Welfare by section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)), all persons who:

1. Are employed by the Research Triangle Institute, Research Triangle Park, N.C.; and

2. Have, in the course of their employment, access to information which would identify individuals who are the subjects of the research on the use and effect of alcohol and drugs which is assisted by the Department of Health, Education, and Welfare under contract numbered ADM 281-76-0019, entitled "Follow-Up of the 1974 National Survey of Junior and Senior High School Students";

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

As provided in section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This authorization does not authorize employees of the Research Triangle Institute to refuse to reveal to qualified personnel of the Department of Health, Education, and Welfare, for the purpose of management or financial audits or program evaluation, the names or other identifying characteristics of individuals who are the subjects of the research conducted pursuant to Department of Health, Education, and Welfare contract numbered ADM 281-76-0019. Such personnel will hold any identifying information so obtained strictly confidential in accordance with 45 CFR 5.71.

This authorization is applicable to all information obtained pursuant to Department of Health, Education, and Welfare contract numbered ADM 281-76-0019 which would identify the individuals who are the subjects of the research conducted under that contract.

Dated: February 14, 1978.

IRVING WOLF,
Acting Deputy Director, National Institute on Alcohol Abuse and Alcoholism.

Dated: February 22, 1978.

ROBERT L. DUPONT,
Director,
National Institute on Drug Abuse.

Dated: February 23, 1978.

DAVID F. KEFAUVER,
Acting Deputy Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 78-6773 Filed 3-16-78; 8:45 am]

[4110-86]

Center for Disease Control

CENTER FOR DISEASE CONTROL PROGRAMS AND POLICIES ADVISORY COMMITTEE (AD HOC)

Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Center for Disease Control announces the following Committee meeting:

CENTER FOR DISEASE CONTROL (CDC) PROGRAMS AND POLICIES ADVISORY COMMITTEE (AD HOC)

Dates: April 11-13, 1978.
Place: Room 207, Building 1, Center for Disease Control 1600 Clifton Road NE., Atlanta, Ga. 30333.
Time: 9 a.m.
Type of meeting: Open.
Contact person: Ms. Patsy Whitesell, Executive Secretary of Committee Bureau of Training, Center for Disease Control 1600 Clifton Road NE., Atlanta, Ga. 30333, phone AC/404-633-3311, extension 6502, FTS 236-7502.
Purpose: The CDC Programs and Policies Advisory Committee (Ad Hoc) will make recommendations to the Secretary, the Assistant Secretary for Health, and the Director, Center for Disease Control pertaining to future direction, programs, and policies for CDC.
Agenda: The Committee will review solicited suggestions on the future direction of CDC from professionals in the fields of public health and preventive medicine, and will develop recommendations on strategies of intervention for priority public health problems in the U.S.

Agenda items are subject to change as priorities dictate.

The meeting is open to the public for observation and participation. Anyone wishing to have a question answered during the meeting by a scheduled speaker should submit the question in writing, along with his or her name and affiliation, through the Executive Secretary to the Chairperson. At the discretion of the Chairperson and as time permits, appropriate questions will be asked of the speakers.

A roster of members and other relevant information regarding the meeting may be obtained from the contact person listed above.

Dated: March 9, 1978.

WILLIAM H. FOEGE,
Acting Director,
Center for Disease Control.

[FR Doc. 78-6951 Filed 3-16-78; 8:45 am]

[4110-86]

SAFETY AND OCCUPATIONAL HEALTH STUDY SECTION

Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Center for Disease Control announces the following National Institute for Occupational Safety and Health Committee meeting:

SAFETY AND OCCUPATIONAL HEALTH STUDY SECTION

Dates: April 20-21, 1978.
Place: Conference Room C, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857.
Time: 7 p.m.
Type of meeting: Closed.
Contact person: Donald F. Flick, Ph.D., Executive Secretary, 5600 Fishers Lane, Parklawn Building, Room 8-63, Rockville, Md. 20857, phone: 301-443-4493.
Purpose: The Committee is charged with the initial review of research, training, demonstration, and fellowship grant applications for Federal assistance in program areas administered by the National Institute for Occupational Safety and Health, and with advising the Institute staff on training and research needs.
Agenda: The Study Section will be performing the initial review of training grant applications for Federal Assistance, and will not be open to the public, in accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code, and the Determination of the Director, Center for Disease Control, pursuant to Pub. L. 92-463.

Dated: March 9, 1978

WILLIAM H. FOEGE,
Acting Director,
Center for Disease Control.

[FR Doc. 78-6952 Filed 3-16-78; 8:45 am]

[4110-03]

Food and Drug Administration

ADVISORY COMMITTEE

Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations (21 CFR 14) relating to advisory committees. The following advisory committee meeting is announced:

Committee name	Date, time, and place	Type of meeting and contact person
Board of Tea Experts.....	Apr. 3 and 4, 10 a.m., room 700, 850 3d Ave., Brooklyn, N.Y..	Open public hearing, Apr. 3, 10 to 11 a.m.; open committee discussion Apr. 3, 11 a.m. to adjournment, Apr. 4, 10 a.m. to adjournment; Robert H. Dick, 850 3d Ave., Brooklyn, N.Y. 11232, 212-965-5739.

General function of the committee. Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all teas imported into the United States pursuant to 21 U.S.C. 42.

Agenda—Open public hearing. Any interested persons may present data, information, or views, or orally or in writing, on issues pending before the board.

Open committee discussion. Discussion and selection of tea standards.

FDA public advisory committee meetings 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. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open 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 chairman determines will facilitate the committee's work.

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 chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be obtained from the Public Records and Documents Center (HFC-18), 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Dated: March 9, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-6784 Filed 3-16-78; 8:45 am]

[4110-03]

PULMONARY-ALLERGY DRUGS ADVISORY COMMITTEE

Renewal

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), the Food and Drug Administration announces the renewal of the Pulmonary-Allergy Drugs Advisory Committee by the Secretary, Department of Health, Education, and Welfare.

DATE: Authority for this committee will expire on May 30, 1978, unless the Secretary formally determines that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Officer (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

Dated: March 9, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-6783 Filed 3-16-78; 8:45 am]

[4110-03]

[Docket No. 78G-0027]

VITENCO, INC.

Filing of Petition for Affirmation of Gras Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Vitenco, Inc., has filed a petition (GRASP 7G0088) proposing affirmation that the use of a lactase enzyme, derived from *Kluyveromyces (Saccharomyces) lactis* and entrapped inside cellulose triacetate fibers, is generally recognized as safe (GRAS) for reducing the lactose content of milk.

DATE: Comments by May 16, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 (21 U.S.C. 321(s), 348, 371(a))) and the regulations for affirmation of GRAS status under § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 7G0088) has been filed by Vitenco, Inc., 594 Marett Rd., Lexington, Mass. 02173, and placed on public display at the office of the Hearing Clerk, Food and Drug Administration, proposing affirmation that the use of a lactase enzyme, derived from *Kluyveromyces (Saccharomyces) lactis* and entrapped inside cellulose triacetate fibers, is generally recognized as safe for reducing the lactose content of milk.

Any petition which meets the format requirements outlined in § 170.35 is filed by the Food and Drug Administration. 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 affirmation.

Interested persons may, on or before May 16, 1978, review the petition and/or file comments (four copies) with the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Comments should include any available information that would be helpful in determining whether the substance is, or is not, generally recognized as safe. A copy of the petition

and received comments may be seen in the office of the Hearing Clerk, address given above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 8, 1978.

HOWARD R. ROBERTS,
Acting Director of Bureau of Foods.

[FR Doc. 78-6785 Filed 3-16-78; 8:45 am]

[4110-03]

CARDIOVASCULAR DEVICE CLASSIFICATION PANEL

Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meeting is announced:

Committee name	Date, time, and place	Type of meeting and contact person
Cardiovascular Device Classification Panel.	Apr. 7 ,9 a.m., room 1409, FB-8, 200 C St. SW., Washington D.C.	Open public hearing 9 to 10 a.m.; open committee discussion 10 a.m. to 2 p.m.; closed committee deliberations 2 to 4 p.m.; Glenn A Rahmoeller (HFK-450), 5787 Georgia Ave., Silver Spring, Md. 20910, 301-427-7560.

General function of the committee. Reviews and evaluates available data concerning the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

Agenda—Open public hearing. Interested parties are encouraged to present information pertinent to this panel's tentative classification findings to the executive secretary. Those desiring to make formal presentations should notify the executive secretary by March 24, 1978 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, references to any data to be relied on, and an indication of the approximate time required to make their comments.

Open committee discussion. During this portion of the meeting, panel members will review their classification recommendation for defibrillators, discuss labeling for defibrillators with a stored energy greater than 400 joules, review clinical data (if available) from testing of teflon-coated guide wires, and review guidelines for the clinical testing of pacemakers and oxygenators as required in support of premarket notification submissions (21 U.S.C. 360(k)).

Closed committee deliberations. The panel members will discuss suggestions from the sponsor of the Hunter-Sessions Vena Cava Balloon Occluder for revising the indications and caution statements.

The panel will also discuss transitional New Drug Applications (NDA's) for biological arterial grafts and supporting Investigational New Drug Applications (INDA's) for these products.

This portion of the meeting will be closed to permit discussion of trade secret data (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 chairman determines will facilitate the committee's work.

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 chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be obtained from the Public Records and Documents Center (HFC-18), 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner, with the concurrence of the Chief Counsel, 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), as amended by the Government in the Sunshine Act (Pub. L. 94-409), permit 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 re-