Corporate Blvd., Rockville, MD 20850, 301– 594–5072, FAX 301–480–4224.

SUPPLEMENTARY INFORMATION: FDA, in cooperation with HIMA, is holding a public workshop to discuss the implementation of a different process for the premarket approval of class III devices by means of a PDP. Section 515(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e (f)) (the act) provides for a product development protocol as an alternate means of premarket approval of class III medical devices. Although the PDP has existed as a means of approval of a medical device since the Medical Device Amendments of 1976 (Pub. L. 94–295) to the act, the PDP has never been completely implemented. As part of it's reengineering initiative, the Center for Devices and Radiological Health (CDRH) of FDA established the PDP Reengineering Team, comprised of FDA staff, in consultation with industry representatives, to develop an efficient, practical PDP process.

The intent of the PDP process is to substitute the conventional device approval model, the sequential process of clinical investigation followed by a premarket approval application, with an early interaction between the sponsor and FDA to produce a focused product development plan that merges the two steps. A PDP team has developed guidelines for creating this focused development protocol that will be described at the public workshop. Workshop participants will have ample opportunity to ask questions as the new PDP process is described and case studies on particular examples of class III devices are presented. Background information, a detailed flow chart, and a descriptive narrative regarding the proposed PDP process can be found at the FDA/CDRH Web site at the address below.

Additional information is available on the FDA Web page (www.fda.gov/cdrh/pdp/pdp.html) or the HIMA Web page (www.himanet.com).

Dated: September 30, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–27433 Filed 10–15–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects

1. Project To Assess Bi/Multilingual Services Offered at Selected Community and Migrant Health Centers—NEW

Recognizing the importance of language-appropriate services to full and effective health care provision, the Office of Minority and Women's Health in the Bureau of Primary Health Care [BPHC], Health Resources and Services Administration [HRSA], proposes to conduct a voluntary telephone survey to assess the composition and provision of bi/multilingual services at a sample of 40 Community and Migrant Health Centers [C/MHCs] selected from those C/MHCs indentified as likely to be serving high percentages of people who speak languages other than English. This effort was developed so that information could be gathered to assist the field, funding agency staff, and policymakers in better understanding what methods are being used to provide services to these populations, what works, what does not, and barriers and facilitators to effective health service provision for speakers of languages other than English.

The information gathered will provide HRSA with an information base upon which to build in making future program decisions regarding C/MHC resource and staffing needs in order to reduce or eliminate the barriers to health care often faced by non-or limited-English-speaking populations. The end result of the program will be to assist the funding agency to help C/MHCs and by extension, other providers of health care for non-or limited-English speaking populations to provide appropriate services. An estimate of the hour burden for the 40 C/MHC Directors selected for the survey is shown below.

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Bi/Multilingual Services Survey	40 C/MHC Directors	1	2	80

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 9, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97–27429 Filed 10–15–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is