



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0489]

Draft Guidance for Industry: Safety of Nanomaterials in Cosmetic Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for Industry: Safety of Nanomaterials in Cosmetic Products."

The draft guidance, when finalized, will represent FDA's current thinking on the safety assessment of nanomaterials in cosmetic products. This guidance is intended to assist industry in identifying the potential safety issues of nanomaterials in cosmetic products and developing a framework for evaluating them.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition (HFS-100), Food and Drug Administration, 5100 Paint Branch Pkwy., College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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft guidance entitled "Guidance for Industry: Safety of Nanomaterials in Cosmetic Products." The draft guidance is intended to assist industry in identifying the potential safety issues of nanomaterials in cosmetic products and developing a framework for evaluating these issues.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the safety of nanomaterials in cosmetic products. 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.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/CosmeticGuidances> or <http://www.regulations.gov>. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: April 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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