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.

[FR Doc. 2014–15020 Filed 6–26–14; 8:45 am]

BILLING CODE 4164–01–P

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

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.*

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/CosmeticGuidances or http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15032 Filed 6–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0490]

Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives; 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 entitled ''Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives.'' The guidance explains FDA's current thinking on the factors to be considered when determining whether changes in manufacturing process, including the intentional reduction in particle size to the nanoscale, for a food substance already in the market affect the identity of the food substance, impact the safety of the use of the food substance, change the regulatory status of the use of the food substance, or warrant a new regulatory submission to FDA.

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

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives'' to the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, 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 requests. 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: Teresa Croce, Center for Food and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1281.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance entitled ''Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives.'' The guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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 applicable statutes and regulations. This guidance represents FDA's current thinking on the factors to be considered when determining whether changes in manufacturing process, including the intentional reduction in particle size to the nanoscale, for a food substance already in the market affect identity of the food substance, impact the safety of the use of the food substance, change the regulatory status of the use of the food substance, or warrant a new regulatory submission to FDA.

In the **Federal Register** of April 25, 2012 (77 FR 24722), we made available a draft guidance entitled ''Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives'' 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. The guidance announced in this notice finalizes the draft guidance dated April 2012.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 §§ 170.101, 170.106, and 171.1 have been approved under OMB control number 0910–0495; the collections of information in §§ 70.25, 71.1, 170.35, and 171.1 have been approved under OMB control number 0910–0016; the collections of information in § 170.39 have been approved under OMB control number 0910–0298; and the collections of information in proposed § 170.36 (62 FR 18938, April 17, 1997) has been approved under OMB control number 0910–0342.

III. Comments

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

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/FoodGuidances* or at *http://www.regulations.gov.* Use the FDA Web site listed in the previous