Application No.	Drug	Applicant
NDA 7–518	Synthetic Vitamin A	Pfizer Laboratories, Division of Pfizer, Inc., 235 East 42nd St., New York, NY 10017
NDA 8–837	Isoniazid Tablets	Barnes Hind, 895 Kifer Rd., Sunnyvale, CA 94806
NDA 8–851	NDK Fluoride Dentifrice (sodium monofluorophosphate)	NDK Co., c/o J.W. Emmer/Kenneth Emmer, 215 Genevieve Dr., Lafayette, LA 70503
NDA 9–395	Paskalium (potassium aminosalicylate)	Glenwood, 111 Cedar Lane, Englewood, NJ 07631
NDA 19–518	Extra Strength Aim (sodium monofluorophosphate)	Chesebrough-Ponds USA Co., 33 Benedict Pl., P.O. Box 6000, Greenwich, CT 06836–6000

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated by the Commissioner, finds that the holders of the applications listed in this document have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, we find that the holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this document, and all amendments and supplements thereto, is hereby withdrawn, effective October 10, 2007.

Dated: September 24, 2007.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E7–19865 Filed 10–9–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0357]

Medical Device User Fee and Modernization Act; Notice to Public of Web Location of 2008 Proposed Guidance Development; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Web location where it will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development. In addition, FDA is establishing a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Deborah A. Wolf, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–2350.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of guidance documents that FDA's Center for Devices and Radiological Health (CDRH) is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidances. This notice announces the Web location of the list of guidances CDRH is intending to work on over the next fiscal year. We note that the agency is not required to issue every guidance on the list, nor is it precluded from issuing guidance documents that are not on the list. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued Level 1 drafts that may be finalized following review of public comments. We will consider stakeholder comments as we prioritize our guidance efforts.

We also note that CDRH's experience over the years has shown that there are many reasons CDRH staff cannot complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the Center is required each year to issue a number of guidances it cannot know about in advance. These may involve newly identified public health issues as well as special control guidance documents that are necessary for the classification of *de novo* devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders.

The Center expects that the recent initiatives it has taken to streamline and track guidance development will improve its capacity to issue more guidance documents. The posting and the establishment of a docket announced through this notice is one of the ways CDRH hopes to enhance the process. Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a specific Docket (see docket number found in brackets in the heading of this document) where comments about the list, draft language for guidance documents on those topics, and suggestions for new or different guidances may be submitted. FDA hopes this docket will become an important tool for receiving information from interested parties and for sharing this information with the public.

Similar information about planned guidance development is included in the annual agency-wide notice issued by FDA under its good guidance practices (21 CFR 10.115(f)(5)). This CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site prior to the beginning of each fiscal year from 2008 to 2012.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments submitted to this docket may include draft guidance documents that stakeholders have prepared for FDA's consideration.

To access the list of the guidance documents CDRH is considering for development in 2008, visit the FDA Web Site at *http://www.fda.gov/cdrh/mdufma/guidance/agenda/fy08.html*.

Dated: October 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19864 Filed 10–9–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of meeting of the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of meeting of the Advisory Committee on Organ Transplantation.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the thirteenth meeting of the Advisory Committee on Organ Transplantation (ACOT), Department of Health and Human Services (HHS). The meeting will be held from approximately 9 a.m. to 5:30 p.m. on November 15, 2007, and from 9 a.m. to 3 p.m. on November 16, 2007, at the Crowne Plaza Hotel Washington, DC—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

ACOT will hear presentations on xenotransplantation; pediatric transplantation; transplantation economics; a description of two National Institutes of Health long-term living donor follow up studies; and Organ Procurement and Transplantation Network Long-Term Follow Up. The ACOT work groups also will update the full Committee on their deliberations on transplant tourism, informed consent, sources of funding for additional data collection, and tissue recovery and transplantation certification/accreditation.

The draft meeting agenda will be available on November 1 on the Department's donation Web site at *http://www.organdonor.gov/acot.html.*

A registration form will be available on October 15 on the Department's donation Web site at *http://www.organdonor.gov/acot.html.* The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701. Individuals without access to the Internet who wish to register may call Sowjanya Kotakonda with PSA at (703) 234–1737. Registration can also be completed electronically at *http://www.psava.com/dot/acot2007/*. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACOT Executive Secretary, Remy Aronoff, in advance of the meeting. Mr. Aronoff may be reached by telephone at 301–443–3264, e-mail: *Remy.Aronoff@hrsa.hhs.gov* or in writing at the address provided below. Management and support services for ACOT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations and ACOT discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting.

Dated: October 2, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–19969 Filed 10–9–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; 67 FR 46519, July 15, 2002; 68 FR 787–793, January 7, 2003; 68 FR 8515–8517, February 21, 2003; 68 FR 64357–64358, November 13, 2003; 69 FR 56433–56445, September 21, 2004; as last amended at 70 FR 19962–19963, April 15, 2005). This Order of Succession supersedes the Order of Succession for the Administrator, HRSA, published at FR 70 19962–19963, April 15, 2005.

This notice updates changes to HRSA's hierarchy affecting the Office of the Administrator; Deputy Administrator; Senior Advisor to the Administrator, Chief Financial Officer; Bureau of Primary Health Care; Office of