4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0839]

Target Animal Safety Data Presentation and Statistical Analysis; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #226 entitled "Target Animal Safety Data Presentation and Statistical Analysis." The purpose of this document is to provide recommendations to industry regarding the presentation and statistical analyses of target animal safety (TAS) data submitted to the Center for Veterinary Medicine (CVM) as part of a study report to support approval of a new animal drug. These recommendations apply to TAS data generated from both TAS and field effectiveness studies conducted in companion animals (e.g., dogs, cats, and horses) and food animals (e.g., swine, ruminants, fish, and poultry).

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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 Communications Staff (HFV-12), 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Virginia Recta, Center for Veterinary Medicine (HFV-164), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0840, virginia.recta@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #226 entitled "Target Animal Safety Data Presentation and Statistical Analysis." It is intended to provide recommendations to industry regarding the presentation and statistical analyses of TAS data submitted to CVM as part of a study report to support approval of a new animal drug. These recommendations apply to TAS data generated from both TAS and field effectiveness studies conducted in companion animals (e.g., dogs, cats, and horses) and food animals (e.g., swine, ruminants, fish, and poultry).

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 "Target Animal Safety Data Presentation and Statistical Analysis." 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 21 CFR part 514 have been approved under OMB control number 0910-0032.

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: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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