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Determination That Benztropine Mesylate Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the 10 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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.