



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1009]

Draft Guidance for Industry on Use of Nanomaterials in Food for Animals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #220) entitled "Use of Nanomaterials in Food for Animals." The draft guidance describes FDA's current thinking regarding the use of nanomaterials or the application of nanotechnology in food for animals. It is intended to assist industry and other stakeholders in identifying potential issues related to safety or regulatory status of food for animals containing nanomaterials or otherwise involving the application of nanotechnology.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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: 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FDA is announcing the availability of a draft guidance for industry (GFI #220) entitled "Use of Nanomaterials in Food for Animals." This draft guidance applies to food ingredients that are intended for use in food for animals and either: (1) Consist entirely of nanomaterials, (2) contain nanomaterials as a component, or (3) otherwise involve the application of nanotechnology.

This guidance is not applicable to other products regulated by FDA, including food substances intended for use in food for humans. This guidance also does not apply to food contact substances or color additives intended for use in food for animals or food for humans.

Medicated feed contains new animal drugs approved for use in or on animal food. This guidance does not apply to a nanomaterial form of a new animal drug or drug component (e.g., drug carrier) in medicated feed. However, it does apply to nanomaterial animal food ingredients in medicated feed.

This guidance is not intended to bring into question the regulatory status of animal food ingredients that naturally exist in the nanoscale range or that contain incidental amounts of

particles in the nanoscale range, and that have already been determined to be generally recognized as safe or approved in response to a food additive petition.

A notice announcing the availability of another draft guidance (GFI #221) entitled "Recommendations for Preparation and Submission of Animal Food Additive Petitions" was published in the Federal Register on September 11, 2013 (78 FR 55727). GFI #221, when finalized, would provide information regarding the submission of food additive petitions (FAPs) for animal food additives. This draft guidance (GFI #220) would provide additional information that would be useful when submitting FAPs for nanomaterial animal food additives and would supplement the information provided in GFI #221.

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 21 CFR 571.1 and 571.6 have been approved under OMB control number 0910-0546; the collections of information in 21 CFR 70.25, 71.1, 170.35, 171.1, 21 CFR parts 172, 173, 179, and 180, and in Form FDA 3503, have been approved under OMB control number 0910-0016.

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: June 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.