Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Pre-screening postcard completion	16,470	1	5/60
Free Water Test Completion	3,790	1	5/60
Initial recruiting postcard completion	1,480	1	5/60
Screening/Recruiting telephone interview	490	1	15/60
Survey interview (in person)	780	1	30/60
Short-term diary completion	780	1	15/60
Biologic specimen collection	780	1	10/60
Toenail analysis phone call	260	1	5/60
Toenail analysis consent forms	260	1	5/60

Dated: July 31, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–19980 Filed 8–5–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Public Health Service (PHS) Act; Delegation of Authority

Notice is hereby given that I have delegated to the Associate Director for Science, CDC, without authority to redelegate, the authority vested in the Director, CDC, under section 301(d), of the PHS Act (42 U.S.C. 241 *et seq.*).

This delegation became effective upon date of signature.

Dated: July 29, 2003.

Julie Louise Gerberding,

Director.

[FR Doc. 03–19953 Filed 8–5–03; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0336]

Determination That Benztropine Mesylate Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the 10 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. These are drug products with approved new drug applications (NDAs) to which one or more approved abbreviated new drug applications (ANDAs) refer. This determination means that the approval status of the ANDAs is unaffected by the withdrawal from sale of the reference product.

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

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

If a listed drug is withdrawn from sale and there are approved ANDAs that refer to that drug, under § 314.161(a)(2) (21 CFR 314.161(a)(2)), the agency must determine whether the listed drug was withdrawn from sale for reasons of safety or effectiveness. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

The holders of the applications listed in the table in this document have informed FDA that the drug products have been withdrawn from sale. The drug products in the table are subjects of approved NDAs to which one or more approved ANDAs refer.

NDA No.	Drug	Applicant
9–193	Cogentin (benztropine mesylate) Tablets, 0.5, 1, and 2 milligrams (mg).	Merck & Co., Inc., BLA–20, P.O. Box 4, West Point, GA 19486–0004.

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