

## 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](mailto: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