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]

BILLING CODE 9111–14–P

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.

[FR Doc. 2010–6246 Filed 3–22–10; 8:45 am]

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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 Morrissette 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

of the Chain Drug Consortium, Boca Raton, Florida, and "The Kroger" label by The Kroger Company of Cincinnati, Ohio). Based on the application and other information received, including the quantitative composition of the substance and labeling and packaging information, DEA has determined that this product (sold under various private labels) may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription (21 U.S.C. 811(g)(1)).

The Deputy Assistant Administrator finds that this product meets the criteria for exclusion from the CSA in accordance with 21 U.S.C. 811(g)(1). Note that this exclusion only applies to the finished drug product in the form of an inhaler (in the exact formulation detailed in the application for exclusion), which is lawfully sold under the Federal Food, Drug, and Cosmetic Act. The extraction or removal of the active ingredient (Levmetamfetamine) from the inhaler shall negate this exclusion and, depending on the circumstances, result in the possession or manufacture of a schedule II controlled substance.

This rulemaking finalizes the addition of Classic Pharmaceuticals, LLC product containing 50 mg Levmetamfetamine in a Nasal Decongestant Inhaler/Vapor Inhaler and marketed under various private labels to the list of excluded nonnarcotic products contained in 21 CFR 1308.22. Therefore, this product is excluded from CSA regulatory provisions pursuant to 21 U.S.C. 811(g)(1).

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612). This rule will not have a significant economic impact on a substantial number of small entities. This rule adds a product to the list of products excluded from the requirements of the CSA.

Executive Order 12866

The Deputy Assistant Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is not "a significant regulatory action." As discussed previously, based on the information received by the manufacturer of the product in question, DEA has determined that this product may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Administrative Procedure Act

The Administrative Procedure Act permits an agency to make a rule effective upon date of publication if it is "a substantive rule which grants or recognizes an exemption or relieves a restriction" (5 U.S.C. 553(d)(1)). Since this rule excludes a nonnarcotic drug product from the provisions of the CSA, and as this rule finalizes an interim rule already in effect excluding this product from CSA regulatory control, DEA finds that it meets the criteria set forth in 5 U.S.C. 553(d)(1) for an exception to the effective date requirement.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ The Interim Rule with Request for Comments amending part 1308 of title 21, Code of Federal Regulations, published in the **Federal Register** August 28, 2009, at 74 FR 44281, is hereby adopted as a final rule without change.

Dated: March 16, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 2010–6176 Filed 3–22–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

Determination of Interest Expense Deduction of Foreign Corporations

CFR Correction

In Title 26 of the Code of Federal Regulations, Part 1 (§§ 1.851 to 1.907), revised as of April 1, 2009, in § 1.882–5, move paragraph (d)(2)(ii)(B) introductory text from the second column on page 435 to the first column on page 436, following paragraph (*2*) through (*3*).

[FR Doc. 2010–6463 Filed 3–22–10; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

Treatment of Overall Foreign and Domestic Losses

CFR Correction

In Title 26 of the Code of Federal Regulations, Part 1 (§§ 1.851 to 1.907), revised as of April 1, 2009, on page 808, in § 1.904(f)–2, in paragraph (c)(5) *Example 4*, following "§ 1.904(f)–2T(c)(5)", add "*Example 4*.".

[FR Doc. 2010–6462 Filed 3–22–10; 8:45 am]

BILLING CODE 1505–01–D