judge, or perform a regulatory function (*e.g.*, compliance inspection), but rather, they are an opportunity to provide CDRH review staff a better understanding of the products they review. Through this notice, CDRH is formally requesting participation from companies, academia, and clinical facilities, including those that have previously participated in the ELP or other FDA site visit programs.

II. CDRH ELP General Training Program

A. Areas of Interest

In this training program, groups of CDRH staff will observe operations at research, manufacturing, academia, and health care facilities. The focus areas and specific areas of interest for visits may include the following:

TABLE 1—AREAS OF INTEREST—OFFICE OF DEVICE EVALUATION

Focus area	Specific areas of interest
Biocompatibility testing	Decision making process for biocompatibility evaluation and test selection (if needed); considerations for use of animal testing vs. in vitro testing; sample preparation of nanoscale, bioabsorbable, and in situ polymerized materials; evaluation of color additives.
Combination products	Devices coated with drug(s) or biologic(s); drug/biologic delivery products.
Emerging manufacturing methods	3-D printing; additive manufacturing; additional or unique validation and verification activities.
Management of clinical trials for medical devices.	Conducting clinical trials, overcoming common obstacles to starting and completing clinical trials, and interacting with various other stakeholders; preparing applications to request approval to conduct Investigational Device Exemption (IDE) clinical studies and responding to feedback received from FDA.
Reprocessing and sterilization	Reprocessing challenges in clinical environment, including techniques for understanding and incorporating these challenges from the clinical environment to labeling and validation studies; techniques for validating cleaning, disinfection, or sterilization instructions; challenges in validating cleaning, disinfection, or sterilization instructions; simulated use testing, particularly for validating sterilization methods and instructions; unique sterilization methods (*e.g.*, use of flexible bags, mixed sterilants sound waves, ultraviolet light, microwave radiation).

TABLE 2—AREAS OF INTEREST—OFFICE OF IN VITRO DIAGNOSTIC DEVICES AND RADIOLOGICAL HEALTH

Focus area	Specific areas of interest
Manufacturing of in vitro diagnostic devices.	Pre-analytical devices (*i.e.*, blood tubes), pathogen collection devices, micro collection/transport devices; general reagents, manual reagents; general assays, common point-of-care devices.
Instrument training of medical devices (manufacturer or clinical laboratory).	Hands-on instrument and system training; clinical implication of common laboratory testing; hands on familiarization of medical imaging equipment in a hospital setting.
Quality system in manufacturing environments based on 21 CFR part 820.	Observation of implemented quality systems practices based on current Good Manufacturing Practices; the manufacturing of medical imaging or therapeutic radiology technologies.

B. Site Selection

CDRH will be responsible for CDRH staff travel expenses associated with the site visits. CDRH will not provide funds to support the training provided by the site to this ELP General Training Program. Selection of potential facilities will be based on CDRH's priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP General Training program and must also have a satisfactory compliance history.

III. Request To Participate

Submit proposals for participation with the docket number found in the brackets in the heading of this document. Received requests may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

The proposal should include a description of your facility relative to focus areas described in tables 1 or 2. Please include the Area of Interest (see tables 1 or 2) that the site visit will demonstrate to CDRH staff, a contact person, site visit location(s), length of site visit, proposed dates, and maximum number of CDRH staff that can be accommodated during a site visit. Proposals submitted without this minimum information will not be considered. In addition, please include an agenda outlining the proposed training for the site visit. A sample request and agenda are available on the ELP Web site at *http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf* and *http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.*

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28857 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1977–N–0356 (Formerly 77N–0240); DESI 1786]

Drugs for Human Use; Drug Efficacy Study Implementation; Nitroglycerin Transdermal Systems; Withdrawal of Hearing Request; Withdrawal of Applications; Final Resolution of Hearing Requests Regarding Transdermal Systems Under Docket

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that all outstanding hearing requests regarding nitroglycerin drug

products in transdermal systems under Docket No. FDA–1977–N–0356 (formerly 77N–0240) (DESI 1786) have been withdrawn. Therefore, shipment in interstate commerce of any nitroglycerin drug product in a transdermal system identified in this docket, or any identical, related, or similar (IRS) product, that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) is unlawful as of the effective date of this notice.

DATES: *Effective Date:* This notice is effective November 16, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–1977–N–0356 for ''Drugs for Human Use; Drug Efficacy Study Implementation; Nitroglycerin Transdermal Systems; Withdrawal of Hearing Request; Withdrawal of Applications; Final Resolution of Hearing Requests Regarding Transdermal Systems Under Docket.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Barbara Wise, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5160, Silver Spring, MD 20993–0002, 301–796–2089, email: *Barbara.Wise@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

When enacted in 1938, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) required that ''new drugs'' (21 U.S.C. 321(p)) be approved for safety by FDA before they could legally be sold in interstate commerce. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were IRS (see 21 CFR 310.6(b)(1)) to the approved drug to be covered by that approval, and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the FD&C Act to require that new drugs be proven effective for their labeled indications, as well as safe, in order to obtain FDA approval. This amendment also required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency reviewed and reevaluated the reports and published its findings in **Federal Register** notices. FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.

All drugs reviewed under DESI are ''new drugs'' under the FD&C Act. If FDA's final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for such indications and are subject to enforcement action as unapproved new drugs. If FDA's final DESI determination classifies the drug product as effective for one or more of its labeled indications, the drug can be marketed for such indications, provided it is the subject of an application approved for safety and effectiveness. Sponsors of drug products that have been found to be effective for one or more indications through the DESI process may rely on FDA's effectiveness

determinations, but typically must update their labeling to conform to the indication(s) found to be effective by FDA and include any additional safety information required by FDA. Those drug products with NDAs approved before 1962 for safety therefore require approved supplements to their original applications if one or more indications are found to be effective under DESI; IRS drug products require an approved NDA or ANDA, as appropriate. Furthermore, labeling for drug products classified as effective may contain only those indications for which the review found the product effective unless the firm marketing the product has received an approval for the additional indication(s).

II. Final Resolution of Hearing Requests Regarding Nitroglycerin Transdermal Systems Under Docket No. FDA–1977–N–0356 (formerly 77N–0240); DESI 1786

In a **Federal Register** notice published in February 1972, FDA announced its evaluation of reports received from NAS/NRC regarding certain single-entity coronary vasodilators, including controlled-release nitroglycerin tablets, for indications relating to the management, prophylaxis, and treatment of angina attacks (37 FR 4001, February 25, 1972). In a **Federal Register** notice published in December 1972, FDA temporarily exempted specified single-entity coronary vasodilators covered by DESI from the time limits established for completing DESI (37 FR 26623 at 26624, December 14, 1972). The December 1972 notice did not initially include controlled-release forms of the drugs, but a notice published in July 1973 allowed the case-by-case addition of controlled-release dosage forms, pending the completion of scientific studies that showed a drug was released in a defined manner which would permit well-controlled clinical trials to determine effectiveness (38 FR 18477, 18478, July 11, 1973; corrected by 38 FR 19920, July 25, 1973).

The December 1972 notice was amended again in August 1977, to announce the addition of controlled-release forms of specified coronary vasodilators, and the availability of guidelines and methods for determining the bioavailability of coronary vasodilators (42 FR 43127, August 26, 1977). The August 1977 notice specifically added nitroglycerin (topical ointment forms, conventional oral forms, and controlled release forms) to the list of drugs allowed to remain on the market while efficacy studies were conducted (42 FR 43127 at 43128). The December 1972 notice was further amended in October 1977, to extend the deadlines for submission of data and applications required for the coronary vasodilator products, and to announce the availability of guidelines for alternative methods of determining bioavailability for these products (42 FR 56156, October 21, 1977). Controlled-release transdermal nitroglycerin patches were included among the types of drugs permitted to remain on the market pending completion of efficacy studies based on their similarity to nitroglycerin ointment products (58 FR 38129 at 38130, July 15, 1993).

In July 1993, FDA revoked the temporary exemption for single-entity coronary vasodilator products containing nitroglycerin in a transdermal delivery system, which had allowed the products to stay on the market beyond the time limit scheduled for the implementation of DESI (58 FR 38129). FDA found the products to be effective for prevention of angina pectoris caused by coronary artery disease, and required sponsors to submit bioavailability/bioequivalence studies within 1 year (see 58 FR 38129 at 38130 to 38131). In March 1999, FDA reclassified one NDA and five ANDAs for nitroglycerin transdermal systems to lacking substantial evidence of effectiveness, based on the sponsors' failure to submit the required bioavailability/bioequivalence data (64 FR 14451, March 25, 1999). In the March 1999 notice, FDA proposed to withdraw approval of the applications and offered an opportunity for a hearing on the proposal to withdraw the applications.

In response to the March 1999 notice, Schwarz Pharma, Inc. (Schwarz Pharma), now a subsidiary of UCB, S.A., which was the sponsor of two of the five ANDAs, and Hercon Laboratories Corp. (Hercon), which was the sponsor of the remaining three ANDAs, requested hearings.[1] G.D. Searle & Co., which was the sponsor of the identified NDA, did not submit a hearing request.

At the request of Hercon, in the **Federal Register** of March 4, 2005 (70 FR 10651 at 10656), FDA withdrew approval of Hercon's three ANDAs that were the subject of the 1999 notice of opportunity for a hearing. On January 10, 2011, FDA sent a letter to Hercon to determine whether it remained interested in pursuing its hearing request. On February 9, 2011, Hercon responded by withdrawing its hearing request. On July 17, 2002, Schwarz Pharma withdrew its hearing request and requested withdrawal of its ANDAs that were the subject of the 1999 notice of opportunity for a hearing.

There are no longer outstanding hearing requests for nitroglycerin drug products in transdermal systems under this docket. Therefore, as proposed in the March 1999 notice of opportunity for hearing, FDA finds that the following applications lack substantial evidence of effectiveness and hereby withdraws approval of the applications under section 505(e) of the FD&C Act (21 U.S.C. 355): ANDA 88–727, DEPONIT (release rate of 0.2 mg of nitroglycerin per hour), held by Schwarz Pharma; ANDA 89–022, DEPONIT (release rate of 0.4 mg of nitroglycerin per hour), held by Schwarz Pharma; and NDA 20–146, NITRODISC, held by G.D. Searle & Co. Shipment in interstate commerce of any nitroglycerin drug product in a transdermal system identified in this docket, or any IRS product, that is not the subject of an approved NDA or ANDA is unlawful as of the effective date of this notice (see **DATES**). Any person who wishes to determine whether a specific product is covered by this notice should write to Barbara Wise at the Center for Drug Evaluation and Research (see **FOR FURTHER INFORMATION CONTACT**). Firms should be aware that, after the effective date of this notice (see **DATES**), FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

III. Discontinued Products

Firms must notify the Agency of certain product discontinuations in writing under section 506C(a) of the FD&C Act (21 U.S.C. 356c). See *http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm.* Some firms may have previously discontinued manufacturing or distributing products covered by this notice without discontinuing the listing as required under section 510(j) of the FD&C Act (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or distributing listed products in response to this notice. All firms are required to electronically update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products covered by this notice (21 CFR 207.21(b)). Questions on electronic drug listing updates should be sent to *eDRLS@fda.hhs.gov.* In addition to the required update, firms can also notify the Agency of product discontinuation by sending a letter, signed by the firm's chief executive officer and fully identifying the

[1] The March 1999 notice incorrectly referred to Hercon as ''Hercon Pharmaceutical Company, Inc.''

discontinued product(s), including the product NDC number(s), and stating that the manufacturing and/or distribution of the product(s) have been discontinued. The letter should be sent electronically to Barbara Wise (see **FOR FURTHER INFORMATION CONTACT**). FDA plans to rely on its existing records, including its drug listing records, the results of any future inspections, or other available information, when it targets violative products for enforcement action.

IV. Reformulated Products

FDA cautions firms against reformulating products into unapproved new drugs and marketing under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combinations of active ingredients have the potential to confuse health care practitioners and harm patients.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28853 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is canceling the November 18, 2015, session and postponing the November 19, 2015, session of the Gastroenterology and Urology Devices Panel meeting. The meeting was announced in the **Federal Register** of October 7, 2015 (80 FR 60686). The November 19, 2015, session has been postponed due to the cancellation of the November 18, 2015, meeting. Future meeting dates will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring MD 20993–0002, *patricio.garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28846 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0394]

Request for Nominations for Voting Members on a Public Advisory Committee; Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Tobacco Products Scientific Advisory Committee, Office of Science, Center for Tobacco Products.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before January 15, 2016 will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after January 15, 2016 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *http://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is:

Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), FAX: 240–276–3655, *TPSAC@fda.hhs.gov*.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Tobacco Products Scientific Advisory Committee.

I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Criteria for Voting Members

The Committee consists of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years. The Committee includes nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members include seven members who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty. The nine voting members also include one member who is an officer or employee of a state or local government or of the Federal Government, and one member who is a representative of the general public.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also