DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 26 2001

3573 '01 SEP 26 P1:39

Roger Schwede
VP, Regulatory Affairs and R&D
Sidmak Laboratories, Inc.
17 West Street
P.O. Box 371
East Hanover, NJ 07936

Re: Docket No. 01P-0245/CP1

Dear Mr. Schwede:

This responds to your citizen petition, dated May 4, 2001, requesting that the Food and Drug Administration (FDA) determine whether disulfiram 250- and 500-mg tablets were withdrawn from the market for reasons of safety or effectiveness.

The FDA has reviewed its records and has determined that disulfiram 250- and 500-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the FDA to maintain the listing of disulfiram 250- and 500-mg tablets in the "Discontinued Drug Product List" of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice announcing the FDA's determination. If you need further information, please do not hesitate to call me at 301-594-2041.

Sincerely yours,

Mary Catchings

Mary Catchings
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

01P-0245 LET 1

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	2 30/60
Form B	70	1	18/60
Form C	120	1	15/60
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]

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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

begin proceedings to withdraw approval of the ANDAs that refer to the drug that was withdrawn from sale.

On May 4, 2001, Sidmak Laboratories, Inc. (Sidmak), submitted a citizen petition (Docket No. 01P–0245/CP1) under 21 CFR 10.25(a) and 10.30 to FDA. Sidmak requested that the agency determine whether disulfiram tablets were withdrawn from the market for reasons other than safety or effectiveness. Disulfiram 250- and 500-mg tablets are the subject of approved NDA 7–883, formerly held by Wyeth Ayerst under the tradename Antabuse. In its petition, Sidmak stated that it acquired all rights to NDA 7–883 from Wyeth Ayerst in December 2000 and that "concurrent with negotiations for this sale, Wyeth Ayerst discontinued the marketing of its disulfiram product."

FDA has reviewed its records and, under § 314.161, has determined that disulfiram 250- and 500-mg tablets approved under NDA 7–883 were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will maintain the listing for these products 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. The approval status of the approved ANDAs that refer to disulfiram 250- and 500-mg tablets is unaffected. Additional ANDAs for dilsulfiram 250- and 500-mg tablets may also be approved by the agency.

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24039 Filed 9–25–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Agricultural Health Study–A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on June 12, 2001, page 31679 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: *Title:* Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture. *Type of Information Collection Request:* Revision (OMB 0925–0406, expiration 11/30/01). *Need and Use of Information Collection:* The Agricultural Health Study is in its third year of follow-up data collection on a prospective cohort of 89,189 farmers, their spouses, and commercial applicators of pesticides from Iowa and North Carolina. Follow-up is not yet complete; an additional two years of follow-up is being requested. *Frequency of Response:* One time. *Affected Public:* Individuals or households, Farms. *Type of Respondents:* Private pesticide applicators and their spouses. The annual reporting burden is as follows: Estimated Number of Respondents: 11,000; *Estimated Number of Responses per Respondent:* 2.2; *Average Burden Hours Per Response:* 1,196; and *Estimated Total Annual Burden Hours Requested:* 13,156. The annualized cost to respondents is estimated at $131, 554. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Michael C.R. Alavanja, Dr. P.H., Division of Epidemiology and Genetics, National Cancer Institute, Executive Plaza South, Suite 8000, 6120 Executive Boulevard, Rockville, MD 20852, or call non-toll free (301)435–4720, or E-mail your request, including your address to *alavanjam@mail.nih.gov*

COMMENTS DUE DATE: GComments regarding this information collection are best assured of having their full effect if received on or before October 26, 2001.

Dated: September 14, 2001.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 01–24033 Filed 9–25–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Fogarty International Center Advisory Board, September 18, 2001, 8:30 am to September 18, 2001, 5 pm, Lawton Chiles International House, 16 Center Drive, (Building 16), Bethesda, MD, 20892 which was published in the Federal Register on September 11, 2001, 66 FR 47234.

The meeting will be held via teleconference on September 18, 2001 at 12 p.m. The meeting is closed to the public.

Dated: September 17, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–24029 Filed 9–25–01; 8:45 am]

BILLING CODE 4140–01–M