

charters of the committees listed in the following table for an additional 2 years beyond charter expiration date. The new charters will be in effect until the dates

of expiration listed in the following table.

DATES: Authority for these committees will expire on the dates indicated in the

following table unless the Commissioner formally determines that renewal is in the public interest.

Name of committee	Date of expiration
Advisory Committee for Pharmaceutical Science and Clinical Pharmacology	January 22, 2016.
Gastrointestinal Drugs Advisory Committee	March 3, 2016.
Bone, Reproductive and Urologic Drugs Advisory Committee (formerly Reproductive Health Drugs Advisory Committee)	March 23, 2016.
Arthritis Advisory Committee	April 5, 2016.
Pharmacy Compounding Advisory Committee	April 25, 2016.
Anesthetic and Analgesic Drugs Advisory Committee	May 1, 2016.
Blood Products Advisory Committee	May 13, 2016.
Pulmonary-Allergy Drugs Advisory Committee	May 30, 2016.
Drug Safety and Risk Management Advisory Committee	May 31, 2016.
Science Advisory Board to the National Center for Toxicological Research	June 2, 2016.
Peripheral and Central Nervous System Drugs Advisory Committee	June 4, 2016.
Psychopharmacologic Drugs Advisory Committee	June 4, 2016.
Transmissible and Spongiform Encephalopathies Advisory Committee	June 9, 2016.
Science Board to the Food and Drug Administration	June 26, 2016.
Allergenic Products Advisory Committee	July 9, 2016.

FOR FURTHER INFORMATION CONTACT:

Michael Ortwerth, Director, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-443-0572 or 1-800-741-8138. For further information related to FDA advisory committees please visit us at: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014-20017 Filed 8-22-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-P-0549]

Determination That SULAR (Nisoldipine) Extended-Release Tablets, 10 Milligrams, 20 Milligrams, 25.5 Milligrams, 30 Milligrams, and 40 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that SULAR (nisoldipine) extended-release tablets, 10 milligrams (mg), 20

mg, 25.5 mg, 30 mg, and 40 mg, 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 approve ANDAs for nisoldipine extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

Emily Gebbia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993-0002, 240-402-0980.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products 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 known generally as the “Orange Book.” Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, is the subject of NDA 20-356, held by Shionogi Inc., and initially approved on February 2, 1995. SULAR is indicated for the treatment of hypertension.

SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, are currently listed in the “Discontinued Drug Product List” section of the Orange Book. Emcure Pharmaceuticals USA, Inc., submitted a citizen petition dated April 28, 2014 (Docket No. FDA-2014-P-0549), under 21 CFR 10.30, requesting that the Agency determine whether SULAR (nisoldipine) extended-release tablets, 25.5 mg, was withdrawn from sale for

reasons of safety or effectiveness. Although the citizen petition did not address the 10 mg, 20 mg, 30 mg, and 40 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg were not withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness. Moreover, the petitioner has identified no data or other information suggesting that SULAR (nisoldipine) extended-release tablets, 25.5 mg, was withdrawn for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of the approved ANDAs that refer to SULAR (nisoldipine) extended-release tablets. Additional ANDAs that refer to SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014-20043 Filed 8-22-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Cellular, Tissue and Gene Therapies 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: Cellular, Tissue and Gene Therapies 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 November 6, 2014, from 9 a.m. to approximately 4:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Gail Dapolito or Rosanna Harvey, Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993, 240-402-8046 or 240-402-8072, email: Gail.Dapolito@fda.hhs.gov or Rosanna.Harvey@fda.hhs.gov or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the draft guidance for industry entitled

"Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products" and the Dear Gene Therapy IND or Master File Sponsor Letter.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

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 on or before October 23, 2014. Oral presentations from the public will be scheduled between approximately 11:05 a.m. and 12:05 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before October 15, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 16, 2014.

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 Gail Dapolito at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/>