



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0928]

Recommendations for Preparation and Submission of Animal Food Additive Petitions; 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 guidance for industry (GFI) #221 entitled "Recommendations for Preparation and Submission of Animal Food Additive Petitions." This guidance describes the types of information that FDA's Center for Veterinary Medicine recommends for inclusion in food additive petitions submitted for food additives intended for use in food for animals. It is intended to help the petitioner submit this information in a consistent and appropriate manner.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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 guidance document.

Submit electronic comments on the 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: Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-7077; AskCVM@fda.hhs.gov, in the subject line please include ATTN: Division of Animal Feeds.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 11, 2013 (78 FR 55727), FDA published the notice of availability for a draft guidance entitled "Recommendations for Preparation and Submission of Animal Food Additive Petitions" giving interested persons until November 12, 2013, to comment on the draft guidance. In the Federal Register of December 10, 2013 (78 FR 74154), FDA published a notice reopening the comment period for the draft guidance giving interested persons until January 9, 2014, to comment on the draft guidance.

FDA received four comments on the draft guidance and considered those comments as we finalized the guidance. The guidance announced in this notice finalizes the draft guidance dated September 2013.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on recommendations for preparation and submission of animal food additive petitions. 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 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 571.1 and 571.6 have been approved under OMB control number 0910-0546.

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 guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: June 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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