the supplemental NDA for Tigan Injection did not require prior agency approval.

III. Marketing of Other Trimethobenzamide Hydrochloride Injection and Capsule Products

In light of King's withdrawal of its hearing requests, FDA's approval of 300-mg Tigan Capsules, and King's revision of the labeling for Tigan Injection, FDA is issuing this notice in final resolution of all matters in this proceeding involving trimethobenzamide hydrochloride injection and capsules. (At a later date, FDA intends to issue a notice resolving all matters in FDA Docket No. 78N–0224 (DESI 11853) involving trimethobenzamide hydrochloride suppositories.)

As stated above, no party other than Beecham submitted a request for a hearing in response to the 1979 notice. Therefore, all other parties waived any possible contentions regarding the legal status of their trimethobenzamide hydrochloride injection and capsule products (including those products listed in the 1971 notice).

Trimethobenzamide hydrochloride capsule products made by several different manufacturers are currently listed with FDA. Continued marketing of an unapproved trimethobenzamide hydrochloride capsule product is unlawful and is subject to regulatory action. Any person wishing to market a trimethobenzamide hydrochloride capsule product must submit and obtain FDA approval of a new NDA or ANDA.

With respect to trimethobenzamide hydrochloride injection, the FDA publication entitled ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the Orange Book), 22d ed. (2002), includes two products other than Tigan Injection on the ''Prescription Drug Product List.'' Four trimethobenzamide hydrochloride injection products are on the Orange Book's ''Discontinued Drug Product List.'' For some of these trimethobenzamide hydrochloride injection products, an ANDA supplement to revise product labeling may be required for continued or renewed marketing. To determine whether an ANDA supplement is required for a particular product, write to the Office of Generic Drugs (see **ADDRESSES**).

Any drug product that is identical, related, or similar to the trimethobenzamide hydrochloride injection and capsule products named above, and is not the subject of an approved application, is covered by the applications named above (i.e., NDAs 17–530 and 17–531) and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (see **ADDRESSES**).

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 502, 505, 52 Stat. 1041, 1050–1053), as amended (21 U.S.C. 321(n), 352, 355), and under the authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.100).

Dated: December 18, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 02–32344 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 17, 2003, from 8:30 a.m. to 5 p.m.

Location: Hilton DC North--Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Jeffrey Cooper, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 301–594–1220, ext. 121, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12523. Please call the information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a device for the treatment of gastroesophageal reflux disease. Background information, including the agenda and questions for the committee, will be available to the public one business day before the meeting, on the Internet at *http://www.fda.gov/cdrh/panel*. Material will be posted on January 16, 2003.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 8, 2003. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 8, 2003, 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 requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, at 301–594–1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 9, 2002.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 02–32277 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Training Tomorrow's Scientists: Linking Minorities and Mentors Through the Web

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Behavioral and Social Sciences Research (OBSSR), the National Institutes of Health (NIH) has submitted