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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 17, 2003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,