and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Aldara™ (4,689,338) represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Aldara™ (4,689,338) is 3,471 days. Of this time, 3,254 days occurred during the testing phase of the regulatory review period, 217 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: August 30, 1987. The applicant claims September 1, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 30, 1987, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: July 26, 1996. The applicant claims July 25, 1996, as the date the new drug application (NDA) for Aldara™ (4,689,338) (NDA 20–723) was initially submitted. However, FDA records indicate that NDA 20–723 was submitted on July 26, 1996.

3. *The date the application was approved*: February 27, 1997. FDA has verified the applicant's claim that NDA 20–723 was approved on February 27, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 14, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before April 13, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 28, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–27584 Filed 10–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0834]

Draft Guidance for Industry on Non-Contraceptive Estrogen Class Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Non-Contraceptive Estrogen Drug Products—Physician and Patient Labeling.'' The draft guidance is intended to serve as a template for sponsors of estrogen class drug products to ensure that such products contain uniform physician and patient labeling information. Once finalized, this draft guidance will replace the ''Labeling Guidance for Estrogen Drug Products, Physician Labeling'' and ''Labeling Guidance for Estrogen Drug Products, Patient Package Insert,'' both of which were revised and published in August 1992.

DATES: Written comments on the draft guidance document may be submitted by December 14, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry can be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of ''Labeling Guidance for Estrogen Drug Products; Physician and Patient labeling'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John C. Markow, Reproductive and Urologic Drug Products, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Non-Contraceptive Estrogen Drug Products; Physician and Patient Labeling.'' Once it has been finalized, the guidance will replace two existing guidance documents: (1) ''Labeling Guidance for Estrogen Drug Products, Physician Labeling'' and (2) ''Labeling Guidance for Estrogen Drug Products, Patient Package Insert,'' both of which were revised and published in August 1992. The draft guidance provides a template for both physician and patient labeling for estrogen class drug products, which sponsors should use with new drug applications and abbreviated new drug applications.

The draft guidance outlines the recommended language for the physician insert and the patient package insert. Included are black box warnings explaining the increased risk of cancer of the uterus associated with the use of estrogens. Once finalized, the recommendations in this draft guidance should be followed for all approved, pending, and future applications.

This draft guidance is a level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on estrogen class labeling. 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 statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and

received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27583 Filed 10–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel PA–98–052, ''Mentored Patient-Oriented Research Career Development Award'' also PA–98–053, ''Midcareer Investigator Award in Patient-Oriented Research''.

Date: November 3–4, 1998.

Time: November 3, 1998, 7:00 pm to 9:00 pm.

Agenda: To review and evaluate grant applications.

Place: The Hyatt Regency Hotel, 100 Bethesda Metro Center, Bethesda, MD 20814.

Time: November 4, 1998, 8:30 am to 3:00 pm.

Agenda: To review and evaluate grant applications.

Place: The Hyatt Regency Hotel, 100 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Diane M. Reid, NIH, NHLBI, DEA, Two Rockledge Center, 6710 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924, (301) 435–0277.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Pathophysiology of HTLV–I and HTLV–II Infection.

Date: November 6, 1998.

Time: 9:30 am to 11:00 am.

Agenda: To review and evaluate grant applications.

Place: Rockledge II, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: C. James Scheirer, Chief, Review Branch, NIH NHLBI, DEA, Two Rockledge Center, 6701 Rockledge Drive, Suite 7216, Bethesda, MD 20892–7924, (301) 435–0266.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Decreasing Weight Gain in African-American Preadolescent Girls.

Date: November 16–17, 1998.

Time: November 16, 1998, 7:00 pm to 10:00 pm.

Agenda: To review and evaluate grant applications.

Place: Hilton Hotel, 620 Perry Parkway, Gaithersburg, MD 20877.

Time: November 17, 1998, 8:00 am to 9:00 am.

Agenda To review and evaluate grant applications.

Place: Hilton Hotel, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Anthony M. Coelho, Leader, Clinical Studies SRG, NIH, NHLB, DEA, Rockledge Center II, 6701 Rockledge Drive, Room 7194, Bethesda, MD 20892–7924, (301) 435–0288.

(Catalogue of Federal Domestic Assistance Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 7, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–27627 Filed 10–14–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncological Sciences Initial Review Group, Pathology B Study Section.

Date: October 14–16, 1998.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Ave, Washington, DC 20007.

Contact Person: Martin L. Padarathsingh, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7804, Bethesda, MD 20892, (301) 435–1717.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Initial Review Group, Visual Sciences C Study Section.

Date: October 14–15, 1998.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1111 30th Street, NW, Washington, DC 20007.

Contact Person: Carole Jelsema, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7850, Bethesda, MD 20892, (301) 435–1248.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Immunological Sciences Initial Review Group, Experimental Immunology Study Section.

Date: October 15–17, 1998.

Time: 8:30 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Airlie House, 6809 Airlie Road, Warrenton, VA 20187.

Contact Person: Calbert A. Laing, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4210, MSC 7812, Bethesda, MD 20892, (301) 435–1221.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Infectious Diseases and Microbiology Initial Review Group, Tropical Medicine and Parasitology Study Section.

Date: October 15–16, 1998.

Time: 8:30 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20852.

Contact Person: Jean Hickman, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4194, MSC 7808, Bethesda, MD 20892, (301) 435–1146.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cellular and Molecular and Developmental Neurosciences.