4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Recommendations for Preparation and Submission of Animal Food Additive Petitions; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #221) entitled "Recommendations for Preparation and Submission of Animal Food Additive Petitions."

This draft guidance describes the types of information that FDA's Center for Veterinary Medicine (CVM) recommends for inclusion in food additive petitions (FAPs) submitted for food additives intended for use in food for animals. It is intended to help the petitioner submit such FAP information in a consistent and appropriate manner.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Sharon Benz, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6864, sharon.benz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI #221) entitled "Recommendations for Preparation and Submission of Animal Food Additive Petitions." It is intended to help petitioners submit FAP information in a consistent and appropriate manner.

The requirements for submitting an animal food additive petition to FDA are set forth in section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) and 21 CFR part 571. This draft guidance provides information for complying with these requirements.

This draft guidance includes the following information:

- How to determine if an animal food ingredient is already the subject of an approved FAP.
- Who to contact for more information about approved food additives.
- Who to contact for more information on how to submit an FAP for approval.
- When and how to request a pre-petition consultation with CVM before submitting an FAP.

- When and how to submit study designs for CVM review.
- What data CVM considers adequate to support an FAP.
- Where to find other FDA guidances that may be helpful when preparing and submitting an FAP to CVM.
- General recommendations for the format of an FAP submission.
- Where and how to submit an FAP.

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 create or confer any rights for or on any person and does not operate to bind 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 §§ 571.1 and 571.6 have been approved under 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 draft guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: September 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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