Dated: August 10, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–21092 Filed 8–13–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2695]

Agency Emergency Processing Under OMB Review; Survey of Biomedical Equipment Manufacturers for Year 2000 Compliance

AGENCY: –Food and Drug Administration, HHS.

ACTION:– Notice.

SUMMARY:– The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information, originally approved under OMB control number 0900–0003, concerns a survey of manufacturers of biomedical equipment about the Year 2000 (Y2K) compliance of their products.

DATES: Submit written comments on the collection of information by August 19, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Thomas B. Shope, Office of Science and Technology (HFZ–140), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–3314, ext. 132, or FAX 301–443–9101.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. This collection is needed immediately because some manufacturers have not yet provided data on their noncompliant products and because other manufacturers have provided either incomplete or preliminary, not final, information. Health care facilities and others are depending upon the information in the FDA-operated Federal Y2K Biomedical Equipment Clearinghouse (the Clearinghouse) as they assess the Y2K compliance of the biomedical equipment used in their facilities. In order to continue this collection activity, it is necessary to extend this activity until February 29, 2000. FDA is requesting OMB approval by August 19, 1999.

– FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Survey of Biomedical Equipment Manufacturers for Year 2000 Compliance

The Deputy Secretary of the Department of Health and Human Services, on behalf of the governmentwide Biomedical Equipment Subgroup of the Chief Information Officer Council's Y2K Subcommittee, is surveying manufacturers of biomedical equipment about the Y2K compliance of their products. The existence of a Y2K date problem in biomedical equipment could pose potentially serious health and safety consequences.

Manufacturers have been asked to post information about noncompliant products on a website and link this to a government website on biomedical equipment. If all of a manufacturer's products are compliant, they may provide a notice of total product compliance. Manufacturers have the option to mail the information to the Department of Health and Human Services (DHHS) for posting on the government website, or they may provide it electronically. All information collected is available to the public through the government website.

FDA, on behalf of DHHS, is continuing to solicit product status information from manufacturers that have not responded to this request and to seek clarification or expansion of specific information that has been received, but is incomplete.

– To be Y2K compliant, a product must be able to accurately process date information in the Y2K and between the 20th and 21st centuries, including leap year calculations. Medical devices and scientific laboratory equipment may experience problems beginning January 1, 2000, if the computer systems, software applications, or embedded chips used in these devices and equipment contain two-digit fields for year representation.

FDA regulates medical devices and needs information regarding the Y2K compliance of these products. Under a previous good manufacturing practices regulation and the current quality system regulation, effective June 1, 1997, manufacturers must investigate and correct problems with medical devices that present a significant risk to public health. This includes devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. Also, section 518 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h) requires notification of users or purchasers when a device presents an unreasonable risk of substantial harm to public health. These regulations, however, do not apply to all biomedical equipment, such as scientific laboratory equipment, but only to medical devices. Therefore, a proactive collection of Y2K compliance information of all biomedical equipment is necessary to prevent a Y2K date problem from causing any public health risk in the patient care services and health research initiatives of the next century.

–FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
450	1	450	8	3,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on mailing lists and data bases on product approvals, FDA believes that approximately 150 manufacturers have not yet provided data to the Clearinghouse on Y2K compliance status of their products. Based on analysis of data already in the Clearinghouse, approximately 300 manufacturers have provided information that is either incomplete or that requires clarification. FDA estimates that it will take manufacturers an average of 8 hours to collect, prepare, and submit the requested information.

William K. Hubbard.

Dated: August 10, 1999

Senior Associate Commissioner for Policy, Planning, and Coordination.

[FR Doc. 99–21082 Filed 8–13–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2673]

Caudill Seed Co., Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Caudill Seed Co., Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of irradiation to control microbial pathogens in alfalfa and other sprouting seeds.

FOR FURTHER INFORMATION CONTACT: JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3116.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9M4673) has been filed by Caudill Seed Co., Inc., 1402 West Main St., Louisville, KY 40203. The petition proposes to amend the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) to provide for the safe use of sources of ionizing radiation to control microbial pathogens in alfalfa and other sprouting seeds.

–The agency has determined under 21 CFR 25.32(j) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 1, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–21081 Filed 8–13–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Complementary and Alternative Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council for Complementary and Alternative Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: August 31–September 1, 1999.

Open: August 31, 1999, 8:30 AM to 1:00 PM.

Agenda: The agenda includes introduction of new Council members, remarks by the Acting Director, NCCAM, and other business of the Council.

Place: Doubletree Hotel, Plaza III Room, 1750 Rockville Pike, Rockville, MD 20852.

Closed: August 31, 1999, 1:00 PM to 6:00 PM.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Doubletree Hotel, Plaza III Room, 1750 Rockville Pike, Rockville, MD 20852.

Open: September 1, 1999, 8:30 AM to 1:00 PM.

Agenda: Continuation of Council business.

Place: Doubletree Hotel, Plaza III Room, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Richard Nahin, Phd, Executive Secretary, National Center for Complementary and Alternative Medicine, National Institutes of Health, 9000 Rockville Pike, Room 5B36, Bethesda, MD 20892, 301–594–2013.

Dated: August 6, 1999.

Anna Snouffer,

Committee Management Specialist, NIH.

[FR Doc. 99–21105 Filed 8–13–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. the grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: August 12–13, 1999.

Time: 10:00 AM to 11:00 AM.

Agenda: To review and evaluate grant applications.

Place: 6000 Executive Blvd., Suite 409, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Sean O'Rourke, Scientific Review Administrator, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Boulevard, Bethesda, MD 20892–7003, 301–443–2861.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: August 25, 1999.

Time: 8:30 AM to 10:00 AM.

Agenda: To review and evaluate grant applications.

Place: 6000 Executive Blvd., Suite 409, Rockville, MD 20852, (Telephone Conference Call).