NDA No.	Drug	Applicant
11–835	HydroDiuril (hydro-chlorothiazide) Tablets, 25, 50, and 100 mg.	Do.
12–383	Colbenemid (colchicine; probenecid) Tablets, 0.5 mg; 500 mg.	Do.
15–921	Haldol (haloperidol) Tablets, 0.5, 1, 2, 5, 10, and 20 mg.	Ortho-McNeil Pharmaceutical, Inc. 1000 Route 202, P.O. Box 600, Raritan, NJ 08869–0600.
17–657	Cephulac (lactulose) Solution, 10 grams/15 mL.	Aventis Pharmaceuticals, 300 Somerset Corporate Blvd., Bridgewater, NJ 08807–2854.
17–814	Indocin (indomethacin) Suppositories, 50 mg.	Merck & Co., Inc.
17–851	Lioresal (baclofen) Tablets, 10 and 20 mg.	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936.
18–654	Versed (midazolam hydrochloride (HCl)) Injection, 1 mg/mL and 5 mg/mL.	Roche Pharmaceuticals, Division of Hoffmann-LaRoche, Inc., 340 Kingsland St., Nutley, NJ 07110.
20–095	Zantac (ranitidine HCl) Geldose Capsules, 150 and 300 mg.	GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709.
20–942	Versed (midazolam HCl) Syrup, 2 mg/mL.	Roche Pharmaceuticals.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Approved ANDAs that refer to the NDAs listed in this document are unaffected by the withdrawal of the products subject to those NDAs, and accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Dated: July 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19946 Filed 8–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0201]

Minimizing Medication Errors—Methods for Evaluating Proprietary Names for Their Confusion Potential; Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) held a public meeting on June 26, 2003, to discuss current methods and approaches used to evaluate proprietary drug names for similarities. In the document that published in the **Federal Register** of May 30, 2003 (68 FR 32529), announcing the June 26, 2003, meeting, the agency requested comments by July 15, 2003, on questions relating to the issues discussed at the meeting. FDA is reopening the comment period until September 5, 2003, on issues discussed at that meeting in response to a request that the agency allow interested parties additional time to review and to submit comments on this issue.

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 questions to *http://www.fda.gov/ohrms/dockets*.

DATES: Submit written or electronic comments by September 5, 2003.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7849, FAX: 301–443–9664.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 30, 2003, FDA published a document announcing a public meeting, which was to be held on June 26, 2003, in cooperation with the Institute for Safe Medication Practices and the Pharmaceutical Research and Manufacturers of America. The purpose of the meeting was to encourage discussion among representatives from industry, the health care professions, consumer groups, academia, and others on how best to minimize the potential for medication errors due to similarities in drug names, including a discussion of current methods and approaches. The Department of Health and Human Services (DHHS), Office of the Secretary published a recommendation (from the November 21, 2002, report from the DHHS Advisory Committee on Regulatory Reform) that called for FDA to shift, in most cases, from performing drug name safety testing to reviewing data submitted by sponsors. At the June 26, 2003, meeting, several tools with the potential to minimize naming errors resulting from look alike and sound alike drug names were considered. Potential tools included sampling, questionnaire construction, handwriting and voice recognition models, expert committees, computer assisted decision analysis, failure modes and effects analysis and premarketing risk management programs. In the document announcing that meeting, the agency requested information in response to FDA questions that had been posted at

http://www.fda.gov/cder/workshop.htm (choose Minimizing Medication Errors—Evaluating the Drug Naming Process; Public Meeting). Comments were to be received by July 15, 2003. However, in response to a request that the agency allow interested parties additional time to review and to submit comments on this issue, FDA is reopening the comment period on issues discussed at that meeting until September 5, 2003.

II. 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 individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the issues on which comments are requested at *http://www.fda.gov/cder/workshop.htm*. Paper copies of the questions may be obtained by contacting Mary Gross (*see* **FOR FURTHER INFORMATION CONTACT**).

Dated: July 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20063 Filed 8–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration and National Institute of Allergy and Infectious Diseases; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the National Institute of Allergy and Infectious Diseases (NIAID), regarding clinical trial design of febrile neutropenia and antifungal combination therapy. The public workshop is intended to provide information for and gain perspectives from advocacy groups, interested health care providers, academia, and industry organizations on various aspects of febrile neutropenic and antifungal drug development.

DATES: The public workshop will be held on Thursday, September 4, 2003, from 1 p.m. to 5 p.m.

ADDRESSES: The public meeting will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814. Seating is limited and available on a first-come, first-served basis. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic registration.

FOR FURTHER INFORMATION CONTACT: John Powers or Leo Chan, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, (301) 827–2530.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with NIAID, regarding two drug development scenarios: (1) Studies of empirical therapy in febrile neutropenic patients; and (2) clinical trial design considerations necessary to adequately determine safety and efficacy of antifungal combination therapies. Both agencies encourage individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop. The input from this public workshop will be used to develop topics for discussion at future meetings of the Antiviral Drugs Advisory Committee.

Because seating is limited, we are asking interested persons to register on a first-come, first-served basis. To register electronically, go to FDA's Web site at *http://www.fda.gov/cder/drug/antimicrobial/default.htm*. Those without access to the Internet can call (301) 827–2530 to register.

Dated: July 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20064 Filed 8–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA 93.145, HRSA 04–008]

AIDS Education and Training Centers, National Evaluation Center Cooperative Agreement (NECCA); Open Competition Announcement

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Open Competition Cooperative Agreement.

SUMMARY: The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) announces that applications will be accepted for fiscal year (FY) 2004 awards for a cooperative agreement to support the AIDS Education and Training Centers' (AETCs) National Evaluation Center (NEC). The NEC will provide evaluation services and support to the network of Regional and National AETCs. The purpose of the NEC is to develop, test, and disseminate methods and models for evaluating the impact of clinical education and training on provider behavior and clinical practice, with respect to changes in knowledge and skills, clinical practice behavior, and clinical outcomes.

The purpose of the Regional and National Minority AETCs is to improve the quality of HIV/AIDS clinical care through the training of health care professionals. The Regional and National Minority AETCs enhance the availability of high quality HIV care through training and support of clinical providers, and prioritize the clinical support and training needs of direct medical care providers, including physicians, nurses, physician's assistants, advance practice nurses, pharmacists, and oral health providers. The Regional and National Minority AETCs conduct assessments of regional HIV/AIDS care delivery systems and develop innovative programs to build, through training and support, HIV/AIDS care capacity to fill identified gaps. The Regional and National Minority AETCs target clinical providers caring for communities of color and populations disproportionately affected by the HIV/AIDS virus, particularly providers and those associated with Ryan White Comprehensive AIDS Resources Emergency (CARE) Act supported facilities.

As an active partner in this cooperative agreement, HRSA will have significant involvement with the applicant regarding program plans, policies, and other issues which may have major implications for any activity undertaken by the applicant under the cooperative agreement. HRSA will partner in the development of methods and tools, and selection of pilot sites. HRSA will also review and approve each phase of evaluation studies, and review and process Office of Management and Budget (OMB) Clearance package(s). Additionally, HRSA will assist and guide in program management and evaluation technical assistance. HRSA will participate, as