The outside of the mailing package and item 2 of the application face page should be labeled, ''Response to RFA FDA OPD–2000.''

If an application for the same study was submitted in response to a previous RFA, but has not yet been acted upon, a submission in response to this RFA will be considered a request to withdraw the previous application. Resubmissions are treated as new applications; therefore, the applicant may wish to address the issues presented in the summary statements from the previous review.

VII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt dates.

Applications will be considered received on time if sent or mailed on or before the receipt dates as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH). Any application that is sent to the NIH, that is then forwarded to FDA and received after the applicable due date, will be deemed unresponsive and returned to the applicant. Instructions for completing the application forms can be found on the NIH home page on the Internet (address ''http://www.nih.gov/grants/funding/phs398/phs398.html''; the forms can be found at ''http://www.nih.gov/grants/funding/phs398/forms—toc.html''). However, as noted previously, applications are not to be mailed to the NIH. Applicants are advised that the FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by the NIH on its applications). Applications must be submitted via mail delivery as stated previously. FDA is unable to receive applications via the Internet.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/95). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to the CSR, NIH. Applications from State and Local Governments may be submitted on Form PHS 5161 (Rev. 7/92) or Form PHS 398 (Rev. 5/95).

The face page of the application should reflect the request for applications number RFA–FDA–OPD–000. The title of the proposed study should include the name of the product and the disease/disorder to be studied along with the IND/IDE number. The format for all subsequent pages of the application should be single-spaced and single-side.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the DHHS or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: July 15, 1999

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–18771 Filed 7–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General Hospital and Personal Use Devices Panel of the Medical Devices 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: General Hospital and Personal Use Devices Panel of the Medical Devices 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 August 2, 1999, 8 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Martha T. O'Lone, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12520. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss possible revisions to the 1995 draft guidance entitled ''Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices With Sharps Injury Prevention Features.'' The committee will also discuss the development of guidance for needle-free devices such as jet injectors intended for the delivery of drugs and biologics and the need for and content of educational programs to encourage the safe and effective use of these devices. Single copies of the 1995 draft guidance are available to the public by calling 1–800–899–0381 or 301–827–0111, and requesting Facts-on-Demand document number 934, or on the Internet using the World Wide Web (WWW) ''http://www.fda.gov/cdrh/ode/doc934.pdf''.

Procedure: On August 2, 1999, from 8:30 a.m. to 5 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 July 23, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. and between approximately 3:45 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those individuals desiring to make formal oral presentations should notify the contact person by July 23, 1999, 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 August 2, 1999, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending issues and applications.

FDA regrets that it was unable to publish this notice 15 days prior to the August 2, 1999, General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner 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: July 16, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–18768 Filed 7–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–138]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Medicare Geographical Classification Review Board (MGCRB) Procedures and Criteria and Supporting Regulations in 42 CFR, Section 412.256;

Form No.: HCFA–R–138;

Use: This regulation sets up an application process for prospective payment system hospitals who choose to appeal their geographic status to the Medicare Geographic Classification Review Board (MGCRB). This regulation also establishes procedural guidelines for the MGCRB.

Frequency: Annually;

Affected Public: Business or other for profit, and Not for profit institutions;

Number of Respondents: 1,000;

Total Annual Responses: 1,000;

Total Annual Hours Requested: 1,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 8, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–18816 Filed 7–22–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–70]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Information Collection Requirements in HSQ–110, Acquisition, Protection and Disclosure of Peer Review Organization Information and Supporting Regulations in 42 CFR, Sections 476.104, 476.105, 476.116, and 476.134;

Form No.: HCFA–R–70 (OMB# 0938–0426);

Use: ''Medicare Disclosure Information, Regulatory'' The Peer Review Improvement Act of 1982 authorizes PRO's to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. These requirements are on the PRO to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties;

Frequency: On occasion;

Affected Public: Business or other for-profit, Individuals or Households, and Not-for-profit institutions;

Number of Respondents: 53;

Total Annual Responses: 53;

Total Annual Hours: 30,683.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://