

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 1, 2013.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. *Investors Bancorp, MHC and Investors Bancorp, Inc.*, both in Short Hills, New Jersey, to acquire Roma Financial Corporation MHC, and Roma Financial Corporation, both in Robbinsville, New Jersey, and indirectly acquire Roma Bank, Robbinsville, New Jersey, and RomAsia Bank, South Brunswick Township, New Jersey, and thereby engage in operating savings associations, pursuant to section 225.28(b)(4)(ii).

Board of Governors of the Federal Reserve System, January 30, 2013.

Michael J. Lewandowski,

Assistant Secretary of the Board.

[FR Doc. 2013-02351 Filed 2-1-13; 8:45 am]

BILLING CODE 6210-01-P

GOVERNMENT ACCOUNTABILITY OFFICE

Health Information Technology Policy Committee Nomination Letters

AGENCY: Government Accountability Office (GAO).

ACTION: Notice on letters of nomination of candidates.

SUMMARY: The American Recovery and Reinvestment Act of 2009 (ARRA) established the Health Information Technology Policy Committee (Health IT Policy Committee) and gave the Comptroller General responsibility for appointing 13 of its 20 members.

As the result of terms ending in April 2013, GAO is accepting nominations of individuals in the following categories of representation or expertise required in ARRA: advocate for patients or consumers, and a member from a labor organization representing health care workers. For appointments to the HIT Policy committee to be made by April 1, 2013 in these categories, I am announcing the following: Letters of nomination and resumes should be submitted between February 1 and 22, 2013 to ensure adequate opportunity for review and consideration of nominees.

ADDRESSES: GAO:

HITCommittee@gao.gov; GAO: 441 G Street NW., Washington, DC 20548.

FOR MORE INFORMATION CONTACT: GAO: Office of Public Affairs, (202) 512-4800. 42 U.S.C. 300jj -12.

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2013-02104 Filed 2-1-13; 8:45 am]

BILLING CODE 1610-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary; Office of the Assistant Secretary for Preparedness and Response; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AN, Office of the Assistant Secretary for Preparedness and Response (ASPR), as last amended at 75 Fed. Reg. 35035-38, dated June 21, 2010. This organizational change is to realign the Division of Emergency Care Coordination Center (ECCC) (ANC5) from under the Office of Preparedness and Emergency Operations (ANC) to operating under the Division of Health Systems Policy (ANE3) under the Office of Policy and Planning (ANE). The change is as follows.

I. Under Part A, Chapter AN, Section AN.20, Functions, Paragraph C, Office of Preparedness and Emergency

Operations (ANC), delete the following component "Division of Emergency Care Coordination Center (ECCC) (ANC5)" in its entirety.

II. Delegations of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

Dated: January 24, 2013.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

[FR Doc. 2013-02385 Filed 2-1-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1145]

Draft Guidance for Industry on Enrichment Strategies for Clinical Trials To Support Approval of Human Drugs and Biological Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the draft guidance for industry entitled "Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products" that appeared in the *Federal Register* of December 17, 2012 (77 FR 74670). In the document, FDA announced the availability of this draft guidance and explained that the comment period would close on February 15, 2013. The Agency is taking this action to allow interested persons additional time to submit comments.

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 18, 2013.

ADDRESSES: Submit electronic comments 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. Identify comments with the docket number

found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Robert Temple, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4212, Silver Spring, MD 20993-0003, 301-796 2270; or

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210; or

Robert L. Becker, Center for Device and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5674, Silver Spring, MD 20993-0003, 301-796-5450.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 17, 2012 (77 FR 74670), FDA announced the availability of this draft guidance and explained that the comment period would close on February 15, 2013. The Agency is extending the comment period to March 18, 2013, to allow more time for public comments.

This document provides guidance to industry on enrichment strategies that can be used in clinical trials intended to support effectiveness and safety claims in new drug applications and biologics license applications. Similar approaches could be used in clinical trials in earlier phases of drug development. This draft guidance defines and discusses three enrichment strategies: Decreasing heterogeneity, predictive enrichment, and prognostic enrichment. The guidance also discusses general clinical trial design considerations, provides examples of potential clinical trial designs, and discusses regulatory considerations when using enrichment strategies.

II. Submission of 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>.

Dated: January 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-02293 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-2012-N-0711]

Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending to May 13, 2013, the comment period for the notice entitled “Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket,” that appeared in the **Federal Register** of December 14, 2012 (77 FR 74485). In that document, we requested comments relevant to conducting a risk assessment to establish regulatory thresholds for major food allergens as defined in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). The document requested comments (including data) that we can use to design and carry out a quantitative risk assessment for establishing regulatory thresholds for major food allergens. We are extending the comment period in response to a request from an industry association.

DATES: Submit either electronic or written comments by May 13, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0711, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0711. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, 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 and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Steven M. Gendel, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1056.

SUPPLEMENTARY INFORMATION

I. Background

In the **Federal Register** of December 14, 2012 (77 FR 74485), we published a document entitled “Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket.” In that document, we requested comments relevant to conducting a risk assessment to establish regulatory thresholds for major food allergens as defined in FALCPA (Title II of Pub. L. 108-282). The document requested comments (including data) that we can use to design and carry out a quantitative risk assessment for establishing regulatory thresholds for major food allergens.

Section 201(qq) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(qq)) defines a “major food allergen” as “[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans” and also as a food ingredient that contains protein derived from such foods, (exempting highly refined oils). FALCPA establishes that foods regulated under the FD&C Act are misbranded unless they declare the presence of major food allergens on the product label using the common or usual name of that major food allergen. FALCPA also provides two mechanisms through which ingredients may become