

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Request for Nominations of Candidates To Serve on the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Department of Health and Human Services

The CDC is soliciting nominations for membership on the Advisory Committee on Immunization Practices (ACIP). The ACIP consists of 15 experts in fields associated with immunization, who are selected by the Secretary of the United States Department of Health and Human Services (DHHS) to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases. The role of the ACIP is to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products. The committee also establishes, reviews, and as appropriate, revises the list of vaccines for administration to children eligible to receive vaccines through the Vaccines for Children (VFC) Program.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the field of immunization practices; multi-disciplinary expertise in public health; expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine; knowledge of vaccine development, evaluation, and vaccine delivery; or knowledge about consumer perspectives and/or social and community aspects of immunization programs. Federal employees will not be considered for membership. Members may be invited to serve for four-year terms.

The next cycle of selection of candidates will begin in the fall of 2013, for selection of potential nominees to replace members whose terms will end on June 30, 2014. Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACIP objectives (<http://www.cdc.gov/vaccines/acip/index.html>).

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of professional training and background, points of view represented, and the committee's function.

Consideration is given to a broad representation of geographic areas within the U.S., with equitable representation of the sexes, ethnic and racial minorities, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government.

Candidates should submit the following items:

- Current *curriculum vitae*, including complete contact information (telephone numbers, mailing address, email address)
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services*

The deadline for receipt of all application materials (for consideration for term beginning July 1, 2014) is November 15, 2013. All files must be submitted electronically as email attachments to: Mrs. Felicia Betancourt, c/o ACIP Secretariat, Email: FBetancourt@cdc.gov.

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0168]

Draft Guidance for Industry and Food and Drug Administration Staff: Recommendations for Labeling Medical Products To Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

*Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person *not* employed by HHS (e.g., CDC, NIH, FDA, etc.).

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff:

Recommendations for Labeling Medical Products To Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex." The purpose of this draft guidance is to make recommendations on the appropriate language to include in the labeling of a medical product to convey that natural rubber latex was not used as a material in the manufacture of the product or product container. FDA is concerned that statements submitted for inclusion in medical product labeling such as "latex-free," "does not contain natural rubber latex," or "does not contain latex" are not accurate because it is not possible to reliably assure that there is an absence of the allergens associated with hypersensitivity reactions to natural rubber latex in the medical product. This draft guidance is not final nor is it in effect at this time.

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 written or electronic comments on the draft guidance by June 10, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff: Recommendations for Labeling Medical Products To Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments concerning this draft guidance 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: Michael T. Bailey, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G120, Silver Spring, MD 20993-0002, 301-796-6530, Michael.Bailey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Contact with devices containing natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins. FDA medical device regulations include provisions that require certain labeling statements on medical devices if the device or device packaging is composed of or contains natural rubber that contacts humans. (See 21 CFR 801.437.) The biological products regulations require that the package label or package insert declare the presence of known sensitizing substances, but do not specifically mention natural rubber latex (21 CFR 610.61(l)). Specific regulations for labeling of natural rubber latex content in medical products or their containers do not exist for drugs or veterinary products.

At this time, there are no regulations requiring the labeling of a medical product to state that natural rubber latex was not used as a material in the manufacture of a medical product or medical product container. However, some manufacturers have included the promotional statements "latex-free" or "does not contain latex" in medical product labeling to inform users that natural rubber latex, dry natural rubber, or synthetic derivatives of natural rubber latex were not used. These labeling statements are not sufficiently specific, not necessarily scientifically accurate and may be misunderstood or applied too widely, and therefore, it is inappropriate to include such statements in medical product labeling. Use of these terms may give users allergic to natural rubber latex a false sense of security when using a medical product. The draft guidance provides recommendations for scientifically accurate labeling that can be used by manufacturers who wish to convey that natural rubber latex was not used as a material in the manufacture of a medical product or medical product container.

II. Significance of Guidance

This draft guidance document 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 labeling medical products to inform users that a product or product container was not made with natural rubber latex. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents also are available at <http://www.regulations.gov>. To receive "Draft Guidance for Industry and FDA Staff: Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex," you may either send an email request to dsmica@fda.hhs.gov for an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1768 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently 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 PRA). The collections of information in 21 CFR part 801 are approved under OMB control number 0910-0485 and the collections of information in 21 CFR part 610 subpart G are approved under OMB control number 0910-0338.

The labeling provisions recommended in this draft guidance are not subject to review by OMB because they do not constitute a "collection of information" under the PRA. Rather, the recommended labeling is a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

V. 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>.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. Ahmed, S.M., T.C. Aw, and A. Adishes, "Toxicological and Immunological Aspects of Occupational Latex Allergy," *Toxicological Reviews*, vol. 23, pp. 123-134, 2004.

Dated: March 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0962]

Drug Development for Chronic Fatigue Syndrome and Myalgic Encephalomyelitis; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, is announcing a public workshop to discuss how best to facilitate and expedite the development of safe and effective drug therapies to treat signs and symptoms related to chronic fatigue syndrome (CFS) and myalgic encephalomyelitis (ME). FDA has determined that CFS and ME are serious conditions for which there are no approved drug treatments. On April 25, 2013, as part of FDA's Patient-Focused Drug Development initiative, patients will provide feedback on disease impact on quality of life and individual experience with current treatment regimens. On April 26, 2013, there will be discussions with academic and Government experts, patient advocates, patients, and clinicians on how to identify sound, quantitative outcome measures that can be used in clinical trials to determine whether disease symptoms improve with specific drug interventions.

Date and Time: The public workshop will be held on April 25, 2013, from 1 p.m. to 5 p.m., and on April 26, 2013, from 8:30 a.m. to 5 p.m.