Dated: June 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15034 Filed 6–26–14; 8:45 am]

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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Draft Guidance for Industry on Use of Nanomaterials in Food for Animals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #220) entitled ''Use of Nanomaterials in Food for Animals.'' The draft guidance describes FDA's current thinking regarding the use of nanomaterials or the application of nanotechnology in food for animals.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 10, 2014.

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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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FDA is announcing the availability of a draft guidance for industry (GFI #220) entitled ''Use of Nanomaterials in Food for Animals.'' This draft guidance applies to food ingredients that are intended for use in food for animals and either: (1) Consist entirely of nanomaterials, (2) contain nanomaterials as a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.

[FR Doc. 2014–15030 Filed 6–26–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0636]

Global Unique Device Identification Database; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled

''Global Unique Device Identification Database (GUDID): Guidance for Industry and Food and Drug Administration Staff.'' This guidance finalizes, as a single document, all sections of, ''Global Unique Device Identification (GUDID): Draft Guidance for Industry.'' The guidance includes, with minor modifications, the previously finalized sections on how device labelers will interface with the GUDID, establish GUDID accounts and begin initial submissions. The guidance also finalizes the sections on the Device Identifier (DI) record, Health Level 7 Structured Product Labeling (HL7 SPL) submission, search/retrieval of devices information, and GUDID submissions and maintaining and submitting electronic records. The guidance also finalizes Appendix A—GUDID Package Information Examples.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Global Unique Device Identification Database (GUDID): Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Bldg. 71, rm. 3128, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to the office from which you are ordering to assist in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For information concerning the guidance as it relates to devices regulated by CDRH:* Indira Konduri, UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3303, Silver Spring, MD 20993–0002, 301–796–5995, email: *udi@fda.hhs.gov.*

For information concerning the guidance as it relates to devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) and section 614 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification (UDI) system for medical devices along with implementation timeframes for certain medical devices. The UDI system final rule was published on September 24, 2013 (78 FR 58786).

In developing the final rule, FDA solicited and considered input from a variety of stakeholders including manufacturers, global regulatory bodies, the clinical community, and patient advocates to ensure that as many perspectives as possible were incorporated. The GUDID is a critical component of the UDI System. The UDI assigned to each device is a globally unique, yet unintelligent code identifying the device, and is composed of the static DI portion and the dynamic production identifier. The GUDID will house the DI, along with key descriptive or ''attribute'' information about the device, which is reported and updated to the GUDID by the device labeler. Being unique for each device, the DI component of the UDI can be effectively used by stakeholders to access the GUDID attribute information for that device.

On September 24, 2013 (78 FR 58545), FDA released a document titled ''Global Unique Device Identification (GUDID): Draft Guidance for Industry'' (the draft guidance). During the 60-day comment period, which ended on November 25, 2013, more than 300 comments were received from 21 entities. In order to finalize the sections with the most questions from GUDID submitters, FDA released the first part of this finalized guidance on June 11, 2014 (79 FR 33568), providing general information to labelers to enable them to obtain a GUDID account and begin initial submissions to the GUDID.

FDA is now, in a single document, finalizing all sections of the draft guidance. The finalized guidance includes, with minor modifications, the previously released information on how device labelers will interface with the GUDID, establish GUDID accounts, and begin initial submissions. The principal modifications include reformatting changes to rearrange sections from 3.2. to 3.1 to improve the document flow, adding a paragraph in section 2 in response to an industry comment, and adding a paragraph in section 4 that had been inadvertently omitted in the document released on June 11, 2014. In addition, this guidance finalizes sections in the draft guidance on the DI record, HL7 SPL submission, search/retrieval of devices information, and GUDID submissions and 21 CFR part 11 requirements. We also are finalizing Appendix A—GUDID Package Information Examples. This guidance supersedes the June 11, 2014, guidance entitled ''Global Unique Device Identification Database (GUDID): Guidance for Industry.''

Elsewhere, we continue to make available on the Internet at the FDA/UDI Web site (*http://www.fda.gov/udi*) updated versions of two appendices of the draft guidance: The section formerly identified as ''Appendix B'' which summarizes the device attribute information that will populate the GUDID, renamed as ''GUDID Data Elements Reference Table'' and the section formerly identified as ''Appendix C'' which summarizes the UDI formats accepted by the issuing Agencies that FDA has accredited to date, renamed as ''UDI Formats by FDA-Accredited Issuing Agency.'' These two documents contain technical specifications and will not be published as a part of this guidance that describes the Agency's interpretation of or policy on a regulatory issue. For those without Internet access or who otherwise would like to receive a hard copy of the currently updated version of either of these documents, formerly published as Appendix B and Appendix C of the draft guidance, should call the people listed under **FOR FURTHER INFORMATION CONTACT** to request the document(s).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking about the GUDID. 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 for interfacing with the GUIDID may be used with prior FDA

approval if such approach satisfies the technical requirements of the GUDID and the requirements of the applicable statute and regulations. If you wish to use an alternative approach for submitting a specific required data element, you may request FDA approval by email or writing to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 3303, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, email: *udi@fda.hhs.gov* (Attention: UDI Regulatory Policy Support). If a labeler has a waiver from electronic submission of GUDID data under 21 CFR 830.320(c), the labeler should send a letter containing all of the information otherwise required by this guidance, as well as any permitted ancillary information that the labeler wishes to submit, within the time permitted to: UDI Regulatory Policy Support at the address indicated in the previous sentence. See 21 CFR 830.320(c)(3).

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*, or at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Global Unique Device Identification Database (GUDID): Guidance for Industry'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1831 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information described 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 collection of information in 21 CFR part 830 pertaining to GUDID labeler accounts and data submissions addressed in this guidance document have been approved under OMB control number 0910–0720.

V. 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.*

Dated: June 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0489]

Guidance for Industry: Safety of Nanomaterials in Cosmetic Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Guidance for Industry: Safety of Nanomaterials in Cosmetic Products.'' The guidance represents our current thinking on the safety assessment of nanomaterials in cosmetic products. This guidance is intended to help industry identify the potential safety issues of nanomaterials in cosmetic products and develop a framework for evaluating them.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition (HFS–125), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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: Kapal Dewan, Center for Food Safety and Applied Nutrition (HFS–125), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1130.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Guidance for Industry: Safety of Nanomaterials in Cosmetic Products.'' This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our 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.

In the **Federal Register** of April 25, 2012 (77 FR 24722), we made available a draft guidance entitled ''Guidance for Industry: Safety of Nanomaterials in Cosmetic Products'' and gave interested parties an opportunity to submit comments by July 24, 2012, for us to consider before beginning work on the final version of the guidance. We received several comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include:

- The addition of several references, such as references pertaining to analytical techniques for measuring physicochemical properties of nanomaterials;
- Revised text concerning potential differences between nanomaterials and their larger-scale counterparts with the same chemical composition. For example, the guidance discusses how the small particle size of a nanomaterial has the potential to alter biodistribution and bioavailability;
- New text concerning thorough characterization of nanomaterials; and
- Revised text concerning toxicology considerations and toxicological testing.

In addition, we made editorial changes to improve clarity.

The guidance announced in this notice finalizes the draft guidance dated April 2012.

II. Comments

Interested persons may submit either electronic comments regarding the guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It