

Approved: March 10, 2010.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

David V. Aguilar,

Acting Deputy Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2010-6387 Filed 3-22-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. FDA-2010-N-0010]

Product Jurisdiction; Change of Address and Telephone Number; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the address and telephone number for the Office of Combination Products (OCP). This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

DATES: Effective Date: April 19, 2010.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5130, Silver Spring, MD 20993-0002, 301-796-8930. To confirm that this change of address and telephone number has occurred, please see our Web site at www.fda.gov/CombinationProducts/default.htm.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR part 3 to reflect a change in the address and telephone number for OCP. Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedures are unnecessary because FDA is merely updating nonsubstantive content.

List of Subjects in 21 CFR Part 3

Administrative practice and procedure, Biologics, Combination products, Drugs, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 3 is amended as follows:

PART 3—PRODUCT JURISDICTION

■ 1. The authority citation for 21 CFR part 3 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 353, 355, 360, 360c-360f, 360h-360j, 360gg-360ss, 360bbb-2, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

§ 3.6 [Amended]

■ 2. Section 3.6 is amended by removing "(HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301-427-1934" and by adding in its place "Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002, 301-796-8930,".

Dated: March 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-329F]

RIN 1117-AB23

Schedules of Controlled Substances; Table of Excluded Nonnarcotic Products: Nasal Decongestant Inhalers Manufactured by Classic Pharmaceuticals, LLC

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: Under this Final Rule, the Drug Enforcement Administration (DEA) is updating the Table of Excluded Nonnarcotic Products found in 21 CFR 1308.22 to include the Nasal Decongestant Inhaler/Vapor Inhaler (containing 50 mg Levmetamfetamine) manufactured by Classic Pharmaceuticals, LLC and marketed under various private labels (to include the "Premier Value" and "Kroger" labels). This nonnarcotic drug product, which may be lawfully sold over the counter without a prescription under the Federal Food, Drug, and Cosmetic Act, is excluded from provisions of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811(g)(1).

DATES: This rulemaking shall become effective on March 23, 2010.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug

and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: On August 28, 2009, the DEA published an interim rule with request for comments [74 FR 44281]. This interim rule updated the Table of Excluded Nonnarcotic Products found in 21 CFR 1308.22 to include the Nasal Decongestant Inhaler/Vapor Inhaler (containing 50 mg Levmetamfetamine) manufactured by Classic Pharmaceuticals, LLC and marketed under various private labels (to include the "Premier Value" and "Kroger" labels). This nonnarcotic drug product, which may be lawfully sold over the counter without a prescription under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), is excluded from provisions of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811(g)(1).

Comments Received

DEA did not receive any comments to its interim rule published August 28, 2009, regarding this exemption. Therefore, DEA is issuing this rulemaking to finalize the interim rule without change.

Background

The CSA, specifically 21 U.S.C. 811(g)(1), states that the Attorney General shall by regulation exclude any nonnarcotic drug which contains a controlled substance from the application of the CSA, if such drug may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), be lawfully sold over the counter without a prescription. This authority has been delegated to the Administrator of DEA and redelegated to the Deputy Assistant Administrator of the Office of Diversion Control pursuant to 28 CFR 0.100 and title 28, part 0, appendix to subpart R, 7(g), respectively.

Such exclusions apply only to nonnarcotic products and are only granted following suitable application to the DEA per the provisions of 21 CFR 1308.21. The current Table of Excluded Nonnarcotic Products found in 21 CFR 1308.22 lists those products that have been granted excluded status.

Pursuant to the application process of 21 CFR 1308.21, DEA received application for exclusion from Classic Pharmaceuticals, LLC, the manufacturer of a Nasal Decongestant Inhaler/Vapor Inhaler which contains the schedule II controlled substance Levmetamfetamine. This inhaler is sold over the counter under various private labels (such as the "Premier Value" label