use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

*Proposed Project:* Statement in Support of Application For Waiver of Inadmissibility OMB No. 0920–0006—Extension—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

Section 212(a)(1) of the Immigration and Nationality Act states that aliens with specific health-related conditions are ineligible to receive visas and ineligible for admission into the United States. The Attorney General may waive application of this inadmissibility on health-related grounds if an application for waiver is filed and approved by the consular office considering the application for a visa. The Division of Migration and Quarantine, NCID uses this application primarily to collect information to establish and maintain records of waiver applicants in order to notify the Immigration and Naturalization Service when terms, conditions and controls imposed by waiver are not met. NCID is requesting the extension of this data for 3 years. There are no costs to respondents.

| Respondents | Number of respondents | Number of responses/respondents | Avg. burden/response (in hrs.) | Total burden (in hrs.) |
|---|---|---|---|---|
| Businesses or organizations | 200 | 1 | 10/60 | 33 |
| Total | | | | 33 |

Dated: September 18, 2001.

**Nancy E. Cheal,**

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

[FR Doc. 01–24022 Filed 9–25–01; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30DAY–49–01]**

### Agency Forms Undergoing Paperwork Reduction Act Review

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) 639–7090. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

*Proposed Project:* Hazardous Substances Emergency Events Surveillance—Extension—OMB No. 0923–0008 Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR is mandated pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, The Superfund Amendments and Reauthorization Act (SARA), to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances into the environment. The primary purpose of this activity, which ATSDR has supported since 1992, is to develop, implement, and maintain a state-based surveillance system for hazardous substances emergency events which can be used to (1) describe the distribution of the hazardous substances releases; (2) describe the public health consequences (morbidity, mortality, and evacuations) associated with the events; (3) identify risk factors associated with the public health consequences; and (4) develop strategies to reduce future public health consequences. The study population will consist of all hazardous substance non-permitted acute releases within the 16 states (Alabama, Colorado, Iowa, Louisiana, Minnesota, Mississippi, Missouri, New Jersey, New York, North Carolina, Oregon, Rhode Island, Texas, Utah, Washington, and Wisconsin) participating in the surveillance system.

Until this system was developed and implemented, there was no national public health-based surveillance system to coordinate the collation, analysis, and distribution of hazardous substances emergency release data to public health practitioners. It was necessary to establish this national surveillance system which describes the public health impact of hazardous substances emergencies on the health of the population of the United States. The data collection form will be completed by the state health department Hazardous Substances Emergency Events Surveillance (HSEES) coordinator using a variety of sources including written and oral reports from environmental protection agencies, police, firefighters, emergency response personnel; or researched by the HSEES coordinator using census data, material safety data sheets, and chemical handbooks. The total estimated annualized burden is 7,356 hours.

| Respondents | Number of respondents | Number of responses/respondents | Avg. burden/response (in hrs.) |
|---|---|---|---|
| State Health Deparatments | 16 | 613 | 45/60 |

Dated: September 17, 2001.

**Nancy E. Cheal,**

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

[FR Doc. 01–24019 Filed 9–25–01; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–48–01]**

### Agency Forms Undergoing Paperwork Reduction Act Review

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) 639–7090. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

**Proposed Project**

The National Death Index (NDI)—Extension—OMB No. 0920–213 National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The National Death Index (NDI) is a service of the National Center for Health Statistics that assists health and medical researchers determine the vital status of their study subjects. The NDI is a national data base containing identifying death record information submitted annually to NCHS by all the state vital statistics offices, beginning with deaths in 1979. Searches against the NDI file provide the states and dates of death and the death certificate numbers of deceased study subjects. With the recent implementation of the NDI Plus service, researchers now have the option of also receiving cause of death information for deceased subjects, thus reducing the need to request copies of death certificates from the states. The NDI Plus option currently provides the ICD codes for the underlying and multiple causes of death for the years 1979–1999. The five administrative forms are completed by health researchers in government, universities, and private industry in order to apply for NDI services and to submit records of study subjects for computer matching against the NDI file. The total burdens for this data collection is 227 hours.

| Form | Number of respondents | Number of responses/ respondents | Avg. burden/response (in hrs.) |
|---|---|---|---|
| Form A | 50 | 1 | 23⁰⁄₆₀ |
| Form B | 70 | 1 | 18⁄₆₀ |
| Form C | 120 | 1 | 18⁄₆₀ |
| Form D | 10 | 50 | 3⁄₆₀ |
| Form E | 40 | 1 | 30⁄₆₀ |

Dated: September 17, 2001.

**Nancy E. Cheal,**

*Acting Associate Director for Policy, Planning, and Evaluation Centers for Disease Control and Prevention (CDC).*

[FR Doc. 01–24020 Filed 9–25–01; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01P–0245]**

### Determination That Disulfiram Tablets, 250 and 500 Milligrams, 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 disulfiram (Antabuse) 250- and 500-milligram (mg) tablets, formerly marketed by Wyeth Ayerst Pharmaceuticals (Wyeth Ayerst), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) for disulfiram drug products, and it will allow FDA to continue to approve ANDAs for disulfiram 250- and 500-mg tablets.

**FOR FURTHER INFORMATION CONTACT:** Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 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 drug selected by the agency as the reference standard for bioequivalence testing. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 to which the ANDA refers.

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,'' 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 (21 CFR 314.162).

Under § 314.161(a)(2) (21 CFR 314.161(a)(2)), the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDAs that refer to the drug that was withdrawn are approved. 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