projects as well as key professional personnel from other participating or collaborating institutions, agencies, organizations outside of the applicant's agency that will be assigned to PE activities (provide curriculum vitae for each in an appendix). Clear identification of applicants' respective roles in the management and operation of the Prevention Epicenter and in individual projects. Descriptions of participants' experience in conducting work similar to that proposed in this announcement.

h. Description of all support staff and services to be assigned to the Prevention Epicenter.

i. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes (a) the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation, (b) the proposed justification when representation is limited or absent, (c) a statement as to whether the design of the study is adequate to measure differences when warranted and (d) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

5. Evaluation (5 points)

a. Quality of plan for monitoring and evaluating scientific and operational accomplishments of the Prevention Epicenter and of individual Center projects.

b. Quality of plan for monitoring and evaluating progress in achieving the purpose and overall goals of this cooperative agreement program.

6. Budget (not scored)

Extent to which the line-item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program.

7. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. progress reports (semiannual);

2. financial status report, no more than 90 days after the end of the budget period; and

3. final financial status and performance reports, no more than 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 I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
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 section 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where to Obtain Additional Information

For this and other CDC announcements, please see the CDC home page on the Internet: http://www.cdc.gov (click on ''Funding''). To receive additional written information and to request an application kit, call 1–888-GRANTS4 (1–888 472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Gladys Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number 770–488–2753, Email address gcg4@cdc.gov

For program technical assistance, contact: Steve Solomon, M.D., Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E. Mailstop A–07, Atlanta, GA 30333, Telephone number 404–639–6476, Email address sls1@cdc.gov

Dated: May 18, 2000.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00093]

States Helping States Through The Association of Food And Drug Officials; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention, (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for States Helping States Through the Association of Food and Drug Officials.

B. Eligible Applicant

Assistance will be provided only to the Association of Food and Drug Officials (AFDO). No other applications are solicited.

AFDO is the only organization qualified to conduct this work because:

1. AFDO is the only organization that represents the state and local food protection regulatory agencies. Regular members are official heads of State or local regulatory agencies or personnel under their supervision. The Association's principle purpose is to act as a leader and resource to state and local regulatory agencies in developing strategies to resolve and promote public health and consumer protection related to the regulation of foods as well as drugs, medical devices and consumer products.

2. AFDO focuses on the administration of the nation's food safety component of public health programs. AFDO has unique perspective on the infrastructure, capacity, strengths and needs of state and local food safety programs.

3. AFDO has experience in carrying out national training efforts that focus on the needs of state and local regulatory agencies.

C. Availability of Funds

Approximately $102,000 is available in FY 2000 to fund this Cooperative Agreement. It is expected that the award will begin on or about September 1, 2000, and will be made for a 12-month

budget period within a project period of up to 5 years.

D. Where To Obtain Additional Information

Program technical assistance may be obtained from: Chuck Higgins, Senior Environmental Health Officer, Environmental Health Services Branch, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Atlanta, GA 30341–3724, Telephone number: (770) 488–4180, Email address: cth4@cdc.gov

Business management technical assistance may be obtained from: Sonia V. Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone number: (770) 488–2724, Email address: svp1@cdc.gov

Dated: May 18, 2000.

John L. Williams,

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

[FR Doc. 00–13029 Filed 5–23–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0046]

Quarterly List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a quarterly update of all guidance documents issued and withdrawn since we compiled the last quarterly list of guidance documents that published on March 14, 2000. FDA committed to publishing quarterly updates in our February 1997 ''Good Guidance Practices'' (GGP's) document, which set forth the agency's policies and procedures for developing, issuing, and using guidance documents. This list is intended to inform the public of the existence and availability of guidance documents issued since the annual comprehensive list was compiled.

DATES: General comments on this list and on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For information on where to obtain single copies of guidance documents listed here, see the specific center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its ''Good Guidance Practices'' (GGP's), which set forth our policies and procedures for developing, issuing, and using guidance documents. We adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of our guidance documents.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, we committed to publishing an annual comprehensive list of guidance documents and quarterly **Federal Register** notices that list all guidance documents that were issued and withdrawn during that quarter, including ''Level 2'' guidance documents. The following list of guidance documents represents all guidances that we issued or withdrew since we published the last quarterly list on March 14, 2000 (65 FR 13771). The guidance documents are organized by the issuing center or office within FDA, and are further grouped by the intended users or relevant regulatory activities. Dates provided in the following list refer to the date the guidance was issued or, where applicable, the last date the document was revised. We provided document numbers where available.

II. Guidance Document Issued by the Center for Biologics Evaluation and Research (CBER)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft guidance entitled ''International Conference on Harmonsation of Technical Requirements for Registration of Pharmaceuticals for Human Use M4: Common Technical Document''	February 11, 2000	FDA Regulated Industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, FAX Information System: 1–888–CBER–FAX (within U.S.)or 301–827–3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
Draft Guidance for Industry: Special Protocol Assessment	December 1999	Do	Do
Draft Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol	February 2000	FDA Personnel	Do