formal presentations should notify the contact person before April 20, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss the new drug application (NDA) 20–630, Remifentanyl, Glaxo Welcome, for use as a general anesthetic, and a report of the post-market experience and phase IV commitments of NDA 20–478, Ultane® (sevoflurane), Abbott Laboratories.

Closed committee deliberations. On April 30, 1996, the committee will review trade secret and/or confidential commercial information. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: March 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–6960 Filed 3–21–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0071]

1995 Revision of the National Shellfish Sanitation Program Manual of Operations, Part I ''Sanitation of Shellfish Growing Areas'' and Part II ''Sanitation of the Harvesting, Processing, and Distribution of Shellfish;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the 1995 revision of the

National Shellfish Sanitation Program (NSSP) Manual of Operations, part I, ''Sanitation of Shellfish Growing Areas,'' and part II, ''Sanitation of the Harvesting, Processing, and Distribution of Shellfish.'' This revision was initiated in cooperation with the Interstate Shellfish Sanitation Conference (ISSC) to help assure that only safe and sanitary shellfish are offered for sale in interstate commerce.

ADDRESSES: Submit written requests for single copies of the manual (free of charge) from the contact person in the nearest Regional Office listed in the table below:

Addresses	Contact Person
FDA, Stoneham District Office, State Programs Branch, One Montvale Ave., Stoneham, MA 02180.	David Field
FDA, New York Regional Office, 850 Third Ave., Brooklyn, NY 11232–1593	Jerry Mulnick
FDA, Baltimore District Office, Investigations Branch, 900 Madison Ave., Baltimore, MD 21201	Al Ondis
FDA, Atlanta Regional Office, State Cooperative Programs, 60 Eighth St. NE., Atlanta, GA 30309	Robert Creasy
FDA, Charleston Resident Post, 334 Meeting St., rm. 505, P.O. Box 21077, Charleston, SC 29413	Donald M. Hesselman
FDA, Tallahassee Resident Post, Hobbs Federal Bldg., 227 North Bronough St., suite 4150 Tallahassee, FL 32301	Marc Glatzer
FDA, Baton Rouge Resident Post, 5353 Essen Lane, suite 220, Baton Rouge, LA 70809	John Veazey
FDA, Detroit District Resident Post, 1560 East Jefferson Ave., Detroit, MI 48207	Nicholas Majerus
FDA, Dallas Regional Office, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247	Linda Collins
FDA, Seattle District Office, 100 Second Ave., suite 2400, Seattle, WA 98104	Tim Sample
FDA, Shellfish Program Implementation Branch (HFS–628), 200 C St. SW., Washington, DC 20204	Stanley Ratcliffe

Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist in processing your requests. The manual is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Paul W. DiStefano, Office of Seafood, Center for Food Safety and Applied Nutrition (HFS–417), 200 C St. SW., Washington, DC 20204, 202–418–3177.

SUPPLEMENTARY INFORMATION: FDA is responsible for the Federal administration of the NSSP, which is a voluntary program involving State shellfish control agencies, the shellfish industry, FDA, and other Federal agencies. Five foreign countries also actively participate in the NSSP through international bilateral agreements.

The NSSP is concerned with the sanitary control of fresh and frozen molluscan shellfish (oysters, clams, mussels, and scallops) offered for sale in interstate commerce. The program has been in existence since 1925. In the interest of assuring uniform administration and technical controls, the NSSP has developed and maintained recommended shellfish control practices. These control practices have been published in the form of a Manual of Operations, parts I and II.

In 1982, interested State officials and members of the shellfish industry formed the Interstate Shellfish Sanitation Conference (ISSC) to provide a formal structure wherein State regulatory authorities could establish regularly updated and uniform guidelines for improving shellfish sanitation and safety. Those persons interested in obtaining additional information about the ISSC should contact: Kenneth Moore, Interstate Shellfish Sanitation Conference, 115 Atrium Way, suite 117, Columbia, SC 29223.

FDA and the ISSC entered into a Memorandum of Understanding (MOU) that was published in the Federal Register of March 30, 1984 (49 FR 12751), agreeing, among other things, that FDA would provide technical assistance to the ISSC and participate in the cooperative program of the Conference to develop or revise program criteria and guidelines.

Based on the MOU, FDA developed draft revisions of the NSSP Manual of Operations, parts I and II, in cooperation with the ISSC. FDA announced the availability of the 1986 revision of part I in the Federal Register of June 5, 1987 (52 FR 21375). An initial working draft of part II was made available for comment in the Federal Register of September 11, 1985 (50 FR 37055), with a revised second draft being made available for further comment in the Federal Register of July 11, 1986 (51 FR 25261). Based on the comments received, and in consideration of later comments expressed by State regulatory officials, industry representatives, and other interested parties at the ISSC's 1987 and 1988 annual meetings in Austin, TX, and Denver, CO, respectively, FDA announced the availability of the 1988 revision of the manual in the Federal Register of February 17,1989 (54 FR 7281). Subsequent revisions were announced in the Federal Register of April 25, 1990 (55 FR 17503), December 13, 1990 (55 FR 51341), and January 13, 1993 (58 FR 4174).

The 1995 manual revision contains changes and improvements to the NSSP that were considered and passed at the ISSC's 1994 and 1995 annual meetings in Tacoma, WA and Orlando, FL, respectively. Noteworthy changes include: (l) A detailed shellfish laboratory evaluation checklist for State and Federal laboratory evaluation officers to use for certifying that laboratories are operated in compliance with criteria of the National Shellfish Sanitation Program; (2) new time temperature controls to prevent

excessive post harvest increases in the levels of *Vibrio vulnificus* bacteria in shellfish harvested from the waters confirmed as an original source of product associated with two or more *V. vulnificus* illnesses. Matrix controls establish times for shellfish to be under refrigeration following harvest. The time from harvest until shellfish are placed under refrigeration needs to decrease as water temperatures rise. Matrix time/temperature controls are recommended for use with shellfish that are harvested from waters with a *Vibrio* problem and then sold for raw consumption; and (3) new tagging procedures to improve the traceability of wet-stored shellstock to its original harvest site. These procedures include a recommendation to use a shipping tag that identifies the certified wet-storage facility and the storage dates for shellstock that has entered interstate commerce and then been wet stored for 90 days or less.

Dated: March 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–6959 Filed 3–21–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

A Comprehensive Alcohol Education Program for Pre-Adolescents Using Interactive Multimedia

Proposed Data Collection

In compliance with Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) is publishing this notice to solicit public comment on the data collection proposed for the study on ''A Comprehensive Alcohol Education Program for Pre-Adolescents Using Interactive Multimedia.'' To request copies of the data collection plans and interview instruments, call Dr. Kendall Bryant, (301) 443–8820 (not a toll-free number).

Comments are invited on: (a) Whether the proposed collection is necessary, including whether the information has a practical use; (b) ways to enhance the clarity, quality, and use of the information to be collected; (c) the accuracy of the agency estimate of burden of the proposed collection; (d) ways to minimize the collection burden of the respondents. Written comments are requested within 60 days of the publication of this notice. Send comments to Dr. Kendall Bryant, Prevention Research Branch, Division of Clinical and Prevention Research (DCPR), NIAAA, NIH, Building 6000, Room 505, 6000 Executive Boulevard, MSC 7003, Bethesda, Maryland 20892–7003.

Proposed Project

The Prevention Research Branch (PRB), intends to conduct the study for ''A Comprehensive Alcohol Education Program for Pre-Adolescents Using Interactive Multimedia.'' The PRB is authorized by Section 452 of Part G of Title IV of the Public Health Service Act (42 U.S.C. 288) as amended by the NIH Revitalization Act of 1993 (Public Law 103–43).

The information proposed for collection will be used by the NIAAA to determine the efficacy of interactive multimedia for delaying the onset of drinking among 7th and 8th grade males and females. Interactive multimedia enables the combination of the elements of television and movies that engage and motivate the target population with computer-based interaction, simulations, and games to (1) increase information about the negative consequences of teen drinking and (2) teach practical skills for avoiding and refusing alcohol. Subject participation will involve (1) focus groups, during development of the multimedia program, and (2) post-development behavioral trials.

The annual burden estimates are as follows:

Type and No. of respondents	Responses per respondent	Total responses	Hours	Total hours
Focus Group Subjects: 40	1	40	0.5	20
Trial Subjects: 268	4	1072	0.5	536
Total Number of Repondents: 308. Total Number of Responses: 1112. Total Hours: 556.				

Dated: March 12, 1996.

Martin K. Truscy,

Executive Officer, NIAAA.

[FR Doc. 96–7014 Filed 3–21–96; 8:45 am]

BILLING CODE 4140–01–M

Proposed Data Collections Available for Public Comment and Recommendations

Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that Federal Agencies provide a 60-day notice in the Federal Register concerning each proposed collection of information. The National Institutes of Health (NIH) is publishing this notice to solicit public comment on a proposed data collection for the Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds (UGSP). To request copies of the data collection plans and instruments, call Mr. Marc Horowitz on (301) 402–5666 (not a toll-free number).

Comments are invited on: (a) Whether the proposed collection is necessary, including whether the information has practical use; (b) ways to enhance the clarity, quality, and use of the collection; (c) the accuracy of the agency's estimate of burden of the proposed collection; and (d) ways to minimize the collection burden of the respondents. Written comments are requested within 60 days of the publication of this notice. Send comments to Marc S. Horowitz, J.D., Director, Loan Repayment and Scholarship Programs, Office of Science Education, NIH, 7550 Wisconsin Avenue, Room 604, Bethesda, MD 20892–9015.

Proposed Project

The NIH intends to make available scholarships to undergraduate students under the NIH Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds (UGSP). The UGSP is authorized by § 487D of the Public Health Service