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In the Federal Register of April 25, 2012 (77 FR 24722), we made available a draft guidance entitled "Guidance for Industry: Safety of Nanomaterials in Cosmetic Products" and gave interested parties an opportunity to submit comments by July 24, 2012,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 06/26/2014 at 8:45 am; Publication Date: 06/27/2014]