FDA/Government/Students.[2] 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Draft Guidance for Industry: Safety of Nanomaterials in Cosmetic Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Industry: Safety of Nanomaterials in Cosmetic Products.'' The draft guidance, when finalized, will represent FDA's current thinking on the safety assessment of nanomaterials in cosmetic products.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 24, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition (HFS–100), Food and Drug Administration, 5100 Paint Branch Pkwy., College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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

[2] See footnote 1.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.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),

Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 240–402–1200. 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette M. McCarthy, Center for Food and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1057, FAX 301–436–2972, email: *Annette.McCarthy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document 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.'' This draft guidance, when finalized, will represent 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 is warranted.

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 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.

II. 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 §§ 170.101, 170.106, 171.1 (21 CFR 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 [1] have been approved under OMB control number 0910–0342.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.regulations.gov* or *http://www.fda.gov/FoodGuidances.* 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. 2012–9936 Filed 4–24–12; 8:45 am]

BILLING CODE 4160–01–P

[1] In April 1997, FDA proposed a voluntary procedure (proposed § 170.36) whereby manufacturers would notify FDA about a view that a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is generally recognized as safe (GRAS) (62 FR 18938, April 17, 1997). FDA invited interested persons who determine that a use of a substance is GRAS to notify FDA of those determinations, under the framework of the 1997 proposed rule, during the interim between the proposed and final rules (62 FR 18938 at 18954). FDA received OMB approval for submissions received under the framework of the 1997 proposed rule.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0370]

AstraZeneca Pharmaceuticals LP; Withdrawal of Approval of a New Drug Application for IRESSA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for IRESSA (gefitinib) Tablets held by AstraZeneca Pharmaceuticals LP (AstraZeneca), 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355. AstraZeneca has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

DATES: Effective April 25, 2012.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6250, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: FDA approved IRESSA (gefitinib) Tablets on May 2, 2003, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. IRESSA is indicated as monotherapy after failure of both platinum-based and docetaxel chemotherapies for the continued treatment of patients with locally advanced or metastatic non-small cell lung cancer who are benefiting or have benefited from IRESSA. On August 26, 2010, FDA requested that AstraZeneca voluntarily withdraw IRESSA (gefitinib) Tablets from the market, because the postmarketing studies required as a condition of approval under subpart H failed to verify and confirm clinical benefit. In a letter dated February 1, 2011, AstraZeneca requested that FDA withdraw approval of NDA 21–399 for IRESSA (gefitinib) Tablets, which AstraZeneca characterized as a business decision, effective September 30, 2011. In that letter, AstraZeneca waived any opportunity for a hearing otherwise provided under §§ 314.150 and 314.530. The letter also stated that approximately 250 patients then receiving IRESSA treatment through the Iressa Access Program would continue treatment under an expanded access program, but no new patients would be added to the protocol. In FDA's letter of February 4, 2011, responding to AstraZeneca's