

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 25, 2012.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title "Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma." Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** ≤lla S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, [lla.Mizrachi@fda.hhs.gov](mailto:lla.Mizrachi@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma—(OMB Control Number 0910-NEW)**

FDA is finalizing the labeling requirements for blood or blood components intended for use in transfusion or for further manufacture under the provisions of the Public Health Service Act (PHS Act) (42 U.S.C. 262-264), and the drugs, devices, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 331, 351-353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled, and to prevent the introduction, transmission, and spread of communicable disease.

Under this rulemaking, FDA is consolidating the regulations related to labeling blood and blood components. Regulations for labeling of blood and blood components will be consolidated

into § 606.121 (Container label) (21 CFR 606.121) and § 606.122 (Circular of information) (21 CFR 606.122). This notice solicits comments on the information collection associated with § 606.121(c)(11), which requires that if the product is intended for further manufacturing use, a statement listing the results of all the tests for communicable disease agents required under § 610.40 (21 CFR 610.40) for which the donation has been tested and found negative must be on the container label; except that the label for Source Plasma is not required to list the negative results of serological syphilis testing under § 610.40(i) and 21 CFR 640.65(b). In addition, this notice also solicits comments on the information collection associated with § 606.121(e)(2)(i), which requires that the product labels of certain red blood cells must include the type of additive solution with which the product was prepared.

The Agency believes the rule amendments and the information collection provisions under § 606.121(c)(11) and (e)(2)(i) in the final rule are part of usual and customary business practice and do not create any new burden for respondent.

The collection of information requirements under §§ 606.121 and 606.122 are approved under OMB control number 0910-0116 and those in 21 CFR 640.70 have been approved under OMB control number 0910-0338. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

In the **Federal Register** of December 30, 2011 (76 FR 82300), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Dated: April 19, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-9894 Filed 4-24-12; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-0001]

**The 15th Annual Food and Drug Administration—Orange County Regulatory Affairs Educational Conference in Irvine, CA; "Sustainable Regulatory Practices"**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of conference.

The Food and Drug Administration (FDA) is announcing the following conference: The 15th Annual Educational Conference cosponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the drug, device, biologics, and dietary supplement industries with an opportunity to interact with FDA reviewers and compliance officers from the Centers and District Offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive Q & A, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

**Date and Time:** The conference will be held on June 6 and 7, 2012, from 7:30 a.m. to 5 p.m.

**Location:** The conference will be held at the Irvine Marriott, 18000 Von Karman Ave., Irvine, CA 92612.

**Contact:** Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, 949-608-4413, Fax: 949-608-4417, or OCRA, Attention to Detail, 5319 University Dr., suite 641, Irvine, CA 92612, 949-387-9046, Fax: 949-266-8461, Web site: [www.ocra-dg.org](http://www.ocra-dg.org). (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

**Registration and Meeting Information:** See OCRA Web site, [www.ocra-dg.org](http://www.ocra-dg.org). Contact Attention to Detail, 949-387-9046.

Before May 8, 2012, registration fees are as follows: \$675 for members, \$725 for non-members and \$475 for FDA/Government/Students.<sup>1</sup> After May 8, 2012, fees will be \$725 for members, \$775 for non-members, and \$475 for

<sup>1</sup> OCRA Student Rate applies to those individuals enrolled full time in a Regulatory or Quality related academic program at an accredited institution. Proof of enrollment is required.

FDA/Government/Students.<sup>2</sup> There will also be a 1-day rate of \$425 for OCRA members and \$475 for non-members.

The registration fee will cover actual expenses, including refreshments, lunch, materials, parking, and speaker expenses.

If you need special accommodations due to a disability, please contact Linda Hartley (see *Contact*) at least 10 days before the conference.

Dated: April 20, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–9968 Filed 4–24–12; 8:45 am]

BILLING CODE 4160–01–P

## 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 July 24, 2012.

**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:**

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**

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.*

[FR Doc. 2012–9934 Filed 4–24–12; 8:45 am]

BILLING CODE 4160–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–D–0490]

#### **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; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft 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 draft guidance, when finalized, will explain 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 affects the safety and regulatory status of the food substance, and whether a new regulatory submission to FDA is warranted.

**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 written or electronic comments on the draft guidance by July 24, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft 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),

<sup>2</sup> See footnote 1.