

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has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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.

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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