

Mid-Atlantic Network of Y&FS, PA	90CY2175	202,500
MINK Network of RHY, MO ..	90CY2176	157,500
Southwest Network of YS, TX	90CY2177	202,500
Southeastern Network of YFS, AL	90CY2178	216,000
Empire State Coalition of YFS	90CY2179	177,300
Mountain Plains Network for Youth, ND	90CY2180	157,500
New England Network/YFS, MA	90CY2181	198,000
Northwest Network of RHYS, WA	90CY2182	180,000
Youth Network Council, IL	90CY2183	225,000
Western States Youth Svcs, AZ	90CY2184	216,000

deviation to supplement the National Runaway Switchboard for the purpose of expanding their services. Congress authorized the establishment of a “national communications system to assist runaway and homeless youth in making contact with their families and service providers” through the Runaway and Homeless Youth Act (RHYA) of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended. Funding for the system was first authorized in fiscal year 1980. (The system currently is authorized through Part C, section 331, of the “Runaway, Homeless, and Missing Children Protection Act,” Pub. L. 108–96.)

The Administration on Children, Youth and Families, Family and Youth Services Bureau (FYSB), herein announces an expansion supplement award to the National Runaway Switchboard (NRS) for two initiatives; a comprehensive research project on runaway and at-risk youth and a comprehensive database conversion.

The results of the comprehensive research project will enable NRS to better understand how to communicate with youth and develop strategies to connect with them and them with the NRS. The comprehensive database conversion will enhance the Switchboard’s capability to download and manage information. This project will provide the NRS with the internal controls necessary to query and analyze data collected in their crisis logs. It is anticipated that the enhanced internal controls will result in a significant improvement in the way needs of runaway, homeless and other youth in at-risk situations are met. This expansion supplement is for a nine month project period for the amount of \$162,637.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0246]

Menley & James Laboratories, Inc. et al.; Withdrawal of Approval of Six New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of six new drug applications (NDAs) from multiple holders of these applications. The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for the applications.

DATES: Effective October 10, 2007.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of June 28, 2007 (72 FR 35498), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of six NDAs because the firms had failed to submit the required annual reports for these applications. The holders of these applications did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by part 314 (21 CFR 314) in § 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the six applications listed in the table of this document.

FOR FURTHER INFORMATION CONTACT:

Curtis O. Porter, Acting Associate Commissioner, Family and Youth Services Bureau, ACYF, ACF, DHHS. Portals Building, 1250 Maryland Avenue, SW., Washington, DC 20024; 202–205–8102.

Dated: September 28, 2007.

Susan Orr,

Associate Commissioner, Administration on Children, Youth and Families.

[FR Doc. E7–19881 Filed 10–9–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Award Announcement; Administration on Children, Youth and Families

AGENCY: Administration on Children, Youth and Families, Administration for Children and Families, Department of Health and Human Services.

ACTION: Award announcement.

CFDA NO.: 93.550, 93.623, 93.557.

SUMMARY: The Administration on Children, Youth and Families (ACYF), Family and Youth Services Bureau (FYSB) announces the approval of a

FOR FURTHER INFORMATION CONTACT:

Curtis O. Porter, Acting Associate Commissioner, Family and Youth Services Bureau, ACYF, ACF, DHHS. Portals Building, 1250 Maryland Avenue, SW., Washington, DC 20024; 202–205–8102.

Dated: September 28, 2007.

Susan Orr,

Associate Commissioner, Administration on Children, Youth and Families.

[FR Doc. E7–19886 Filed 10–9–07; 8:45 am]

BILLING CODE 4184–01–P

Application No.	Drug	Applicant
NDA 6–410	Benzedrex (propylhexadrine) Nasal Spray	Menley & James Laboratories, Inc., Commonwealth Corporate Center, 100 Tournament Dr., Horsham, PA 19044

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 aminosaliclate)	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.