

0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 301-796-3110.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” Under current law, radiopharmaceuticals that are compounded by entities that are not registered with FDA as outsourcing facilities, and radiopharmaceuticals that are repackaged, are subject to all applicable provisions of the FD&C Act related to the production of drugs. Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act (21 U.S.C. 353a) (see section 503A(d)(2)),<sup>1</sup> compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 (21 U.S.C. 355) (concerning new drug approval requirements), section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements). In addition, the FD&C Act does not provide an exemption for repackaged radiopharmaceuticals.

FDA is issuing this guidance to describe the conditions under which the Agency generally does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when a State-licensed nuclear pharmacy, Federal facility, or other facility that is not an outsourcing facility and that holds a RAM license for medical use issued by the NRC or by an Agreement State compounds or repackages radiopharmaceuticals for human use.

Elsewhere in this issue of the **Federal Register**, FDA has announced the availability of a separate guidance

document concerning compounding and repackaging of radiopharmaceuticals by outsourcing facilities entitled “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.”

In the **Federal Register** of December 29, 2016 (81 FR 96011), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on February 27, 2017. FDA received comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes that are reflected in this final guidance. For example, in response to requests in comments for clarification regarding the beyond-use-date, FDA added a recommendation that sterile radiopharmaceuticals should be compounded in compliance with USP Chapter <797>. In addition, to address questions raised in comments, FDA clarified the applicability of this guidance to various settings in which radiopharmaceuticals are administered, such as nuclear medicine departments and imaging centers, by clarifying that the policies in the guidance apply to facilities that are not outsourcing facilities and that hold a RAM license for medical use issued by the NRC or by an Agreement State.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

##### II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control number 0910–0858.

##### III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 20, 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–3305]

#### Allergenic Products 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 Allergenic Products Advisory Committee (APAC). 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 November 7, 2018, from 9 a.m. to 4 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. 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 those unable to attend in person, the meeting will also be webcast and will be available at the following link: <https://collaboration.fda.gov/vrbpac2018/>.

**FOR FURTHER INFORMATION CONTACT:** Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, [serina.hunter-thomas@fda.hhs.gov](mailto:serina.hunter-thomas@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 website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee

<sup>1</sup> Section 503A of the FD&C Act describes the conditions that must be met for drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act. Section 503A(d)(2) of the FD&C Act states that “this section shall not apply to . . . radiopharmaceuticals.”

information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* On November 7, 2018, the Center for Biologics Evaluation and Research's APAC will meet in open session to discuss the use of challenge studies in the clinical development of allergenic products for the diagnosis and treatment of allergy due to aeroallergens. 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:* On November 7, 2018, from 9 a.m. to 4 p.m., the meeting is open to the public. 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 31, 2018. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:30 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 23, 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 October 24, 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 Serina Hunter-Thomas 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: September 20, 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-3463]

**Aurolife Pharma, LLC, et al.;  
Withdrawal of Approval of Seven  
Abbreviated New Drug Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of seven abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of October 26, 2018.

**FOR FURTHER INFORMATION CONTACT:** Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, [Trang.Tran@fda.hhs.gov](mailto:Trang.Tran@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 072112 .....	Clorazepate Dipotassium Capsules, 3.75 milligrams (mg), 7.5 mg, and 15 mg.	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 074863 .....	Clemastine Fumarate Syrup, Equivalent to (EQ) 0.5 mg base/5 milliliters (mL).	Workhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 080925 .....	Isocaine 3% (mepivacaine hydrochloride (HCl)) Injection USP, 3%.	Septodont, Inc., c/o Arent Fox, LLP, 1717 K St. NW, Washington, DC 20006.
ANDA 084048 .....	Octocaine (lidocaine HCl and epinephrine) Injection USP, 2%; 0.01 mg/mL and 2%; 0.02 mg/mL.	Do.
ANDA 084697 .....	Isocaine 2% (mepivacaine HCl and levonordefrin) Injection USP, 2%; 0.05 mg/mL.	Do.
ANDA 086033 .....	Isosorbide Dinitrate Sublingual Tablets USP, 2.5 mg ....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 087504 .....	Chloroquine Phosphate Tablets USP, EQ 150 mg base	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.

Therefore, approval of the applications listed in the table, and all

amendments and supplements thereto, is hereby withdrawn as of October 26,

2018. Introduction or delivery for introduction into interstate commerce of