

begin proceedings to withdraw approval of the ANDAs that refer to the drug that was withdrawn from sale.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 Sidmak requested that the agency determine whether disulfiram tablets were withdrawn from the market for reasons other than safety or effectiveness.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records and, under § 314.161, has determined that disulfiram 250- and 500-mg tablets approved under NDA 7-883 were not withdrawn from sale for reasons of safety or effectiveness.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 disulfiram 250- and 500-mg tablets may also be approved by the agency.

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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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]

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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]

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