may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of appearance and request for hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug products. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the applications, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 505 (21 U.S.C. 355)) and under authority delegated to the Director, CDER (21 CFR 5.82).

VI. References

The following references are on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Horwitz et al., ''Phenylpropanolamine & Risk of Hemorrhagic Stroke: Final Report of The Hemorrhagic Stroke Project,'' May 2000 in Comment No. C230, Docket No. 76N–052N and Comment No. C114, Docket No. 81N–0022.

2. Phenylpropanolamine Case Reports From 1991–2000 on File in Docket Nos. 76N–052N and 81N–0022.

3. Consumer Healthcare Products Association (CHPA), ''Comments on the Hemorrhagic Stroke Project Report,'' May 24, 2000, in Comment No. C231, Docket No. 76N–052N and Comment No. C113, Docket No. 81N–0022.

4. Food and Drug Administration, Summary Minutes of Nonprescription Drugs Advisory Committee Meeting, October 19, 2000.

Dated: June 1, 2001.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 01–20300 Filed 8–13–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0068]

FDA Tissue Reference Group—The Process; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''FDA Tissue Reference Group—The Process.'' This public workshop is intended to provide information about the tissue reference group history, process, and other related matters. The FDA public workshop follows the American Association of Tissue Banks annual meeting held from August 25 to August 28, 2001.

Date and Time: The public workshop will be held on August 29, 2001, from 9:30 a.m. to 11:30 a.m.

Location: The public workshop will be held at the Marriott Wardman Park Hotel, 2660 Woodley Rd. NW., Washington, DC 20008.

Contact: Martha Wells, Center for Biologics Evaluation and Research (HFM–305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6106, or Ruth Solomon (address above), 301–827–6107, FAX 301–827–2844.

Registration: No preregistration is required. Registration at the site will be done on a space available basis on the day of the public workshop, beginning at 8:30 a.m. There is no registration fee. If you need special accommodations due to a disability, please contact Martha Wells at least 7 days in advance.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 per page. The public workshop transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

SUPPLEMENTARY INFORMATION: The Tissue Reference Group (TRG) is part of the Tissue Action Plan, which was developed to implement the ''Proposed Approach to the Regulation of Cellular and Tissue-based Products'' dated February 28, 1997 (62 FR 9721, March 4, 1997). The purpose of the TRG is to provide a single reference point for product specific questions from sponsors or their designated representatives about jurisdiction, policy, and regulation of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The agenda for the public workshop includes the following: (1) History of the TRG; (2) TRG process for making recommendations to the FDA Center Directors; (3) request for designation process; (4) confidentiality and the Freedom of Information Act process; and (5) factors for regulation of HCT/Ps solely under section 361 of the Public Health Service Act. The public workshop information is posted on the Internet at http://www.fda.gov/cber/meetings/trgproc082901.htm.

Dated: August 8, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20362 Filed 8–13–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Wendy R. Sanhai, Ph.D., at the Office of Technology Transfer,