

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.*

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## 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).

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## 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*.”

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