Department's Office of Special Counsel for Ethics.

VIII. Establish a new ''Chapter KV,'' as follows: Office of Administrative Services and Facilities Management:

KV.00 Mission
KV.10 Organization
KV.20 Functions

KV.00 Mission. The Office of Administrative Services and Facilities Management (OASFM) is the principal advisor to the Deputy Assistant Secretary for Program Operations on all areas of administrative services and facilities management for the Administration for Children and Families (ACF).

KV.10 Organization. The Office of Administrative Services and Facilities Management (OASFM) is headed by a Director who reports to the Deputy Assistant Secretary for Program Operations.

KV.20 Functions. The Office of Administrative Services and Facilities Management (OASFM) directs and manages ACF's administrative support services, facilities management programs and activities.

Provides agency-wide guidance on administrative issues; prepares, coordinates and disseminates information, policy, and/or procedural guidance on administrative and facilities management issues. Directs and/or coordinates management initiatives to improve ACF administrative and facilities management services with the goal of continually improving services while reducing costs.

Maintains budgetary controls on administrative services accounts, reconciling accounting reports and invoices, and monitoring all spending. Controls OASFM Visa credit card for small purchases. Establishes and manages contracts and/or blanket purchase agreements (BPAs) for administrative support and facilities management services, including space design, building alteration and repair, telecommunications, reprographics, physical security, moving, labor, records and property management and inventory, systems furniture acquisitions and assembly, fleet management, and the Information Resource Center (library).

Provides management and oversight of ACF mail delivery services and activities, including Federal and contractor postal services nationwide, covering all classes of U.S. Postal Service mail, priority and express mail services, and courier services, etc.

Directs all activities associated with the ACF Master Housing Plan, including coordination and development of the agency long-range space budget; planning, budgeting, identification, solicitation, acceptance and utilization of office and special purpose space, repairs, and alterations; principal liaison with General Services Administration (GSA) and other Federal agencies, building managers and facilities engineers, architects and commercial representatives, for space acquisition, negotiation of lease terms, dealing with sensitive issues such as handicapped barriers, space shortages, and security. Develops and maintains space floor plans and inventories, directory boards, and locator signs. OASFM serves as the lead for ACF in coordination and liaison with Departmental, GSA, Federal Protective Service, and other Federal agencies on implementation of Federal security directives. Responsible for planning and executing the Agency's environmental health, safety, and physical security programs, ensuring that appropriate occupational health and safety and occupant emergency evacuation plans are in place. Serves as principal liaison with private and/or Federal building managers for all administrative services and facilities management activities. Responsible for issuing, and managing and controlling badge and cardkey systems to control access to agency space for security purposes.

Develops and/or implements agency telecommunications management policy in accordance with Federal regulations and procedures. Reviews and directs payment of all agency telephone invoices. Recommends and advises on the design and function of telecommunications systems, based on user needs, costs and technological availability. Communicates directly with private industry service providers to coordinate the acquisition, installation and maintenance of voice/data telecommunications equipment and systems. Responsible for other sources of communications capability such as pagers, cellular phone service, cable TV service, and audio conferencing equipment and service. Coordinates the implementation of personal video and video conferencing. Updates and maintains the ACF LAN-based telephone directory, handles the distribution of all commercial directories, and updates and maintains the databases for telephone lines, and equipment inventories.

Plans, manages/operates employee transportation programs, including shuttle service and fleet management, employee and visitor parking, and commuter services and programs including transit subsidies and ridesharing. Develops and implements ACF travel policies and procedures consistent with Federal requirements. Provides technical assistance and oversight; coordinates ACF use of the Travel Management System; manages employee participation in the American Express Credit Card program for travel.

Purchases and tracks common use supplies, stationery and publications; manages equipment repair services and reprographics management activities; controls and maintains equipment and personal property inventories; develops and coordinates records (paper) and forms management, and real property activities.

Dated: January 14, 1997.

Olivia A. Golden,

*Acting Assistant Secretary for Children and Families.*

[FR Doc. 97–2236 Filed 1–28–97; 8:45 am]

**BILLING CODE 4184–01–P**

## Food and Drug Administration

**[Docket No. 96E–0354]**

## Determination of Regulatory Review Period for Purposes of Patent Extension; DIFFERIN Solution

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for DIFFERIN Solution and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product,

medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product DIFFERIN Solution (adapalene). DIFFERIN Solution is indicated for the topical treatment of acne vulgaris. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DIFFERIN Solution (U.S. Patent No. Re. 34,440) from Centre International de Recherches Dermatologiques (CIRD), and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 24, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DIFFERIN Solution 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 DIFFERIN Solution is 2,814 days. Of this time, 1,651 days occurred during the testing phase of the regulatory review period, while 1,163 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: September 18, 1988. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on September 18, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: March 26, 1993. The applicant claims March 19, 1993, as the date the new drug application (NDA) for DIFFERIN Solution (NDA 20–338) was initially submitted. However, FDA records indicate that NDA 20–338 was submitted on March 26, 1993.

3. *The date the application was approved*: May 31, 1996. FDA has verified the applicant's claim that NDA 20–338 was approved on May 31, 1996.

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 433 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 31, 1997, 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 July 28, 1997, 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: January 17, 1997.

Stuart L. Nightingale,

*Associate Commissioner for Health Affairs.*

[FR Doc. 97–2141 Filed 1–28–97; 8:45 am]

BILLING CODE 4160–01–F

## Advisory Committees; Notice of Meetings

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

**MEETINGS:** The following advisory committee meetings are announced:

### Drug Abuse Advisory Committee

*Date, time, and place*. February 10, 1997, 8:30 a.m., and February 11, 1997, 9 a.m., Holiday Inn—Gaithersburg, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Type of meeting and contact person*. Open public hearing, February 10, 1997, 8:30 a.m. to 9:30 a.m.; unless public participation does not last that long; open committee discussion, 9:30 a.m. to 11 a.m.; closed presentation of data, 11 a.m. to 2 p.m.; closed committee deliberations, 2 p.m. to 5:30 p.m.; open public hearing, February 11, 1997, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5:30 p.m.; Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Drug Abuse Advisory Committee, code 12535.