Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 17, 2003

Dated: July 18, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–20949 Filed 8–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0294]

Anesthetic and Life Support 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 Anesthetic and Life Support Drugs Advisory Committee. This meeting was announced in the **Federal Register** of July 31, 2003 (68 FR 44955). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Johanna M. Clifford, 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 FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 31, 2003, FDA announced that a meeting of the Anesthetic and Life Support Drugs Advisory Committee would be held on September 9 and 10, 2003. On page 44956, in the first column, the *Agenda* portion of the meeting is amended to read as follows:

Agenda: On September 10, 2003, the committee will discuss the abuse liability of and Risk Management Plans for Palladone (Hydromorphone Hydrochloride) Purdue Pharma, LP, a modified-release hydromorphone drug product indicated for the treatment of moderate to severe pain in opioid tolerant patients.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 12, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–20951 Filed 8–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic 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: Dermatologic and Ophthalmic 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 September 9 and 10, 2003, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: 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, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 9, 2003, the committee will discuss the efficacy and safety of submission tracking number biologics licensing application 125075/0, Efalizumab (Raptiva) by Genentech, Inc., to be used in the treatment of adult patients with moderate to severe plaque psoriasis. On September 10, 2003, the committee will discuss new drug application (NDA) 21–576, Methyl Aminolevulinate Hydrochloride (methyl aminolevulinate cream, 168 milligram/gram) by PhotoCure ASA, for treatment of basal cell carcinoma.

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 September 1, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 3, 2003, 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 contact Kimberly Littleton Topper 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: August 12, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–20952 Filed 8–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0349]

Draft Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Control Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Reviewers: Instructions and Template for Chemistry,

Manufacturing, and Control (CMC) Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications (INDs)'' dated August 2003. The draft guidance document, when finalized, will provide instructions to CMC reviewers of human somatic cell therapies on what information should be recorded and assessed as part of their review of an original IND. The draft guidance document, when finalized, will also provide CMC reviewers the format in the corresponding human somatic cellular therapy CMC template to prepare their reviews.

DATES: Submit written or electronic comments on the draft guidance by November 17, 2003, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance 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: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Control (CMC) Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications (INDs)'' dated August 2003. The draft guidance document provides instructions and a template that are intended to be tools to assist CMC reviewers of human somatic cell therapy INDs. The draft guidance document is intended to help ensure that all applicable regulatory requirements are reviewed for the appropriate stage of product development.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will provide instructions to CMC reviewers of human somatic cell therapies on what information should be recorded and assessed as part of their review of an original IND. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: August 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20950 Filed 8–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[Announcement Number: HRSA–03–110]

Maternal and Child Health Federal Set-Aside Program; Special Projects of Regional and National Significance; State Oral Health Collaborative Systems (SOHCS) Grant Program (CFDA #93.110)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that approximately $2,950,000 in fiscal year (FY) 2003 funds is available to fund up to 59 one-year grants to support States' efforts to develop, implement or otherwise strengthen State oral health collaborative strategies that increase access to oral health services for Medicaid and State Children's Health Insurance Program (SCHIP) eligible children, and other underserved children and their families. Eligibility is open to MCH agencies in the 50 States and nine specified jurisdictions, unless another governmental or non-governmental agency is approved. Awards will be made under the program authority of section 501(a)(2) of the Social Security Act, the Maternal and Child Health (MCH) Federal Set-Aside Program (42 U.S.C. 701(a)(2)), *i.e.,* Special Projects of Regional and National Significance (SPRANS). Funds for these awards were appropriated under Pub. L. 108–07, the ''Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2003.'' Up to $50,000 in FY 2003 funds is available for each one-year grant; up to an additional $50,000 in FY 2003 funds may become available for the grant during the course of the same one-year project period, depending upon the availability of funds.

DATES: The deadline for receipt of applications is August 25, 2003. *Applicants are required to submit one ink-signed original and two copies of the completed application.* The projected award date will be prior to September 30, 2003.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1–877–477–2123 (1–877–HRSA–123) beginning July 25, 2003, or register on-line at: *http://www.hrsa.*