

programmatic limitations regarding which ethnic groups they can serve. We believe that by allowing them to increase the number of sites, that it would be a cost-effective way of helping more refugees develop the skills that help their marriages succeed and give their children a better chance of success in the U.S. Without it, these sites might struggle to provide refugee clients with the programs they need in order to achieve self-sufficiency.

The proposed project period is 9/30/2005–9/29/2006.

Assistance to support grantees in developing better approaches to the delivery of services provided to refugees is authorized by section 412(c)(1)(A) of the Immigration and Nationality Act (8 U.S.C. 1522(c)(1)).

**FOR FURTHER INFORMATION CONTACT:**

Administration for Children and Families, Office of Refugee Resettlement, 370 L'Enfant Promenade, SW., Washington, DC 20447, Loren Bussert—(202) 401-4732, [lbussert@acf.hhs.gov](mailto:lbussert@acf.hhs.gov).

Dated: September 15, 2005.

**Nguyen Van Hanh,**

*Director, Office of Refugee Resettlement.*

[FR Doc. 05-18847 Filed 9-20-05; 8:45 am]

BILLING CODE 4184-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0143]

**High Chemical Co. et al.; Withdrawal of Approval of 13 New Drug Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 13 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 September 21, 2005.

**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 January 28, 2005 (70 FR 4134), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 13 NDAs because the firms had failed to submit the required annual reports for these applications. On April 28, 2005, the agency withdrew that notice (70 FR 22054) and reissued the corrected NOOH (70 FR 22052). FDA received two responses to the NOOH:

1. The Kendall Co. (Kendall), 15 Hampshire St., Mansfield, MA 02048, notified the agency that they no longer market the following products: NDA 10-337, Fling Antiperspirant Foot Powder; NDA 10-823, BIKE Foot and Body Powder; and NDA 10-824, BIKE Anti-Fungal Aerosol Spray. Kendall informed FDA that their historical files show they sold their rights to these three products (including the licenses) many years ago; however, they did not notify the agency of the sale. Because Kendall sold the products many years ago, they have no record of the new application holder. Neither The Kendall Co. nor the new license holder requested a hearing.

2. Bayer HealthCare LLC, Biological Products Division, 800 Dwight Way, Berkeley, CA 94701-1966, notified the agency that NDA 10-541, BY-NA-MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder, is not a product produced at their Berkeley site, and that they would forward the NOOH to Bayer HealthCare LLC, Pharmaceutical Division, 400 Morgan Lane, West Haven, CT 06516-4175. Bayer HealthCare LLC in West Haven, CT, informed the agency that NDA 10-541, BY-NA-MID, is not their product and that they have no regulatory files for this product. Bayer HealthCare LLC did not request a hearing.

No other firms responded to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 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 13 applications listed in the table of this document.

| Application No. | Drug  | Applicant   |
|-----------------|---|---|
| NDA 0-763       | Sterile Solution Procaine Injection 2% (Procaine Hydrochloride (HCl))                             | High Chemical Co., 1760 N. Howard St., Philadelphia, PA 19122                   |
| NDA 2-959       | Nicotinic Acid (Niacin) Tablets   | The Blue Line Chemical Co., 302 South Broadway, St. Louis, MO 63102             |
| NDA 4-236       | Sherman (thi-amine HCl) Elixir  | Do.   |
| NDA 4-368       | Ascorbic Acid Tablets   | Do.   |
| NDA 5-159       | D.S.D. (diethylstilbestrol dipropionate)  | Do.   |
| NDA 9-452       | Multifuge (piperazine citrate) Syrup  | Do.   |
| NDA 10-055      | Fire Gard Three-Alarm Burn Relief (Methylcellulose)   | Gard Products, Inc., 2560 Tara Lane, Brunswick, GA 31520                        |
| NDA 10-337      | Fling Anti-perspirant Foot Powder   | Bauer & Black, A Division of The Kendall Co., One Federal St., Boston, MA 02110 |
| NDA 10-541      | BY-NA-MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder | Miles Inc., Cutter Biological, P.O. Box 1986, Berkeley, CA 94701                |
| NDA 10-823      | BIKE Foot and Body Powder   | Bauer & Black, A Division of The Kendall Co.                                    |
| NDA 10-824      | BIKE Anti-Fungal Aerosol Spray  | Do.   |
| NDA 11-233      | TKO with Entrin Roll-On Liquid  | Modern-Labs, Inc., Maple Rd., Gambrills, MD 21504                               |
| NDA 19-432      | Spectamine (lofetamine Hydrochloride 1-123) Injection   | IMP Inc., 8050 El Rio, Houston, TX 77054  |

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 of Food and Drugs, 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 September 21, 2005.

Dated: August 29, 2005.

**Steven Galson,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 05-18873 Filed 9-20-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Dallas District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

**Date and Time:** The public workshop is scheduled for Wednesday, February 8, 2006, from 8:15 a.m. to 5 p.m. and Thursday, February 9, 2006, from 8:15 a.m. to 4 p.m.

**Location:** The public workshop will be held at the Crowne Plaza Hotel Houston Medical Center, 6701 South Main, Houston, TX 77030, 713-797-1110, FAX: 713-796-8291.

**Contact:** David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, e-mail: [oraswrsbr@ora.fda.gov](mailto:oraswrsbr@ora.fda.gov).

**Registration:** Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of \$485

(member), \$560 (nonmember), or \$460 (government employee nonmember). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to [http://www.socra.org/html/FDA\\_Conference.htm](http://www.socra.org/html/FDA_Conference.htm) (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800-SoCRA92 (800-762-7292), or 215-345-7369, or via e-mail: [socramail@aol.com](mailto:socramail@aol.com). Attendees are responsible for their own accommodations. To make reservations at the Crowne Plaza Hotel Houston Medical Center at the reduced conference rate, contact the Crowne Plaza Hotel Houston Medical Center (see *Location*) before January 17, 2005. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact David Arvelo (see *Contact*) at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The workshop on FDA clinical trials statutory and regulatory requirements, helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA regulation of the conduct of clinical research; (2) medical device, drug, and biological product aspects of clinical research; (3) investigator initiated research; (4) pre-investigational new drug application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bio research inspections; and (11) what happens after the FDA inspection. FDA has made education of the research community a high priority to ensure the quality of clinical data and protect research subjects. The workshop

helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities by Government agencies directed to small businesses.

Dated: September 15, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-18871 Filed 9-20-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Psychopharmacologic 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:** Psychopharmacologic 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 October 25, 2005, from 8 a.m. to 5 p.m. and on October 26, 2005, from 8 a.m. to 3 p.m.

**Location:** Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel phone number is 301-977-8900.

**Contact Person:** Karen Templeton-Somers, 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, FAX: 301-827-6776, e-mail: [somersk@cder.fda.gov](mailto:somersk@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://>