

be obtained by writing the Freedom of Information Staff (address above). The request should identify by the NDA number the EA's and FONSI's requested. Separate requests should be submitted for each NDA. For additional information regarding the submission of freedom of information requests call 301-443-6310.

Dated: September 13, 1996.

William K. Hubbard,
*Associate Commissioner for Policy
Coordination.*

[FR Doc. 96-24149 Filed 9-19-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96G-0324]

Roquette America, Inc., and American Maize-Products Co.; Filing of a Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Roquette America, Inc., and American Maize-Products Co. have filed a petition (GRASP 6G0421) proposing to affirm that beta-cyclodextrin is generally recognized as safe (GRAS) as a flavor protectant in human food.

DATES: Written comments by December 4, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3083.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)), and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Roquette America, Inc., and American Maize-Products Co., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001, have filed a petition (GRASP 6G0421) proposing to affirm that beta-cyclodextrin is GRAS as a flavor protectant in human food.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the

agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Interested persons may, on or before December 4, 1996, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 14, 1996.

Eugene C. Coleman,
*Acting Director, Office of Premarket
Approval, Center for Food Safety and Applied
Nutrition.*

[FR Doc. 96-24148 Filed 9-19-96; 8:45 am]

BILLING CODE 4160-01-F

**Advisory Committee Meeting;
Postponement**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Antiviral Drugs Advisory Committee scheduled for September 26 and 27, 1996. The meeting was announced by a notice in the Federal Register of September 4, 1996 (61 FR 46652). This meeting is being postponed to allow time to incorporate the results of additional study information which have recently become available for the

new drug application 20-705, delavirdine (Rescriptor®, Pharmacia and Upjohn Co.) for use in the treatment of human immunodeficiency virus (HIV) infection. The meeting will be rescheduled at a later date and will be announced in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Rhonda W. Stover, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455; or call the FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Antiviral Drugs Advisory Committee, code 12531.

Dated: September 13, 1996.

Michael A. Friedman,
Deputy Commissioner for Operations.

[FR Doc. 96-24147 Filed 9-19-96; 8:45 am]

BILLING CODE 4160-01-F

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 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on June 13, 1996 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to 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 after 10/1/95, 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 (0925-0406, expiration 8/13/96). Need and Use of Information Collection: The Agricultural Health Study is in its third year of data collection on a prospective cohort of 75,000 farmers, their spouses, and commercial applicators of pesticides from Iowa and North

Carolina. Baseline questionnaires have been completed by these applicators and by spouses of the farmer applicators. These questionnaires collected information about demographics, occupational history, medical history and family medical history. Frequency of Response: Single time reporting. 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: 13,590; Estimated Number of Responses per Respondent: 1.0; Average Burden Hours Per Response: .6143; and Estimated Total Annual Burden Hours Requested: 8,348. The annualized cost to respondents is estimated at: \$83,480. 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) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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, D.C. 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 Cancer Epidemiology and Genetics, National Cancer Institute, EPN 430,6130 Executive Boulevard, Rockville, MD 20852, or call (310) 496-9093, or E-mail your request, including your address to: alavanjam@epndce.nci.nih.gov

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before October 21, 1996.

Dated: September 10, 1996.

Philip D. Amoruso,

NCI Executive Director.

[FR Doc. 96-24209 Filed 9-19-96; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given to amend the notice of the National Cancer Institute Board of Scientific Advisors Prevent Program Working Group meeting which was published in the Federal Register (61 FR 47758) on September 10, 1996 to extend the time of the open session of the meeting.

The Board meeting was scheduled to hold an open session on September 17, 1996 from 8 a.m. to 8:30 a.m. The time has been changed to 8:45 a.m. to 12:30 p.m. The open agenda will include a chemoprevention discussion, presentation by the American Association for Cancer Research on its views on prevention research, and remarks by the NCI Director.

Dated: September 13, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96-24208 Filed 9-19-96; 8:45 am]

BILLING CODE 4140-01-M

Division of Research Grants; 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 Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Behavioral and Neurosciences.

Date: October 21, 1996.

Time: 9:00 a.m.

Place: Holiday Inn-Capitol, Washington, DC.

Contact Person: Dr. Samuel C. Rawlings, Scientific Review Administrator, 6701 Rockledge Drive, Room 5160, Bethesda, Maryland 20892, (301) 435-1243.

Name of SEP: Behavioral and Neurosciences.

Date: October 22, 1996.

Time: 9:00 a.m.

Place: Holiday Inn-Capitol, Washington, DC.

Contact Person: Dr. Samuel C. Rawlings, Scientific Review Administrator, 6701 Rockledge Drive, Room 5160, Bethesda, Maryland 20892, (301) 435-1243.

Name of SEP: Behavioral and Neurosciences.

Date: October 23-25, 1996.

Time: 8:00 a.m.

Place: The Renaissance Mayflower Hotel, Washington, DC.

Contact Person: Dr. David L. Simpson, Scientific Review Administrator, 6701 Rockledge Drive, Room 5192, Bethesda, Maryland 20892, (301) 435-1278.

Name of SEP: Biological and Physiological Sciences.

Date: October 28-30 1996.

Time: 6:00 p.m.

Place: La Posada, Santa Fe, NM.

Contact Person: Dr. Harish Chopra, Scientific Review Administrator, 6701 Rockledge Drive, Room 511, Bethesda, Maryland 20892, (301) 435-1169.

Name of SEP: Clinical Sciences.

Date: November 4-6, 1996.

Time: 8:30 a.m.

Place: Doubletree Hotel, Rockville, MD.

Contact Person: Dr. Gertrude McFarland, Scientific Review Administrator, 6701 Rockledge Drive, Room 4110, Bethesda, Maryland 20892, (301) 435-1784.

Name of SEP: Biological and Physiological Sciences.

Date: November 8, 1996.

Time: 8:30 a.m.

Place: American Inn, Bethesda, MD.

Contact Person: Dr. Nicholas Mazarella, Scientific Review Administrator, 6701 Rockledge Drive, Room 5128, Bethesda, Maryland 20892, (301) 435-1018.

Name of SEP: Multidisciplinary Sciences.

Date: November 18, 1996.

Time: 8:00 a.m.

Place: Holiday Inn-Georgetown, Washington, DC.

Contact Person: Dr. Eileen Bradley, Scientific Review Administrator, 6701 Rockledge Drive, Room 5120, Bethesda, Maryland 20892, (301) 435-1179.

Name of SEP: Multidisciplinary Sciences.

Date: November 21, 1996.

Time: 2:00 p.m.

Place: NIH, Rockledge 2, Room 5118, Telephone Conference.

Contact Person: Dr. Paul Parakkal, Scientific Review Administrator, 6701 Rockledge Drive, Room 5118, Bethesda, Maryland 20892, (301) 435-1172.

Purpose/Agenda: To review Small Business Innovation Research.

Name of SEP: Biological and Physiological Sciences.

Date: October 18, 1996.

Time: 8:00 a.m.

Place: Hyatt Regency, Bethesda, MD.

Contact Person: Dr. Harish Chopra, Scientific Review Administrator, 6701 Rockledge Drive, Room 5112, Bethesda, Maryland 20892, (301) 435-1169.

Name of SEP: Biological and Physiological Sciences.

Date: October 21, 1996.

Time: 8:00 a.m.

Place: Holiday Inn, Chevy Chase, MD.

Contact Person: Dr. Anthony Carter, Scientific Review Administrator, 6701 Rockledge Drive, Room 5108, Bethesda, Maryland 20892, (301) 435-1167.

Name of SEP: Multidisciplinary Sciences.