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

to the Office of Management and Budget (OMB) a requests for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 21, 2002, page 64652 and allowed 60-days for public comments. No public comments were received. The purposes of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implement on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: *Title*: Training Tomorrow's Scientists: Linking Minorities and Mentors Through the Web. Type of Information *Collection Request:* REVISION, OMB control number 0925–0475, Expiration Date 1/31/2003. *Need and Use of Information Collection*: This website allows federally-funded researchers supported by any of 27 Institutes and Centers of the NIH to submit an electronic form describing his or her research areas, as well as interests in mentoring minority students or junior faculty. The researcher's description is posted on the website for searching by interested minority applicants. Minority students or junior faculty search the website to identify researchers with whom they would like to work. The research projects in the database are located all over the country and involve cutting edge research activities by scientists funded through the Institutes and Centers of the NIH. These research projects range from studies of children to research on older adults, from laboratory research to field research, from social research to a combination of biological and behavioral research. Applicants conduct an electronic search using categories such as research areas of interest, desired geographic location of the researcher, and their level of education. The primary objective of the program is to ensure that, in the coming decades, a concentration of minority researchers will be available to address behavioral and social factors important in improving the public health and eliminating racial disparities. Increasing the number of minority scientists in the U.S. will expand our currently limited knowledge about the epidemiology and treatment of diseases in minority population. *Frequency of Response*: On occasion. *Affected Public*: Individuals or households. *Type of Respondents*: Students, Post-doctorals, Junior Faculty, and Principal Investigators. The annual reporting burden is as follows: *Estimated Number of Respondents*: 50; *Estimated Number of Responses per Respondent*: 1; *Average Burden Hours Per Response*: 10 minutes; and *Estimated Total Annual Burden Hours Requested*: 8. There is no annualized cost to respondents. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Dana Sampson, Program Analyst, OBSSR, OD, NIH, Building 1, Room 256, 1 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 402–1146 or E-mail your request, including your address to: *SampsonD@od.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: December 13, 2002.

John Jarman,

Executive Officer, Office of the Director, National Institutes of Health.

[FR Doc. 02–32365 Filed 12–23–02; 8:45 am]

BILLING CODE 4140–01–M

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 writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Improved Non-Viral Mammalian Expression Vector

Gary Nabel, Zhi-yong Yang (NIAID/VRC).

DHHS Reference No. E–318–2002/0 filed 24 Sep 2002.

Licensing Contact: Carol Salata; 301/435–5018; *salatac@od.nih.gov.*

This invention provides an improved expression vector that generates a higher level of protein than vectors currently in use. The expression vector is unique in that it uses a specific translational enhancer in combination with specific enhancer/promoters to yield high levels of protein expression and enhanced immunogenicity for DNA vaccines. This is particularly important because the potency of these vaccines in humans is marginal and this type of improvement can increase the effectiveness of various DNA vaccines. The expression vector cassettes can be used in other gene based vaccines as well, or for production of recombinant proteins from eukaryotic expression vectors. The invention may be useful in the production of genetic vaccines and gene therapies for a wide variety of diseases, including cancer and viral diseases such as HIV.