IV. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including our review of comments received as a result of this notice, we will publish a notice in the **Federal Register** announcing the results of our evaluation.

V. Response to Public Comments

Because of the large number of comments we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble and will respond to them in a forthcoming rulemaking document.

VI. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity).

The RFA requires agencies to analyze options for regulatory relief for small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million to $25 million or less in any 1 year (for details, see the Small Business Administration's publication that set forth size standards for health care industries at 65 FR 69432). For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This notice merely recognizes AOA as a national accreditation organization that has requested approval for deeming authority for ambulatory surgical centers that are participating in the Medicare program. Since these provider entities must be routinely monitored to determine compliance with Medicare requirements, we believe that this organization's accreditation program has the potential to reduce both the regulatory and administrative burdens associated with the Medicare program requirements.

This notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

Therefore, we have determined, and the Secretary certifies, that this proposed notice would not result in a significant impact on small entities and would not have an effect on the operations of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice would have no consequential effect on State, local, or tribal governments. We believe the private sector costs of this notice would fall below this threshold as well.

In accordance with Executive Order 13132, this notice would not significantly affect the rights of States and would not significantly affect State authority. This notice describes only processes that must be undertaken to fulfill our obligation to enforce our regulations as required by the April 8, 1997 (62 FR 16985) regulation.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 1865(b)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(b)(3)(A)).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 17, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–12929 Filed 5–23–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0159]

Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on focus groups as used by FDA. These focus groups gauge public opinion, and policymakers can use focus group findings to test and refine their ideas so they can conduct further research whose findings can be used to adopt new policies and to allocate or redirect significant resources to support these policies.

DATES: Submit written or electronic comments on the collection of information by July 23, 2002.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Focus Groups as Used by the Food and Drug Administration

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such complements other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more indepth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

FDA estimates the burden for completing the forms for this collection of information as follows:

The total annual estimated burden imposed by this collection of information is 2,884 hours annually.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (includes screening)	Total Hours
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication)	10	100	9	1.58	1,422
Center for Devices and Radiological Health	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, online sales of medical products, latex gloves)	5	25	9	2.08	468
Center for Food Safety and Applied Nutrition	Varies (e.g., food safety, nutrition, dietary supplements, and consumer education)	8	32	9	1.58	455
Center for Veterinary Medicine	Varies (e.g., food safety, labeling, cosmetic safety and labeling)	5	25	9	2.08	468
Total		29	187		1.71	2,884

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Annually, FDA projects about 29 focus group studies using 187 focus groups lasting an average of 1.71 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: May 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–13163 Filed 5–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective Drugs 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: Pediatric Subcommittee of the Anti-Infective Drugs 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 June 11, 2002, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: perezt@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: Beginning at 8 a.m., the subcommittee will discuss and receive comments on the ''written request template'' for the proton pump inhibitors in the treatment of gastroesophageal reflux disease in pediatric patients. Starting at 1 p.m., the subcommittee will discuss a ''preliminary priority list'' of drugs for which: (1) Additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population and (2) the drug has no remaining marketing exclusivity or patent protection. This list is mandated by the Best Pharmaceuticals for Children Act and the National Institutes of Health is the designated lead. At 4:30 p.m., representatives from Europe will provide information to the subcommittee on the ongoing pediatric initiatives in the European Union. Following this at 5 p.m., the agency will provide an update to the subcommittee on the pediatric labeling that has resulted from the exclusivity initiative under the FDA Modernization Act and the annual update on the pediatric rule, completed studies, deferrals, and waivers. The background material for this meeting will be posted on the Internet when available or one working day before the meeting on the Internet at www.fda.gov/ohrms/dockets/ac/menu.htm.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by June 3, 2002. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. and 2 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 3, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Thomas H. Perez at least 7 days in advance of the meeting.

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

Dated: May 20, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–13106 Filed 5–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science; 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: Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science.

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 June 12, 2002, from 8:30 a.m. to 5:30 p.m., and June 13, 2002, from 8 a.m. to 5 p.m.

Location: Hilton DC North—Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Kathleen Reedy and Jayne Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: reedyk@cder.fda.gov, petersonj@cder.fda.gov or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 12, 2002, the subcommittee will: (1) Identify and define technology and regulatory uncertainties/hurdles, possible solutions, and strategies for the successful implementation of process analytical technologies (PATs) in pharmaceutical development and manufacturing; (2) discuss general principles for regulatory application of PATs including principles of method validation, specifications, and feasibility of the parametric release concept; and (3) discuss necessary general FDA