that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6207, Silver Spring, MD 20993–0002, 301–796–5418.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application no.	Drug	Applicant
NDA 019961	GANITE (gallium nitrate) Injectable; Injection, 25 milligrams (mg)/milliliter (mL).	Chapter 7 Trustee of Genta Inc., 1628 John Kennedy Blvd., Philadelphia, PA 19103
NDA 020707	SKELID (tiludronate disodium) Tablet; Oral, Equivalent to (EQ) 200 mg Base.	Sanofi Aventis US LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 022023	EMEND (fosaprepitant dimeglumine) Powder; Intravenous, EQ 115 mg Base/Vial.	Merck and Co Inc., RY33 200, P.O. Box 2000, Rahway, NJ 07065.
NDA 050039	GARAMYCIN (gentamicin sulfate ophthalmic solution) Solution; Drops, EQ 0.3% Base.	Schering Plough Corp., 2000 Galloping Hill Rd., Mail Stop K 6 1, Kenilworth, NJ 07033.
NDA 202343	JUVISYNC (simvastin; sitagliptin phosphate) Tablet; Oral, 10 mg, EQ 100 mg Base; 20 mg, EQ 100 mg Base; 40 mg, EQ 100 mg Base; 10 mg, EQ 50 mg Base; 20 mg, EQ 50 mg Base; 40 mg, EQ 50 mg Base.	Merck Sharp and Dohme Corp., 351 North Sumneytown Pike, UG 2CD 015, P.O. Box 1000, North Wales, PA 19454.
ANDA 071259	TRIMETHOPRIM (trimethoprim) Tablet; Oral, 200 mg.	TEVA Pharmaceuticals USA Inc., 650 Cathill Rd., Sellersville, PA 18960–1512.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03458 Filed 2–14–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings With Food and Drug Administration Staff; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with

FDA Staff.'' The purpose of this guidance is to provide an overview of the mechanisms available to application sponsors through which to obtain FDA feedback regarding potential or planned medical device submissions reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), including the Pre-Submission program (formerly the pre-Investigational Device Exemption (pre-IDE) program). In addition, the guidance provides recommendations regarding information that should be included in a Pre-Submission Package. This guidance also describes the procedures that CDRH and CBER intend to follow when manufacturers, their representatives, or application sponsors request a meeting with review staff.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Program Operations Staff (IDE), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5640; or Elizabeth Hillebrenner, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5616, Silver Spring, MD 20993–0002, 301–796–6346; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

Since its establishment in 1995, the pre-IDE program has been a successful resource for both medical device applicants and the FDA. Originally, this program was designed to provide applicants a mechanism to obtain FDA feedback on future IDE applications prior to their submission. Over time, the pre-IDE program evolved to include feedback on other device submission program areas, such as Premarket Approval (PMA) applications, Humanitarian Device Exemption applications, Evaluation of Automatic Class III Designations (de novo petitions), Premarket Notification (510(k)) Submissions, and Clinical Laboratory Improvement Amendments Waiver by Application, as well as to address questions related to whether a clinical study requires submission of an IDE.

The purpose of this guidance is to update the pre-IDE program to reflect this broader scope and make important modifications to reflect changes in the premarket program areas as a result of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85). This guidance also further expands the scope of the program to include those devices regulated by CBER, including those that are regulated as biologics under the Public Health Service Act and require submission of an Investigational New Drug Application (IND) and/or a Biologics License Application. Accordingly, FDA is changing the name for this program from the pre-IDE program to the Pre-Submission (Pre-Sub) program.

Though successful, the Pre-Sub program has faced challenges, and the guidance is intended to address them and improve the Pre-Sub program by: (1) Describing the types of information that FDA would recommend submitting in order to get the best possible feedback from FDA; (2) outlining the process by which FDA meetings should be scheduled; and (3) explaining the Agency's expectations regarding advice given during the Pre-Sub process. This guidance outlines clear recommendations for sponsors and FDA staff.

In addition to the Pre-Sub program, the guidance addresses other types of FDA feedback already available to applicants through other mechanisms. The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) established two types of formal early collaboration meetings (''determination meetings'' as described in section 513(a)(3)(D) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and ''agreement meetings'' as described in section 520(g)(7) of the FD&C Act) to provide clear direction for testing and development of devices requiring clinical investigations to support marketing. FDAMA also requires that FDA, upon written request, must meet with a PMA applicant no later than 100 days after the receipt of a PMA application that has been filed to discuss the review status of the application (referred to as a ''day-100 meeting'' and described in section 515(d)(3) of the FD&C Act). For other premarket submissions under review, FDA will also grant meetings on an informal basis to discuss our requests for additional information to better ensure that the formal response to FDA's request will fully address the outstanding questions (these meetings are referred to as ''submission issue meetings''). FDA will respond to requests for a determination (called ''study risk determinations'') whether a proposed device study is exempt from or subject to the IDE regulation (21 CFR part 812). For device studies that are subject to the IDE regulations, FDA will also provide its determination whether the study is a significant risk or nonsignificant risk study in response to a voluntary request for this information. In some cases, sponsors may wish to inform or educate FDA about ongoing device development or planned submissions without a specific request for feedback. FDA will, as resources allow, grant requests for such ''informational meetings.''

As part of the Medical Device User Fee Amendments of 2012 (MDUFA III), FDA committed to instituting a structured process for managing Pre-Subs. This final guidance establishes such a structured process for submission and management of Pre-Subs as well as other types of requests for feedback. In addition, the guidance describes how FDA will internally track these requests as ''Q-Submissions,'' or ''Q-Subs,'' including what types of submissions will be handled as supplements and amendments to an initial Q-Sub. FDA has also revised the optional CDRH Cover Sheet (Form FDA 3514) to include submission types that more closely track with the types of feedback requests discussed in the guidance.

FDA intends to provide the best possible advice in accordance with the information provided by the sponsor, to ensure it is captured accurately in the meeting minutes drafted by the sponsor,

and commit to that advice unless the circumstances sufficiently change such that our advice is no longer applicable, such as when a sponsor changes the intended use of their device after we provide feedback. It is also our intention to hold timely meetings with appropriate staff and managers present, as resources permit. However, both our ability to provide advice and to hold timely meetings are dependent on our receiving the necessary information from the sponsor in advance of the meeting.

Finally, the guidance describes the procedures that CDRH and CBER intend to follow when manufacturers, their representatives, or application sponsors request a meeting with review staff as the preferred method of feedback in response to a Pre-Sub, as an early collaboration meeting, or to discuss an existing regulatory submission. This guidance also recommends how to prepare for meetings with FDA staff.

In the **Federal Register** of July 13, 2012 (77 FR 41413), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by October 11, 2012. Seventeen sets of comments were received with multiple recommendations pertaining to the administrative processes and policies regarding the Pre-Sub program and meetings with FDA staff. The guidance was revised to provide a broader overview of available mechanisms for FDA feedback prior to a planned submission, with references to other existing guidance documents for those mechanisms where available. The guidance was also reorganized to discuss the various feedback mechanisms first, with a second section including specifics about meeting procedures that apply to all types of FDA feedback mechanisms where a meeting or teleconference is requested. Finally, an acceptance checklist for these submissions has been added as an appendix to clearly outline how FDA intends to determine if a Q-Sub meets the definition of the identified Q-Sub type, and to determine if a qualifying request is administratively complete. It is not necessary for each element in the checklist to be present for the submission to be accepted. Instead, the acceptance checklist is intended to ensure only that the submission includes sufficient information for FDA to provide the requested feedback and/or identify the appropriate FDA attendees so that the meeting or teleconference can be scheduled.

FDA received comments regarding the proposed timeframes for feedback to be provided to the applicant. Specifically, the guidance outlines a proposed target of 75 days, but generally no longer than 90 days, for feedback in response to a Pre-Sub. Comments requested that FDA modify the guidance to include a timeframe of 60 days for response to a Pre-Sub. As part of the MDUFA III Commitment Letter (Ref. 1), FDA agreed to improve the Pre-Sub process ''as resources permit,'' but, because there were no additional resources provided for this program as part of the overall MDUFA III program, the recommended timeframe for FDA feedback in a Pre-Sub represents the time in which FDA believes that feedback generally can be provided without the application of additional resources to this specific program.

Some comments expressed concern regarding FDA's recommendation that if more than 1 year has passed since our last feedback on key clinical trial design elements without a submission to the Agency, the sponsor should contact the review branch to confirm that the previous advice is still valid. The guidance has clarified that the reason for this recommendation is because clinical practice (including available alternative therapies or diagnostics) is rapidly evolving. The guidance has been further modified to clarify that a new Pre-Sub to the Agency is no longer recommended. Instead, confirmation that prior feedback is still valid can be accomplished through a phone call to the lead reviewer or branch chief.

In response to other minor substantive and editorial comments, FDA revised the guidance document to clarify the processes and policies as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on requests for FDA feedback, including the Pre-Sub program, and meetings with FDA staff. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1677 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance also refers to previously approved information collections found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 803 are approved under OMB control number 0910–0437; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 are approved under OMB control number 0910–0231; and the collections of information for Request for Feedback on Medical Device Submissions are approved under OMB control number 0910–0756.

V. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

VI. Reference

The following reference is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. MDUFA III Commitment Letter, April 18, 2012, available at *http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf*.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03453 Filed 2–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Food and Drug Administration/Xavier University PharmaLink Conference—Leadership in a Global Supply Chain

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University PharmaLink Conference: Leadership in a Global Supply Chain.'' The public conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA, and includes presentations from key FDA officials, global regulators, and industry experts. Each presentation challenges the status quo and conventional wisdom to create synergies focused on finding solutions which make a difference. The experience level of the audience has fostered engaged dialog that has led to innovative initiatives.

Dates and Times: The public conference will be held on March 19 and 20, 2014, from 8:30 a.m. to 5 p.m. and March 21, 2014, from 8:30 a.m. to 12:15 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073 or 513–745–3020.

Contact Persons:

For information regarding this notice: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East 7th Street, Cincinnati, OH, 45202, 513–246–4134, email: *steven.eastham@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073, email: *phillipsm4@xavier.edu.*

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2 1/2 days of the conference. There will be onsite registration. The cost of registration is as follows:

TABLE1.—REGISTRATION FEES [1]

Attendee type	Registration fees
Industry	$1,895
Small Business (<100 employees)	$1,295
Startup Manufacturer	$300
Academic	$300
Media	Free
Government	Free

[1] The fourth registration from the same company is free—all four attendees must register at the same time.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the ''Registration'' link on the conference Web site at *http://www.XavierPharmaLink.com.* FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Matty Toomb, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH 45202, 513–421–9100. To make reservations online, please visit the ''Venue & Logistics'' link at *http://www.XavierPharmaLink.com.* The hotel is expected to sellout during this timeframe, so early reservation in the conference room-block is encouraged.

If you need special accommodations due to a disability, please contact Marla Phillips (see Contact Persons) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will engage those involved in FDA-regulated global supply chain quality and management through the following topics:

- The Impact of ''The CDER Challenge'' to Industry
- FDA and the Medicines and Healthcare Products Regulatory Agency (MHRA) Investigator Insights
- Operationalizing Effective Contract Partnerships
- Comparing Metrics with Other Companies—is There a Way? Why is it Vital?
- Complex Supply Chain Development
- The FDA Safety and Innovation Act (FDASIA): The New Frontier
- Why Your Incoming Supply is Not Reliable—Shifting Paradigms
- Innovation Versus Safety—The Impact of the Center for Drug Evaluation and Research's Restructure
- MHRA Perspective on Global Supply Chain Challenges
- How Did They Do That? Learn from Other Industries!

The conference includes:

- Networking by topic
- Case studies
- Small group discussions
- Action plans
- Keynote dinner at the Cincinnati Reds Baseball Stadium with the Chief Executive Officer of Patheon, James Mullen

The most pressing challenges of the global pharmaceutical industry require solutions which are inspired by collaboration to ensure the ongoing health and safety of patients. These challenges include designing products with the patient in mind, building quality into the product from the onset, selecting the right suppliers, and considering total product life-cycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing the job right the first time. FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices.

The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03454 Filed 2–14–14; 8:45 am]

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