should note 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), NIH. Any application sent to NIH that is then forwarded to FDA and received after the applicable due date will be judged nonresponsive and returned to the applicant. Application forms can be found on the Internet (address http://www.fda.gov/orphan). However, as noted above, do not mail applications to NIH. Applicants should know FDA does not adhere to the page limits or the type size and line spacing requirements imposed by NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/01). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed except for the receipt dates and the mailing label address. Do not send applications to the CSR, NIH. Applications from State and local governments may be sent on Form PHS 5161–1 (Rev. 7/00) or Form PHS 398 (Rev. 5/01). The face page of the application should reflect the request for applications number RFA–FDA–OPD–2002. The title of the proposed study should include the name of the product and the disease/disorder to be studied and the IND/IDE number. The format for all following pages of the application should be single-spaced and single-sided. Data information included in the application will generally not be publicly available prior to the funding of the application. Data included in the application 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) even after funding has been granted. To designate information that an applicant believes to be trade secret or confidential commercial information that remains exempt from disclosure after funding, sponsors should use the legend below. Information collection requirements requested on Form PHS 398 (Rev. 5/01) has been sent by the PHS to the Office of Management and Budget (OMB) and was 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 DHHS or by a court, data contained in the portions of this application which have been specifically identified by the applicant as containing restricted information shall not be disclosed to the public or used except for evaluation purposes.

Dated: August 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21622 Filed 8–22–01; 2:46 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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). The meeting will be open to the public.

Name of Committee: Circulatory System 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 September 10, 2001, from 9 a.m. to 6 p.m., and September 11, 2001, from 8 a.m. to 6 p.m.

Location: Marriott Hotel, Salons D, E, and F, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact: Megan Moynahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 171, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 10, 2001, the committee will discuss, make recommendations, and vote on two premarket approval applications (PMAs) for septal occluders. On September 11, 2001, the committee will discuss, make recommendations, and vote on two PMAs, one for a surgical sealant and one for a biological glue. Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at http://www.fda.gov/cdrh/panelmtg.html. Material for the September 10, 2001, meeting will be posted on September 7, 2001; material for the September 11, 2001, meeting will be posted on September 10, 2001.

Procedure: 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 August 31, 2001. On both days, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of each topic and for approximately 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 31, 2001, 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.

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

Dated: August 20, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–21528 Filed 8–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: September 5, 2001; 9:00 a.m.–1:00 p.m.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

The full Commission will meet on Wednesday, September 5, from 9:00 a.m. to 1:00 p.m. The public can join the meeting in person at the address listed above or by Audio Conference Call by calling 1–888–323–2715 and providing the following information: