are invalid. For example, planning is often based on the following assumptions: (1) That victims will be decontaminated by first responders on the scene; (2) that victims will be transported by ambulances that can be directed to a hospital designated for contaminated casualties; and (3) that hospitals will receive advance notice that casualties will be arriving, so that special preparations can me made to receive them (e.g., lining floors and walls with plastic tarps; donning respirators and chemical resistant clothing).

We propose assessing 10 incidents over a three-year period involving patients treated at hospitals for actual or possible contamination by chemicals which could pose a threat of illness or injury to the hospital staff that treat them. Data will be collected not only from hospitals but from other emergency medical and public safety organizations, and even members of the public who have become involved in the response. This is because the actions of these groups can have a profound effect on how hospitals carry out their emergency tasks. The lessons-learned during these responses will be collected by a field research team using semi-structured, open-ended interviews of those involved in the responses, for example: patients and their families, hospital staff, police, firefighters, emergency medical technicians, emergency dispatchers, and others who have knowledge of the response.

Certain standardized data will also be collected, such as: number of victims, chemical identity, distribution of casualties among area hospitals, time of incident, time of hospital notification, type of protective clothing and respiratory protection used by hospital staff. A review of the existing field disaster research literature has failed to identify other studies that have collected this type of information. The results of the project will be used to develop and update training materials for hospitals and other emergency responders. There are no costs to respondents.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Emergency Responders	100	2	1	200
Patients and/or Family	40	2	1	80
Total				280

Dated: July 31, 2003.

Thomas A. Bartenfeld,

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

[FR Doc. 03–19979 Filed 8–5–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–60–03]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project: Assessment of Exposure to Arsenic through Household Water, OMB No. 0920–0472—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background

Arsenic is a naturally occurring element present in food and water as both organic and inorganic complexes. Epidemiologic evidence shows a strong link between ingestion of water containing inorganic arsenic and an increase in certain cancers (e.g., bladder cancer, lung cancer). Although consumption of arsenic-contaminated food is the major source of arsenic exposure for the majority of U.S. citizens, in some areas of the United States, elevated levels of arsenic occur frequently in water. In such areas, ingestion of water can be the primary source of arsenic exposure.

Currently, point-of-use (POU) devices are the preferred method of treatment of private domestic well water containing elevated levels of arsenic. Bottled water and POU treatment systems are considered effective means of managing arsenic exposure based on the assumption that people's other water exposures, such as bathing, brushing of teeth, cooking, and drinking occasionally from other taps, contribute relatively minor amounts to a person's total daily intake of arsenic.

We propose to conduct a study to methodically test the validity of the commonly made assumption that secondary water exposures, such as bathing, will not result in a significant increase in arsenic exposure above background dietary levels. Specifically, we are interested in assessing total urine arsenic levels and levels of organic and inorganic arsenic species among people in areas in which ingestion of arsenic-containing water is controlled by either POU treatment or use of bottled water.

Potential participants who are interested in being part of the study will be interviewed by telephone. Recruited participants will be asked to participate in a survey interview about potential exposures to arsenic. Participants in the study will use short-term diaries to record diet, water consumption, and bathing frequency. In addition, we will assess long-term arsenic exposure by analyzing toenail samples for total arsenic.

The total annualized burden hours are estimated to be 2,689.

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.