

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 millicuries (mCi)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sodium iodide I 123, oral solution, 2 mCi/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993-0002, 301-796-6650.

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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA’s approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR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.

SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 mCi/mL, is the subject of NDA 017630, held by GE Healthcare, and initially approved on March 24, 1976. SODIUM IODIDE I 123 is indicated for use in the evaluation of thyroid function or morphology.

SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 mCi/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

International Isotopes, Inc. submitted a citizen petition dated September 6, 2017 (Docket No. FDA-2017-P-5592), under 21 CFR 10.30, requesting that the Agency determine whether SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 mCi/mL, was withdrawn from sale for reasons of safety or effectiveness.

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 SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 mCi/mL, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 mCi/mL, was withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 mCi/mL, 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 this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 mCi/mL, 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. ANDAs that refer to SODIUM IODIDE I 123 (sodium iodide I-123), oral solution, 2 mCi/mL, 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: May 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1726]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on June 12, 2018, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington, DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel’s telephone number is 301-977-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993-0002, Evella.Washington@fda.hhs.gov; 301-796-6683, 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 website at <https://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.

SUPPLEMENTARY INFORMATION:

Agenda: On June 12, 2018, the committee will discuss, make recommendations, and vote on the premarket approval application sponsored by Cordis, Inc. for the INCRAFT AAA Stent Graft System, which is intended for the endovascular treatment of infra-renal abdominal aortic aneurysms in patients with appropriate anatomy. The INCRAFT device is being evaluated in the INSPIRATION study, a multicenter, prospective, non-randomized investigation. The study met its primary safety and effectiveness endpoints, but results also showed higher than anticipated rates of certain adverse events. The committee discussion will focus on how these events impact the long-term safety and effectiveness, as well as the benefit/risk profile of the device.

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 website 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 website after the meeting. Background material is available at <https://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 June 5, 2018. Oral presentations from the public will be scheduled on June 12, 2018, between approximately 1 p.m. and 2 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 May 25, 2018. 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 May 29, 2018.

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 disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov, 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: May 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1565]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the regulations which state that protocols for samples of biological products must be submitted to the Agency.

DATES: Submit either electronic or written comments on the collection of information by July 10, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 10, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of July 10, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2018-N-1565 for "Request for Samples