Dated: September 17, 2001.

Nancy E. Cheal,

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

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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

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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