling for New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GIF) #231 entitled "Distributor Labeling for New Animal Drugs." This draft guidance discusses FDA's current thinking with respect to the factors it considers in determining whether to take regulatory action against distributor labeling for a new animal drug that differs from the labeling approved as part of a New Animal Drug Application or Abbreviated New Animal Drug Application (NADA/ANADA) in ways other than those permitted by regulation.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Dorothy McAdams, Center for Veterinary Medicine, Division of Surveillance (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5763, email: dorothy.mcadams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #231 entitled "Distributor Labeling for New Animal Drugs." "Distributor labeling" refers to the labeling of an approved new animal drug marketed by a distributor who distributes the product under its own label or proprietary name. Unlike the approved labeling, which the Center for Veterinary Medicine reviews as part of a NADA/ANADA approval process to ensure the safe and effective use of the drug and compliance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and its implementing regulations, distributor labeling does not ordinarily go through a premarket approval process.

FDA regulations (21 CFR 514.80) require that distributor labeling be identical to the labeling approved in the NADA/ANADA, except for a different and suitable proprietary name and the name and address of the distributor preceded by an appropriate qualifying phrase. These requirements are meant to ensure that distributor labeling complies with the requirements of the

FD&C Act and its implementing regulations and to prevent distributor label products from reaching the market with labeling that compromises the safe and effective use of the new animal drug.

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 current thinking of FDA on distributor labeling for new animal drugs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it 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 § 514.80 have been approved under OMB control number 0910-0284.

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: September 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-22772 Filed: 9/9/2015 08:45 am; Publication Date: 9/10/2015]