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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-409]

RIN 1117-ZA30

Schedules of Controlled Substances: Table of Excluded Nonnarcotic Products: Nasal Decongestant Inhaler/Vapor Inhaler

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule.

SUMMARY: The Drug Enforcement Administration is amending the table of Excluded Nonnarcotic Products to update the company name for the drug product Nasal Decongestant Inhaler/Vapor Inhaler (containing 50 milligrams levmetamfetamine) to Aphena Pharma Solutions - New York, LLC. This over-the-counter, nonnarcotic drug product is excluded from the provisions of the Controlled Substances Act.

DATES: This interim final rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Interested persons may file written comments on this rule pursuant to 21 CFR 1308.21(c). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that

the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. Interested persons are defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 CFR 1300.01(b).

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-409" on all electronic and written correspondence, including any attachments. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments, in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments:

Please note that all comments received in response to this docket are considered part of the public record and will be made available for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information

(such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this interim final rule is available at *http://www.regulations.gov* for easy reference.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and they are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety. 21 U.S.C. 801.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of all scheduled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

The CSA 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 (FD&C Act), [21 U.S.C. 301 *et seq*.] be lawfully sold over-the-counter without a prescription. 21 U.S.C. 811(g)(1).

Such exclusions apply only to specific nonnarcotic drugs following suitable application to the DEA in accordance with 21 CFR 1308.21. The current table of Excluded Nonnarcotic Products is found in 21 CFR 1308.22. The authority to exclude such substances has been delegated to the Administrator of the DEA, 28 CFR 0.100, and redelegated to the Deputy Assistant Administrator of the Office of Diversion Control, section 7 of 28 CFR part 0, appendix to subpart R.

Background

On December 10, 2013, pursuant to the application process of 21 CFR 1308.21, the DEA received correspondence from Aphena Pharma Solutions – New York, LLC (Aphena Pharma) stating that it had acquired Classic Pharmaceuticals LLC and requesting that the current exclusion for the drug product Nasal Decongestant Inhaler/Vapor Inhaler be transferred to Aphena Pharma. Aphena Pharma also stated that the manufacturing process (i.e., facility) and the formulation for the drug product Nasal Decongestant Inhaler/Vapor Inhaler had not changed.

Based on the application and other information received, the DEA has determined that this product may, under the FD&C Act, be lawfully sold over-the-counter without a prescription. 21 U.S.C. 811(g)(1). In addition, the Deputy Assistant Administrator of the Office of Diversion Control finds that the active ingredient in this drug product (levmetamfetamine) is a schedule II controlled substance[1] and is not a narcotic drug as defined by 21 U.S.C. 802(17). The Deputy Assistant Administrator of the Office of Diversion Control therefore finds and concludes that this drug product continues to meet the criteria for exclusion from the CSA pursuant to 21 U.S.C. 811(g)(1).

[1] Levmetamfetamine is controlled in schedule II of the CSA because it is an isomer of methamphetamine.

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 FD&C Act over-the-counter without a prescription. The extraction or removal of the active ingredient (levmetamfetamine) from the inhaler shall negate this exclusion and result in the possession of a schedule II controlled substance.

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA), including notice of proposed rulemaking and the pre-promulgation opportunity for public comment, if it is determined to be impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(B). The DEA finds for good cause that it is unnecessary to seek public comment prior to amending the table of Excluded Nonnarcotic Products to update the listing for this product, as the amendment is technical in nature and would not result in any substantive change. The DEA is merely changing the name of the company associated with the Nasal Decongestant Inhaler/Vapor Inhaler as the result of the acquisition of Classic Pharmaceuticals LLC by Aphena Pharma. The manufacturing process (i.e., facility) and the formulation for the drug product Nasal Decongestant Inhaler/Vapor Inhaler have not changed as a result of this acquisition.

The APA requires the publication of a substantive rule to be made not less than 30 days before its effective date. 5 U.S.C. 553(d). However, this requirement need not apply for "a substantive rule which grants or recognizes an exemption or relieves a restriction" or "as otherwise provided by the agency for good cause found and published with the rule." 5 U.S.C. 553(d)(1). This rule continues the exclusion of a nonnarcotic

drug product from the provisions of the CSA. Given that this amendment to the table of Excluded Nonnarcotic Products is technical in nature and thereby would not warrant any further delay, the DEA finds that there is good cause to make this rule effective immediately upon publication.

Regulatory Analyses

Executive Orders 12866 and 13563

This regulation has been developed in accordance with the Executive Orders 12866, "Regulatory Planning and Review," section 1(b) and Executive Order 13563, "Improving Regulation and Regulatory Review." The DEA has determined that this rule is not a significant regulatory action, and accordingly this rule has not been reviewed by the Office of Management and Budget. This product was previously exempted under a different company name. This action will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

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," to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and

promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. This rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Unfunded Mandates Reform Act of 1995

The DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA.

Paperwork Reduction Act

This rule does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals,

businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; 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. However, pursuant to the CRA, the DEA has submitted a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended to read as follows:

PART 1308— SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. In § 1308.22, remove the company name "Classic Pharmaceuticals LLC", and add to the table, in alphabetical order, the company name listed below to read as follows:

§ 1308.22 Excluded substances.

* * * * *

EXCLUDED NONNARCOTIC PRODUCTS

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
* * * * * * *					
Aphena Pharma Solutions – New York, LLC.	Nasal Decongestant Inhaler/Vapor Inhaler.		IN	Levmetamfetamine (l-Desoxyephedrine)	50.00
* * * * * * *					

Dated: October 20, 2015.

Louis J. Milione,
Deputy Assistant Administrator, Office of Diversion Control.
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