both glass slide PT programs and programs employing alternative media, including computer-based PT programs.

CLIAC solicits oral and written testimony on the use of computer-based cytology PT programs. Requests to make an oral presentation should be submitted in writing to the contact person listed below by close of business, March 1, 1996. Written comments should not exceed five single-spaced, typed pages in length and should be received by the contact person listed below by close of business, February 29, 1996.

Agenda items are subject to change as priorities dictate.

For Further Information Contact:
John C. Ridderhof, Dr. P.H., Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE., Mailstop G–25, Atlanta, Georgia 30341–3724, telephone (770) 488–7660, Fax (770) 488–7663.

Dated: February 8, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. 96–3244 Filed 2–13–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 91N–0428]

Briefing Document for Biological Response Modifiers Advisory Committee; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Addendum to the Points to Consider on Human Somatic Cell and Gene Therapy (1991).'' This draft addendum is being made available as briefing material for the February 1996 Biological Response Modifiers Advisory Committee meeting. This action is being taken to ensure that all interested parties are aware of the information in the document that will be the subject of the committee's discussion.

DATES: Written comments by March 28, 1996.

ADDRESSES: Submit written requests for single copies of the draft Points to Consider (PTC) addendum to the Division of Congressional and Public Affairs (HFM–11), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail, or FAX by calling the CBER Voice Information System at 1–800–835–4709.

Persons with access to the INTERNET may obtain the document in several ways. Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators:
http://www.fda.gov/cber/cberftp.html
ftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requesters should connect to FDA's FTP Server, FTP.FDA.GOV (192.73.61.21). CBER documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 or 6.x document (*.w51,wp6), or both. Finally, the document can be obtained by ''bounce-back e-mail''. A message should be sent to: ''GTSA@A1.CBER.FDA.GOV''.

Submit written comments on the draft PTC addendum to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft PTC addendum and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Suzanne L. Epstein, Center for Biologics Evaluation and Research (HFM–521), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0450.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of briefing material being supplied to the advisory committee as background information for the meeting. The draft PTC addendum is being made available as briefing material prior to the advisory committee meeting to ensure that all interested parties have an opportunity to obtain and review the material in advance of the meeting. A notice announcing the February 1996 Biological Response Modifiers Advisory Committee meeting and agenda was published in the Federal Register of January 31, 1996 (61 FR 3427 at 3428).

In the Federal Register of November 29, 1991 (56 FR 61022), FDA announced the availability of a draft PTC document entitled ''Points To Consider in Human Somatic Cell Therapy and Gene Therapy.'' At that time, most gene therapy proposals involved ex vivo use of retroviral vectors to transduce cultured cells, which were then administered to patients. Since that time, the range of proposals has expanded to include additional classes of vectors and also the in vivo use of vectors (direct vector administration to patients). Accordingly, FDA has drafted an addendum to the 1991 PTC in Human Somatic Cell and Gene Therapy that includes current information regarding the production, testing, and administration of recombinant vectors for gene therapy. Prior to making a draft PTC addendum available for industry use, FDA is presenting the issues discussed in the document at the next advisory committee meeting.

As with other PTC documents, FDA does not intend the draft PTC addendum to be all-inclusive and cautions that not all information may be applicable to all situations. The draft PTC addendum is intended to provide information and does not set forth requirements. FDA anticipates that manufacturers and other interested parties may develop alternative methods and procedures, and discuss them with FDA. FDA recognizes that advances will continue in the area of somatic cell and gene therapy, and FDA intends to update and revise the document in order to improve its usefulness. The draft PTC addendum does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any person, but is intended merely for guidance.

Comments received from the meeting and comments submitted to the Dockets Management Branch will be considered in determining whether revision of the draft PTC addendum is warranted. At a later date after the meeting, a Federal Register notice will be published to announce the availability of the PTC addendum for industry use. The PTC addendum will provide CBER's current thinking regarding issues related to gene therapy.

The briefing document and received comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 8, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–3322 Filed 2–9–96; 3:00 pm]

BILLING CODE 4160–01–F

[Docket No. 96G–0035]

Solvay Enzymes, Inc.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Solvay Enzymes, Inc., has filed a petition (GRASP 6G0420) proposing to affirm that the use of dextranase enzyme preparation derived from *Chaetomium gracile* is generally recognized as safe (GRAS) in cane and beet sugar processing.

DATES: Written comments by April 29, 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: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

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 Solvay Enzymes, Inc., c/o 1001 G St. NW, suite 500 West, Washington, DC 20001, has filed a petition (GRASP 6G0420) proposing that dextranase enzyme preparation derived from *Chaetomium gracile* be affirmed as GRAS for use in cane and beet sugar processing.

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 April 29, 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: January 29, 1996.

Alan M. Rulis,

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

[FR Doc. 96–3324 Filed 2–13–96; 8:45 am]

BILLING CODE 4160–01–F

Agency for Toxic Substances and Disease Registry

[ATSDR–104]

Quarterly Public Health Assessments Completed

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice is a quarterly announcement which contains the following: A list of sites for which ATSDR has completed public health assessments, or issued an addendum to a previously completed public health assessment, during the period July–September 1995. This list includes sites that are on, or proposed for inclusion on, the National Priorities List (NPL), and non-NPL sites for which ATSDR has prepared a public health assessment, and a site for which an assessment was prepared in response to a request from the public.

FOR FURTHER INFORMATION CONTACT: Robert C. Williams, P.E., DEE, Director, Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E–32, Atlanta, Georgia 30333, telephone (404) 639–0610.

SUPPLEMENTARY INFORMATION: The most recent list of completed public health assessments and public health assessments with addenda was published in the Federal Register on October 30, 1995 [60 FR 55271]. The quarterly announcement is the responsibility of ATSDR under the regulation, Public Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities [42 CFR Part 90]. This rule sets forth ATSDR's procedures for the conduct of public health assessments under section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) [42 U.S.C. 9604(i)].

Availability

The completed public health assessments are available for public inspection at the Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, Building 33, Executive Park Drive, Atlanta, Georgia (not a mailing address), between 8 a.m. and 4:30 p.m., Monday through Friday, except legal holidays. The completed public health assessments are also available by mail through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, or by telephone at (703) 487–4650. A charge is applied by NTIS for these public health assessments. The NTIS order numbers are listed in parentheses following the site name.

Public Health Assessments or Addendum Completed or Issued

Between July 1, 1995, and September 30, 1995, public health assessments were issued for the sites listed below:

NPL Sites

Connecticut

Linemaster Switch Corporation—Woodstock—(PB95–270468)

Illinois

Acme Solvent Reclaiming Incorporated—Winnebago—(PB95–261293)

Belvidere Municipal Landfill #1—Belvidere—(PB95–260790)