

must be specific, measurable, attainable, time phased, and realistic.

3. **Operational Plan**—Submit an operational plan that addresses means for achieving each of the objectives established in Section 2 (objectives) above. Provide a concise description of each component or major activity and how it will be implemented. The plan must identify and establish a time line for the completion of each component or major activity.

4. **Evaluation Plan**—Submit a quantitative plan for monitoring progress toward achieving each of the objectives stated in Section 2 (objectives) above.

5. **Organizational Capacity/Program Management**—Describe the capacity of the organization/group to perform the technical assistance activities relating to Breast and Cervical Programs. Provide an organizational chart and a curricula vitae (not to exceed 2 pages per person) for each member of the organization that will be providing technical assistance.

6. **Budget**—Submit a detailed budget and narrative justification for the activities that is consistent with the purpose of the program and the proposed activities.

#### F. Submission and Deadline

Submit an original and two copies of PHS 5161-1 (OMB Number 0937-0189) on or before August 15, 2000, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

**Deadline:** The application will be considered as meeting the deadline if it is either:

- Received on or before the stated deadline date; or
- Sent on or before the deadline date. (Applicant must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable proof of timely mailing.)

**Late Application:** If the application does not meet the criteria in 1.a. or 1.b. above it will be a considered late application and will be returned to the applicant.

#### G. Evaluation Criteria

The application will be evaluated according to the following criteria by an independent review group appointed by CDC.

1. **Statement of Need.** The extent to which the applicant identifies specific opportunities and existing gaps related to the purpose of the program. (10 points)

2. **Objectives.** The degree to which short-and long-term objectives are specific, measurable, attainable, time phased, and realistic. (15 points)

3. **Operational Plans.** The adequacy of the applicant's plan to carry out the proposed activities, including the extent to which the applicant plans to work collaboratively with other organizations and individuals who may have an impact on breast and cervical cancer prevention and control objectives. (30 points)

4. **Organizational Capacity/Program Management.** The extent to which the organization appears to have the organizational capacity and program management to develop and manage the program. The extent to which proposed staff appear to be qualified and possess capacity to perform the technical assistance described. The extent to which staff has expertise working with American Indian/Alaska Natives populations with the management of women health care programs, including Breast and Cervical Cancer Early Detection Activities. (30 points)

5. **Evaluation Plan.** The extent to which the evaluation plan appears capable of monitoring progress toward meeting project objectives. (15 points)

6. **Budget.** The extent to which each line-item budget and narrative justification is reasonable and consistent with the purpose and objectives of the program. (Not weighted)

#### H. Other Requirements

##### Technical Reporting Requirements

Provide CDC with the original plus two copies of the following:

- Annual written progress report must be submitted 30 days after the end of each budget period.
- Financial status report (FSR) must be submitted 90 days after the end of each budget period.
- Final financial and performance reports, must be submitted 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment II in the application package.

AR-9 .....	Paperwork Reduction Act Requirements
AR-10 .....	Smoke-Free Workplace Requirements
AR-11 .....	Healthy People 2010
AR-12 .....	Lobbying Restrictions
AR-15 .....	Proof of Non Profit Status

#### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317(k)(2) of the Public Health Service Act (42 U.S.C. 241(a) and 247b(k)(2)), as amended. The Catalog of Federal Domestic Assistance Number for this program is 93.283.

#### J. Where To Obtain Additional Information

To obtain additional information contact: Cynthia Collins, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00148, Centers for Disease Control and Prevention (CDC), Room 3000, 2920 Brandywine Road, Atlanta, GA 30341, telephone (770) 488-2757, E-mail address: CCollns@CDC.GO

See also the CDC home page on the Internet:  
<http://www.cdc.gov>

For program technical assistance, contact: Annie Voigt, Program Consultant, Section C, Program Services Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K-57, Atlanta, GA 30341-3724, telephone (770) 488-4707, fax (770) 488-3230.

Dated: July 7, 2000.

**Mary Anne Bryant,**

*Acting Director, Procurement and Grants Office Centers for Disease Control and Prevention (CDC).*

[FR Doc. 00-17702 Filed 7-12-00; 8:45 am]

BILLING CODE 4163-18-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

##### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements to Develop Core State-Based Surveillance Model Programs, RFA OH-00-007, and Development of New or Enhanced Models for State-Based Occupational Surveillance, RFA OH-00-008

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements to Develop Core State-Based Surveillance

Model Programs, RFA OH-00-007, and Development of New or Enhanced Models for State-Based Occupational Surveillance, RFA OH-00-008.

**Times and Dates:** 8 a.m.–8:30 a.m., August 2, 2000 (Open).

8:30 a.m.–5 p.m., August 2, 2000 (Closed).

8 a.m.–5 p.m., August 3, 2000 (Closed).

**Place:** Embassy Suites, 1900 Diagonal Road, Alexandria, Virginia 22314.

**Status:** Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92-463.

**Matters to be Discussed:** The meeting will include the review, discussion, and evaluation of applications received in response to RFA-OH-00-007 and RFA OH-00-008.

**Contact Person for More Information:** Michael J. Galvin, Jr., Ph.D., Health Science Administrator, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, 1600 Clifton Road, N.E., m/s D30 Atlanta, Georgia 30333. Telephone 404/639-3525, e-mail mtg3@cdc.gov.

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.

Dated: July 7, 2000.

**Julia M. Fuller,**

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

[FR Doc. 00-17700 Filed 7-12-00; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00D-1360]

#### Draft Guidance for Industry: Food-Contact Substance Notification System; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Preparation of Premarket Notifications for Food Contact Substances: Administrative." This document is intended to provide guidance for industry regarding the preparation of premarket notifications for food-contact substances (FCS). FDA is providing this draft guidance as part

of its implementation of the premarket notification process for FCS established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Submit written comments on this draft guidance by September 26, 2000 to ensure their adequate consideration in the preparation of the final document.

**ADDRESSES:** Submit written requests for single copies of the draft guidance entitled "Preparation of Premarket Notifications for Food Contact Substances: Administrative" to the Office of Premarket Approval (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. The document may also be obtained by calling the Office of Premarket Approval at 202-418-3080 or by fax at 202-418-3131. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3083.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDAMA (Public Law 105-115) amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a premarket notification (PMN) process as the primary method for authorizing new uses of food additives that are FCS. A "food contact substance" is defined in section 409(h)(6) of the act as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." FDA expects most new uses of FCS that previously would have been regulated by issuance of a listing regulation in response to a food additive petition or would have been exempted from the requirement of a regulation under the threshold of regulation process (21 CFR 170.39) will be the subject of PMN's. FDA is announcing the availability of a draft guidance document entitled "Preparation of Premarket Notifications for Food Contact Substances: Administrative." This document is

intended to provide guidance for industry regarding the preparation of premarket notifications for FCS. FDA is providing this draft guidance as part of its implementation of the premarket notification process for FCS established by FDAMA. Elsewhere in this issue of the **Federal Register** FDA is proposing regulations necessary to implement the notification process for FCS.

##### **II. Significance of Guidance**

This draft guidance document represents the agency's current thinking on the data and information that should be submitted in a premarket notification for the use of a FCS. This draft guidance document 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.

This draft guidance document is a level 1 guidance under the agency's good guidance practices (62 FR 8961, February 27, 1997).

##### **III. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document by September 26, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Such comments will be considered when determining whether to amend the draft guidance.

##### **VI. Electronic Access**

The draft guidance may also be accessed on the Internet site for the Center for Food Safety and Applied Nutrition at <http://www.cfsan.fda.gov>.

Dated: June 27, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 00-17654 Filed 7-12-00; 8:45 am]

**BILLING CODE 4160-01-F**