

enforcement discretion as follows: FDA intends to initiate enforcement action against any such currently marketed and listed product that is manufactured on or after February 26, 2013, or that is shipped on or after May 28, 2013. Further, FDA intends to take enforcement action against any person who manufactures or ships such products after these dates. Any person who has submitted or submits an application for a drug product covered by this notice but has not received approval must comply with this notice.

The Agency, however, does not intend to exercise its enforcement discretion as outlined previously if the following apply: (1) A manufacturer or distributor of drug products covered by this notice is violating other provisions of the FD&C Act, including, but not limited to, violations related to FDA's current good manufacturing practice, adverse event reporting, labeling, or misbranding requirements other than those identified in this notice, or (2) it appears that a firm, in response to this notice, increases its manufacture or interstate shipment of drug products covered by this notice above its usual volume during these periods.³

Nothing in this notice, including FDA's intent to exercise its enforcement discretion, alters any person's liability or obligations in any other enforcement action, or precludes the Agency from initiating or proceeding with enforcement action in connection with any other alleged violation of the FD&C Act, whether or not related to a drug product covered by this notice. Similarly, a person who is or becomes enjoined from marketing unapproved or misbranded drugs may not resume marketing of such products based on FDA's exercise of enforcement discretion as described in this notice.

Drug manufacturers and distributors should be aware that the Agency is exercising its enforcement discretion as described previously only in regard to drug products covered by this notice that are marketed under a National Drug Code number listed with the Agency in full compliance with section 510 of the

FD&C Act before November 27, 2012. As previously stated, drug products covered by this notice that are currently marketed but not listed with the Agency on the date of this notice must, as of the effective date of this notice, have approved applications before their shipment in interstate commerce. Moreover, any person or firm that has submitted or submits an application but has yet to receive approval for such products is still responsible for full compliance with this notice.

V. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the FD&C Act. Other firms may discontinue manufacturing or distributing listed products in response to this notice. Firms that wish to notify the Agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including NDC number(s), and stating that the manufacturing and/or distribution of the products has (have) been discontinued. The letter should be sent electronically to Lori Cantin (see **ADDRESSES**). Firms should also electronically update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of products covered by this notice. Questions on electronic drug listing updates should be sent to: eDRLS@fda.hhs.gov. FDA plans to rely on its existing records, including its drug listing records, the results of any subsequent inspections, or other available information, when it targets violations for enforcement action.

Dated: November 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0276]

Guidance for Industry: Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

withdrawal of a guidance entitled "Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products," that was announced in the **Federal Register** on June 8, 2010.

DATES: The withdrawal is effective November 28, 2012.

FOR FURTHER INFORMATION CONTACT: Ele Ibarra-Pratt, Center for Tobacco Products, Office of Compliance and Enforcement, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 1-877-287-1373, CTPCompliance@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act) into law. Section 204 of the Tobacco Control Act amended section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act), 15 U.S.C. 4402, to prescribe revised requirements for health warning statements that must appear on smokeless tobacco product packages and advertisements, and to require the submission of warning plans for smokeless tobacco product packages and advertisements to FDA for review and approval, rather than to the Federal Trade Commission (FTC). Section 3(b)(3) of the Smokeless Tobacco Act requires the equal distribution and display of warning statements on packaging, and the quarterly rotation of warning statements in advertising, for each brand of smokeless tobacco product "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA. These requirements took effect on June 22, 2010.

In a notice published in the **Federal Register** of June 8, 2010 (75 FR 32481), FDA announced the availability of a guidance entitled "Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products." This guidance provided information to industry and the public, including that "[a]t this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that a smokeless tobacco manufacturer, distributor, importer, or retailer must have an FDA-approved rotational warning plan, so long as a rotational warning plan has been submitted to FDA by July 22, 2010." FDA believed that allowing additional time for the review of warning plans would permit an orderly transition of regulatory authority from the FTC to FDA to review and approve warning plans.

³ If FDA finds it necessary to take enforcement action against a product covered by this notice, the Agency may take action relating to all of the defendant's other violations of the FD&C Act at the same time. For example, if a firm continues to manufacture or market a product covered by this notice after the applicable enforcement date has passed, to preserve limited Agency resources, FDA may take enforcement action relating to all of the firm's unapproved drugs that require applications at the same time (see, e.g., *United States v. Sage Pharmaceuticals*, 210 F.3d 475, 479-480 (5th Cir. 2000) (permitting the Agency to combine all violations of the FD&C Act in one proceeding, rather than taking action against multiple violations of the FD&C Act in "piecemeal fashion").

FDA is withdrawing this guidance because it is no longer warranted. FDA has completed its review of all of the warning plans for smokeless tobacco products that were submitted to FDA by July 22, 2010, and the transition from FTC to FDA of the responsibility for reviewing warning plans for smokeless tobacco products has been accomplished. Further, this guidance included an incomplete definition of smokeless tobacco. Section 101(c) of the Tobacco Control Act amended the Smokeless Tobacco Act to give smokeless tobacco the meaning that term is given by section 900(18) of the Federal Food, Drug, and Cosmetic Act. Under this definition, "smokeless tobacco" means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral *or nasal* cavity. (Emphasis added) Thus, withdrawal of this guidance on enforcement policy will also help to prevent any confusion that may have been created by the misstatement of this definition.

For information regarding the submission of warning plans for smokeless tobacco products, you may contact the Office of Compliance at FDA's Center for Tobacco Products (see **FOR FURTHER INFORMATION CONTACT**).

We note that FDA has made available for public comment a draft guidance that, when finalized, will represent the Agency's current thinking on the "Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products." You can obtain an electronic version of this draft guidance document at either <http://www.regulations.gov/> or <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>. You can comment on this or any other guidance at any time.

Dated: November 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-28809 Filed 11-27-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1154]

Framework for Pharmacy Compounding: State and Federal Roles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting entitled "Framework for Pharmacy Compounding: State and Federal Roles." At this public meeting, FDA and State representatives will share their perspectives.

Date and Time: The public meeting will be held on December 19, 2012, from 3 p.m. to 5 p.m. Onsite registration will be on a first-come, first-served basis beginning at 2 p.m.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993.

Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

If you need special accommodations due to a disability, please contact Steve Morin, FDA Office of Special Health Issues, 301-796-0161, email: Steve.Morin@fda.hhs.gov no later than December 14, 2012.

Contact Person: Patricia Kuntze, Food and Drug Administration, 10903 New H Ave., Bldg. 32, Rm. 5322, Silver Spring, MD 20993; patricia.kuntze@fda.hhs.gov.

Streaming Webcast of the Meeting: This public meeting will also be Webcast. Persons interested in viewing the Webcast should use the access connection at <https://collaboration.fda.gov/pharmacycompounding/>. The Webcast will begin on December 19, 2012, at 3 p.m. ET.

If you have never attended a Connect Pro meeting before, test your connection at: https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. Get a quick overview at: http://www.adobe.com/go/connectpro_overview. Adobe, the Adobe logo, Acrobat and Acrobat Connect are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries.

If for some reason the test page does not work, that is not a definite indicating factor that the actual Webcast will not work. The test link sometimes appears to be broken on some individuals' computers. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

This Webcast will be closed captioned.

Comments: In order to obtain public comment, FDA is also soliciting either electronic or written comments on the issues discussed in section II of this document. The deadline for submitting comments is January 18, 2013.

Regardless of attendance at the meeting, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 or electronic comments to <http://www.regulations.gov>. 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. In addition, when submitting comments on issues as outlined in section II of this document, please identify the issue you are addressing. 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>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **Comments**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

The recent outbreak of fungal meningitis associated with drugs produced and sold by New England Compounding Center has raised serious questions about the regulation of pharmacy compounding (Refs. 1 and 2). Historically, regulation of pharmacy compounding has focused on drawing a line between traditional pharmacy compounding and other manufacturing. Generally, day-to-day oversight of traditional pharmacy compounding has been seen as the primary responsibility of the States, which license pharmacies and regulate the practice of pharmacy, while other manufacturing falls under the purview of FDA. Going forward, FDA believes the focus should be shifted from attempting to draw a bright line between traditional pharmacy compounding and other manufacturing to clearly defining traditional pharmacy