

announcement: Policy Research and Studies on Welfare Reform Outcomes; proposed project title; name of researcher(s); organizational affiliation; and the address, telephone number, and e-mail address of the lead investigator. (This will be the mailing address used by ASPE/ACF to request full proposals from selected applicants.) The title page must include an indication, by number, of the research question(s) presented within this announcement that are being addressed or indicate that the research question is not one of those contained in the announcement. The proposed data set must also be included. The title page must include the total number of months needed for completion of the project and the project's proposed start and end date. This should be the only information on page one.

2. *Statement of research question.* The statement should briefly discuss the relevance of the proposed work to the purposes of this announcement. The statement will be reviewed for policy relevance and the importance of the research question. Please indicate, by number, which research question(s) presented within this announcement are being addressed or indicate that the research question is not one of those contained in the announcement.

3. *Statement of proposed methods.* This section should describe the conceptual model, the data source and the analytic methods. This description should explicitly relate data sources and analytic methods to the research issues to be addressed. This section must also contain information regarding the researcher's ability to obtain the data and information on when data will be available, if they are not already. Note that in the final proposal the researcher will have to provide assurances that the data is available.

4. *Experience.* The principal investigator's relevant research experience must be described. Other key staff must be identified with a brief description of their relevant experience and an indication of the tasks or activities for which they will be primarily responsible.

5. *Estimated budget.* This section must include an estimate of staff time and other direct costs. Information about other funding sources and the contribution that the ASPE/ACF funds will make must be discussed. Only a total project budget need be submitted at this time.

#### Part IV. The Review Process

An independent review panel will review and score all abstracts that are submitted by the deadline date and which meet the screening criteria (all

information and in formats required by this announcement). The panel will review the abstracts using the evaluation criteria listed below to score each abstract. The review results will be the primary elements used by the Assistant Secretary for Planning and Evaluation and the Assistant Secretary for Children and Families in making decisions regarding full application submission. The Department also reserves the option to discuss abstracts with other Federal or State staff, specialists, experts, and the general public. Comments from these sources, along with those of the reviewers, will be kept from inappropriate disclosure and may be considered in determining which applicants will be requested to submit a competitive application for review.

1. *Research Question(s):* The research must address important unanswered questions of local or national policy significance. The proposed research must contribute significantly to understanding the outcomes of welfare reform. Short-term research studies should provide information likely to be relevant to TANF reauthorization discussions. (35 points)

2. *Methodology/Merits of the Research Design:* The research design must identify the study population, indicate data sources and demonstrate the availability and reliability of proposed data sources and the appropriateness and reliability of data collection instruments or observational techniques as well as the validity of analytic methods proposed for addressing the research questions and hypotheses. The conceptual model and the analysis plan must be clearly explained. It is important to explain the time frame for the proposed work and that explanation must be clear and reasonable. (25 points)

3. *Experience.* The abstract must provide information on the principal investigator's relevant research experience and demonstrate capability to use the proposed data and methods. The relevant experience and proposed roles of other key staff must be presented. (30 points)

4. *Budget.* Applicants must provide an estimate of the total proposed budget, including information about other funding sources. The contribution of ASPE/ACF funding must be presented. The budget must be reasonable for the proposed scope of work. (10 points)

#### *Estimate of Schedule*

ASPE and ACF anticipate that abstracts will be reviewed and selected applicants notified to submit full proposals approximately 30 days

following the deadline for submission of abstracts. We expect that full proposals will be required to be submitted within 45 days of the date of the notification letter.

The Catalogue of Federal Domestic Assistance Numbers are 93.239 and 93.647 for ASPE and ACF, respectively.

Dated: February 18, 2000.

**Margaret A. Hamburg,**  
*Assistant Secretary for Planning and Evaluation.*

Dated: February 16, 2000.

**Howard Rolsto,**  
*Director, Office of Planning, Research and Evaluation, Administration for Children and Families.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Medical Device Quality Systems Inspection Technique; Notice of Workshop

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a workshop on the FDA Quality System Inspection Technique (QSIT). The topics to be discussed include: The development of QSIT, compliance program and warning letter pilot, management controls, corrective and preventative actions, design controls, production and process controls, and industry perspective of QSIT. The purpose of this QSIT workshop is to increase understanding of QSIT in the medical device community. By explaining this new inspection technique, FDA intends to ensure that the medical device industry takes appropriate action to establish effective quality systems and to prevent regulatory problems when inspections occur.

*Date and Time:* The workshop will be held on March 8, 2000, from 8:30 a.m. to 4:30 p.m.

*Location:* The workshop will be held at the Condado Plaza Hotel, 999 Ashford Ave., San Juan, PR 00907.

*Registration:* Send registration information (including name, title, firm name, address, telephone, and fax number) along with a registration fee of \$125.00 to Jose P. Rodriguez, Director of Special Programs and Seminars, the Puerto Rico Manufacturers Association, P.O. Box 195477, San Juan, PR 00919-

5477, 787-759-9445, ext. 204, FAX 787-756-7670. The fee covers refreshments, organization and site costs, and materials. Space is limited; therefore interested parties are encouraged to register early. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please inform Jose P. Rodriguez (address above) at least 7 days in advance of the workshop.

*Contact:* H. Gordon Cox, Supervisory Investigator, FDA San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 787-729-6801.

**SUPPLEMENTARY INFORMATION:** In the fall of 1999, the FDA field offices began using QSIT nationwide as the primary tool for medical device good manufacturing practice/quality system (GMP/QS) inspections. QSIT was developed using a collaborative effort with stakeholders, and it was tested in three districts.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise.

The workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities directed to small businesses.

Dated: February 23, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Vaccines and Related Biological Products Advisory Committee.

*General Function of the Committee:* To provide advice and

recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 9, 2000, 8 a.m. to 6 p.m., and on March 10, 2000, 8 a.m. to 3 p.m.

*Location:* Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

*Contact Person:* Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391.

Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On March 9, 2000, the committee will discuss the safety and efficacy of a combination vaccine from SmithKline Beecham for the prevention of Diphtheria/Tetanus, Pertussis, Polio, and Hepatitis B. On March 10, 2000, the committee will: (1) Complete recommendations pertaining to the influenza virus vaccine formulations for the 2000 to 2001 season, (2) hear a short briefing on the Vaccine Safety Action Plan, and (3) be updated on the status of vaccines for the prevention of rotavirus disease.

*Procedure:* On March 9, 2000, from 9:15 a.m. to 6 p.m., and on March 10, 2000, from 8 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 3, 2000. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 9:45 a.m. and between approximately 4 p.m. and 4:15 p.m. on March 9, 2000. Oral presentations from the public will be heard on March 10, 2000, between approximately 10:20 a.m. and 10:30 a.m., between approximately 12:30 p.m. and 12:45 p.m., and between approximately 2:45 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 1, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations:* On March 9, 2000, from 8 a.m. to 9:15 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information. (5 U.S.C. 552b(c)(4)). These portions of the

meeting will be closed to discuss issues relating to pending or proposed investigational new drug applications.

FDA regrets that it was unable to publish this notice 15 days prior to the March 9 and 10, 2000, Vaccines and Related Biological Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 16, 2000.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 00-4589 Filed 2-23-00; 3:44 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### Proposed Project: Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration—(OMB 0915-0212)—Extension

In response to Executive Order 12862, the Health Resources and Services Administration (HRSA) is proposing to conduct voluntary customer surveys of its "partners" to assess strengths and weaknesses in program services. A generic approval is being requested from OMB to conduct the partner surveys. HRSA partners are typically State or local governments, health care facilities,