
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.fda.gov/Drugs/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: September 26, 2011.

Leslie Kux, Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FR Doc. 2011–25116 Filed 9–28–11; 8:45 am]

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Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA’s regulations and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

The goal of this public workshop is to present information that will enable regulated industry to better comply with the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and to better understand FDA’s food defense guidance documents, especially in light of growing concerns about food protection. Information that FDA presents will be based on Agency position as articulated through regulation, guidance, and information previously made available to the public. Topics to be discussed at the workshop (both by FDA and non-FDA speakers) include: (1) Food defense awareness and definitions, (2) FDA food defense tools such as ALERT and Employees FIRST, (3) regulations issued under the Bioterrorism Act, (4) food defense guidance documents, (5) investigating food-related incidents effectively, (6) physical plant security, (7) crisis management, and other related topics. For more information, please visit http://www.fapc.biz/fooddefense.html. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the Agency’s regulatory and policy perspectives on food protection, increase compliance with FDA regulations, and heighten food defense awareness.

Dated: September 23, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process and Request for Nominations for a Nonvoting Industry Representative on the Vaccines and Biological Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve the Vaccines and Related Biological Products Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nomination will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by October 31, 2011, for the vacancy listed in this document. Concurrently, nomination materials for prospective candidates should be sent to FDA by October 31, 2011.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Donald Jehn (see FOR FURTHER INFORMATION CONTACT).

FOR FURTHER INFORMATION CONTACT: Donald Jehn, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, FAX: 301–827–0294, e-mail: donald.jehn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative on the CBER Advisory Committee.

I. Vaccines and Related Biological Products Advisory Committee

The Vaccines and Related Biological Products Advisory Committee (the Committee) advises the Commissioner...