CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 15, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–9103 Filed 4–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: OCSE–157 Child Support Enforcement Program Annual Data Report.

OMB No.: 0970–0177.

Description: The information obtained from this form will be used to report Child Support Enforcement activities to the Congress as required by law, to complete incentive measures and performance indicators utilized in the program, and to assist the Office of Child Support Enforcement in monitoring and evaluating State Child Support programs.

Respondents: State, local or tribal governments.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–157	54	1	4.0	216.0

Estimated Total Annual Burden Hours: 216.0.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives if within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *katherine_t._astrich@omb.eop.gov.*

Dated: April 18, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–9084 Filed 4–21–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of March 30, 2004 (69 FR 16582). The amendment is being made to reflect changes in the introductory paragraph and in the following portions of the document: *Date and Time*, *Location*, *Agenda*, and *Procedure*; and to add a portion entitled "*Closed Committee Deliberations*.'' There are no other changes.

FOR FURTHER INFORMATION CONTACT: Dornette Spell-LeSane or Kimberly Littleton Topper, 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 *topperk@cder.fda.gov* or *spelllesaned@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), codes 3014512541 or 3014512534. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 30, 2004, FDA announced that a meeting of the Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee would be held on May 6 and May 7, 2004. On page 16582, in the first and second columns, the introductory paragraph, *Date and Time*, *Location*, *Agenda*, and *Procedure* portions of the meeting notice are amended; and a portion entitled "*Closed Committee Deliberations*'' is added to read as follows:

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.

Date and Time: The meeting will be held on May 6, 2004, from 8 a.m. to 5:30 p.m. and May 7, 2004, from 8 a.m. to 3:30 p.m.

Location: On May 6, 2004, from 8 a.m. to 5:30 p.m. and May 7, 2004, from 8 a.m. to 11 a.m., the committee will meet at the Center for Drug Evaluation and Research Advisory Committee Conference Room (rm. 1066), 5630 Fishers Lane, Rockville, MD. On May 7, 2004, from 11 a.m. to 3:30 p.m., the two committees will meet separately at two locations. The Nonprescription Drugs Advisory Committee will remain at the previously listed location for its separate meeting. The Dermatologic and Ophthalmic Drugs Advisory Committee will meet at the Food and Drug Administration, Parklawn Building, Chesapeake Conference Room, third floor, 5600 Fishers Lane, Rockville, MD for its separate meeting.

Agenda: On May 6, 2004, from 8 a.m. to 5:30 p.m. and May 7, 2004, from 8 a.m. to 11 a.m., the committee will discuss efficacy and labeling issues for over-the-counter drug products used in the treatment of tinea pedis (interdigital)

in patients 12 years of age and over. On May 7, 2004, from 11 a.m. to 12 noon, each separate committee meeting will be open to the public, unless public participation does not last that long. From 12 noon to 3:30 p.m., each separate committee meeting will be closed to permit discussion and review of trade secret and/or confidential information.

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 April 23, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 6, 2004. On May 7, 2004, oral presentations from the public will be scheduled for each separate committee between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 23, 2004, 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 presentations.

Closed Committee Deliberations: On May 7, 2004, from 12 noon to 3:30 p.m., the committee meetings will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b (c)(4)).

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 15, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–9070 Filed 4–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004–N–0181]

Critical Path Initiative; Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to obtain input on activities that could reduce existing hurdles in medical product design and development. As described in a recently released Report, ''Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products,'' there is an urgent need to modernize the product development toolkit, to make the development process more predictable and less costly. FDA is seeking input in identifying and prioritizing the most pressing medical product development problems, and the areas that provide the greatest opportunities for rapid improvement and public health benefits. To this end, we are establishing this open docket to obtain input from industry, patients, academics investors, and all interested parties.

DATES: Submit written or electronic comments through July 30, 2004.

ADDRESSES: Submit written comments concerning this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Lisa Rovin, Office of the Commissioner (HFP–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857–0001, 301–827–1443.

SUPPLEMENTARY INFORMATION:

I. Background

On March 16, 2004, FDA released a report, ''Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products.'' (The full report is available at *http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf*.) The report notes the recent slowdown in new medical products submitted for approval to FDA, and describes ways in which the product development process, the ''critical path,'' could be modernized to make product development more predictable and less costly. According to Acting FDA Commissioner Lester Crawford, ''A new focus on updating the tools currently used to assess the safety and efficacy of new medical products will very likely bring tremendous public health benefits.''

Recent investments in basic medical research and translational research are intended to promote scientific discoveries and move some of them into medical testing. At that point, however, a potential medical product's journey from concept to commercialization is far from complete. To produce a commercial medical product, developers must successfully negotiate a ''critical path'' to ascertain whether the potential drug, device, or biologic is effective and sufficiently safe for use, and how it can be safely and reliably manufactured. Each of the three dimensions of the critical path—assessment of safety testing, proof of efficacy, and industrialization—presents its own set of scientific and technologic challenges, often unrelated to the science behind the mechanism of action of the product.

- The ethics of human testing required that there be a reasonable assurance of safety before people are exposed in clinical trials. The tools used to predict preclinical safety (e.g., animal toxicology) are time consuming and cumbersome. In some cases, particularly for assessment of products based on recent innovative science, entirely new tools must be developed. There is an urgent need for new biomarkers for evaluating safety during human trials.
- Demonstrating the medical effectiveness of a product is one of the most difficult challenges in product development. Even identifying the best way to assess whether a product is effective (what symptoms or physiologic indicators should be followed, and for how long) can present significant unknowns.
- Product development companies must figure out how to manufacture large amounts of the product reliably. Turning a laboratory prototype into a mass-produced medical product requires solutions to problems in physical design, characterization, manufacturing scaleup and quality control. These problems can be rate-limiting for new technologies, which are frequently more complex than traditional products.

Because of its unique vantage point, FDA can work with outside experts in companies and the academic community to coordinate, develop, and/or disseminate solutions to critical path problems, to improve the efficiency of product development industrywide.

The first step is to identify and prioritize the most pressing medical product development problems, and the areas that provide the greatest opportunities for rapid improvement and public health benefits. It is critical that we enlist all relevant stakeholders in this effort. Such a national ''Critical Path Opportunities List'' is intended to bring concrete focus to tasks (whether best undertaken by industry, academia, FDA, by others, or jointly) that can modernize the critical path.

For additional information, you may visit FDA's critical path home page at *www.fda.gov/oc/initiatives/criticalpath*.