

SUPPLEMENTARY INFORMATION:**I. Background**

We are announcing the availability of a revised guidance for industry entitled "Listing of Ingredients in Tobacco Products." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115).

The revised guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Tobacco Control Act.

The Tobacco Control Act (Pub. L. 111-31), enacted on June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health. Among its many provisions, the Tobacco Control Act added section 904 to the FD&C Act (21 U.S.C. 387d), establishing requirements for tobacco product ingredient submissions.

The revised guidance discusses tobacco products that are newly deemed subject to chapter IX of the FD&C Act. Cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act, including section 904, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Under that authority, FDA issued a rule deeming all other products that meet the statutory definition of "tobacco product", set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), except for accessories of those products, as subject to chapter IX of the FD&C Act (81 FR 28974). FDA published the final rule on May 10, 2016 and it became effective on August 8, 2016. As a result, manufacturers or importers (or their agents) of tobacco products subject to the deeming rule are now required to comply with chapter IX of the FD&C Act, including the ingredient listing requirements in section 904(a)(1).

Section 904(a)(1) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products on the

market as of June 22, 2009, the list of ingredients had to be submitted by December 22, 2009. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products not on the market as of June 22, 2009, section 904(c)(1) requires that the list of ingredients be submitted at least 90 days prior to delivery for introduction into interstate commerce. Section 904(c) of the FD&C Act also requires submission of information whenever any additive, or the quantity of any additive, is changed.

As described in the preamble to the final deeming rule, for products other than cigarettes, cigarette tobacco, RYO, and smokeless tobacco that are on the market as of August 8, 2016, FDA does not intend to enforce the section 904(a)(1) ingredient listing submission requirement until 6 months from the effective date of the rule or 12 months from the effective date for small-scale tobacco product manufacturers. However, in the revised guidance, FDA is announcing an additional 6-month compliance policy for newly deemed tobacco products on the market as of August 8, 2016. Under this policy, FDA will not enforce the ingredient listing submission requirement until August 8, 2017, for businesses that are not considered small-scale tobacco product manufacturers, and February 8, 2018, for small-scale tobacco product manufacturers. Manufacturers of tobacco products introduced into interstate commerce after August 8, 2016, must submit the ingredient information required by section 904(a)(1) at least 90 days before the product is delivered for introduction into interstate commerce, as with cigarettes, cigarette tobacco, RYO, and smokeless tobacco first marketed after June 22, 2009 (section 904(c)(1) of the FD&C Act).

II. Significance of Guidance

FDA is issuing this revised guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ingredient listing. 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.

III. Paperwork Reduction Act of 1995

This revised guidance also refers to previously approved collections of information found in FDA regulations. The revised draft guidance includes information and recommendations for how to provide ingredient listing submissions. The collections of

information in section 904(a)(1) of the FD&C Act have been approved under OMB control number 0910-0650.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the revised guidance at either <https://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-31587 Filed 12-28-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2016-N-0002]

Abbott Laboratories, et al.; Withdrawal of Approval of Four New Drug Applications and Two Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: *Effective Date:* January 30, 2017.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications 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 pursuant to the process 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
NDA 019080	ProSom (estazolam) Tablets, 1 milligram (mg) and 2 mg.	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064.
NDA 020195	Fentanyl Oralet (fentanyl citrate) Troche/Lozenge, Equivalent to (EQ) 0.1 mg base, EQ 0.2 mg base, EQ 0.3 mg base, and EQ 0.4 mg base.	Cephalon, Inc., 41 Moores Rd., Frazer, PA 19355.
NDA 021726	Niravam (alprazolam) Orally Disintegrating Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg.	UCB, Inc., 1950 Lake Park Dr., Building 2100, Smyrna, GA 30080.
ANDA 084287	Methyltestosterone Tablets USP, 10 mg	Impax Laboratories, Inc., 31047 Genstar Rd., Hayward, CA 94544.
ANDA 084310	Methyltestosterone Tablets USP, 25 mg	Do.
NDA 205208	Desvenlafaxine Fumarate Extended-Release Tablets, EQ 50 mg base and EQ 100 mg base.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective January 30, 2017. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-31625 Filed 12-28-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-4317]

Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities." Specifically, this guidance

sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities, and it describes the conditions under which FDA does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 27, 2017. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by February 27, 2017.

ADDRESSES: You may submit comments as follows:

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):** 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-2016-D-4317 for "Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities." 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