exempt from the major food allergen labeling requirement. An individual may petition for an exemption by providing scientific evidence, including the analytical method used, that an ingredient ''does not cause an allergic response that poses a risk to human health.'' (21 U.S.C. 403(w)(6)(C)). Alternatively, an individual may submit a notification that contains either scientific evidence showing that an ingredient ''does not contain allergenic protein'' or that a determination has previously been made through a premarket approval process that the ingredient ''does not cause an allergic response that poses a risk to human health.'' (21 U.S.C. 403(w)(7)(A)).

In addition to their intended use as ingredients, the unintended presence of major food allergens in foods may occur through cross-contact. Cross-contact describes the inadvertent introduction of an allergen into a product that would not intentionally contain that allergen as an ingredient. Most cross-contact can be avoided by controlling the production environment. While we have used several risk management strategies to reduce the risk of exposure to unlabeled major food allergens, we have not established regulatory thresholds or action levels for major food allergens. The establishment of regulatory thresholds or action levels for major food allergens would help us determine whether, or what type of, enforcement action is appropriate when specific problems are identified and also help us establish a clear standard for evaluating claims in FALCPA petitions that an ingredient ''does not cause an allergic response that poses a risk to human health'' or ''does not contain allergenic protein.'' Regulatory thresholds also would help industry to conduct allergen hazard analyses and develop standards for evaluating the effectiveness of allergen preventive controls. We have previously evaluated the approaches that could be used for establishing thresholds for food allergens, as we reported in March 2006. Since the publication of that report, there have been significant advances in both scientific tools and data resources related to food allergens. Therefore, we intend to determine if the currently available data and analysis tools are sufficient to support a quantitative risk assessment and, if so, to use these data and tools to evaluate the public health impact of establishing specific regulatory thresholds for one or more of the major food allergens.

We recently received requests from trade associations for an extension of the comment period until either April 1, 2013, or May 13, 2013. These requests conveyed the concern that the current 60-day comment period does not allow sufficient time to collect responsive information and data to submit to FDA.

We considered the requests and, through this notice, are extending the comment period for all interested persons until May 13, 2013.

II. Request for 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.*

III. References

FDA has placed the following reference on display. To view the reference, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box. The reference may also be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

1. Threshold Working Group. 2006. Approaches to Establish Thresholds for Major Food Allergen and for Gluten in Food. Available at *http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106108.htm.*

Dated: January 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02319 Filed 2–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0068]

International Conference on Harmonisation; Draft Guidance on S10 Photosafety Evaluation of Pharmaceuticals; 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 ''S10 Photosafety Evaluation of Pharmaceuticals.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. The draft guidance includes criteria for initiation of and triggers for additional photosafety testing and should be read in conjunction with the ICH M3(R2) guidance, section XIV(14) Photosafety Testing. The purpose of the draft guidance is to recommend international standards for photosafety assessment and to harmonize such assessments that support human clinical trials and marketing authorization for pharmaceuticals.

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 March 21, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the 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.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Abigail Jacobs, Center for Drug Evaluation and Research (ONDIO), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0174.

Regarding the ICH: Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3342, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry

associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In November 2012, the ICH Steering Committee agreed that a draft guidance entitled ''S10 Photosafety Evaluation of Pharmaceuticals'' should be made available for public comment. The draft guidance is the product of the S10 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the S10 Expert Working Group.

The ICH S10 draft guidance provides guidance on when photosafety testing is warranted, and on possible testing strategies. It represents the consensus that exists regarding assessment of photosafety to support clinical development and marketing authorization of pharmaceuticals. It supplements the ICH M3(R2) guidance,[1] which (1) provides certain information regarding timing of photosafety testing relative to clinical development and (2) recommends that an initial assessment of photoreactive potential be conducted and, if appropriate, an experimental evaluation be undertaken before exposure of large numbers of subjects. However, the ICH M3(R2) guidance does not address testing strategies.

This 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 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. 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 (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov* or *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: January 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02296 Filed 2–1–13; 8:45 am]

BILLING CODE 4160–01–P

[1] See the ICH guidance ''M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals,'' available on the Internet at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Loan Repayment Program for Repayment of Health Professions Educational Loans

Announcement Type: Initial
CFDA Number: 93.164
Key Dates: February 15, 2013 first award cycle deadline date; August 16, 2013 last award cycle deadline date; September 13, 2013 last award cycle deadline date for supplemental loan repayment program funds; September 30, 2013 entry on duty deadline date.

I. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget request for Fiscal Year (FY) 2013 includes $20,179,074 for the IHS Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service as defined in the IHS LRP policy clarifications at *http://www.ihs.gov/loanrepayment/documents/LRP_Policy_Updates.pdf*, in Indian health programs.

This program announcement is subject to the appropriation of funds. This notice is being published early to coincide with the recruitment activity of the IHS, which competes with other Government and private health management organizations to employ qualified health professionals.

This program is authorized by 25 U.S.C. Section 1616a.

II . Award Information

The estimated amount available is approximately $20,179,074 to support approximately 455 competing awards averaging $44,270 per award for a two year contract. One year contract continuations will receive priority consideration in any award cycle. Applicants selected for participation in the FY 2013 program cycle will be expected to begin their service period no later than September 30, 2013.

III. Eligibility Information

1. Eligible Applicants

Pursuant to Section 108(b), to be eligible to participate in the LRP, an individual must:

(1) (A) Be enrolled—

(i) In a course of study or program in an accredited institution, as determined by the Secretary, within any State and be scheduled to complete such course of study in the same year such individual applies to participate in such program; or

(ii) In an approved graduate training program in a health profession; or

(B) Have a degree in a health profession and a license to practice in a state; and

(2) (A) Be eligible for, or hold an appointment as a Commissioned Officer in the Regular Corps of the Public Health Service (PHS); or

(B) Be eligible for selection for service in the Regular Corps of the PHS; or

(C) Meet the professional standards for civil service employment in the IHS; or

(D) Be employed in an Indian health program without service obligation; and