$Q_j = (T_j)(P_j)$

Where:

T_j = Average time spent in failure condition j (in hours).

P_j = Probability of occurrence of failure mode j (per hour).

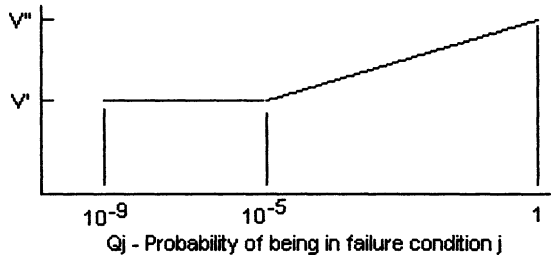
Note: If P_j is greater than 10^{-3} per flight hour, then a 1.5 factor of safety must be applied to all limit-load conditions specified in Subpart C.

(iii) For residual-strength substantiation, the airplane must be able to withstand two-thirds of the ultimate loads defined in subparagraph (c)(2)(ii).

(iv) If the loads induced by the failure condition have a significant effect on fatigue or damage tolerance, then their effects must be taken into account.

(v) Freedom from aeroelastic instability must be shown up to a speed determined from Figure 3. Flutter-clearance speeds V′ and V″ may be based on the speed limitation specified for the remainder of the flight using the margins defined by § 25.629(b).

Figure 3
Clearance speed



V′ = Clearance speed as defined by § 25.629(b)(2).

V″ = Clearance speed as defined by § 25.629(b)(1).

$Q_j = (T_j)(P_j)$

Where:

T_j = Average time spent in failure condition j (in hours).

P_j = Probability of occurrence of failure mode j (per hour).

Note: If P_j is greater than 10^{-3} per flight hour, then the flutter clearance speed must not be less than V''.

(vi) Freedom from aeroelastic instability must also be shown, up to V′ in Figure 3 above, for any probable system-failure condition combined with any damage required or selected for investigation by § 25.571(b).

(3) Consideration of certain failure conditions may be required by other subparts of part 25 regardless of calculated system reliability. Where analysis shows the probability of these failure conditions to be less than 10^{-9}, criteria other than those specified in this paragraph may be used for structural substantiation to show continued safe flight and landing.

(d) *Failure indications.* For system-failure detection and indication, the following apply:

(1) The system must be checked for failure conditions, not extremely improbable, that degrade the structural capability below the level required by part 25, or that significantly reduce the reliability of the remaining system. To the extent practicable, these failures must be detected and annunciated to the flight crew before flight. Certain elements of the control system, such as mechanical and hydraulic components, may use special periodic inspections, and electronic components may use daily checks, in lieu of warning systems, to achieve the objective of this requirement. These certification-maintenance requirements must be limited to components that are not readily detectable by normal warning systems, and where service history shows that inspections provide an adequate level of safety.

(2) The existence of any failure condition, not extremely improbable, during flight, that could significantly affect the structural capability of the airplane and for which the associated reduction in airworthiness can be minimized by suitable flight limitations, must be signaled to the flight crew. Failure conditions that result in a factor of safety between the airplane strength and the loads of Subpart C below 1.25, or flutter margins below V″, must be signaled to the crew during flight.

(e) *Dispatch with known failure conditions.* If the airplane is to be dispatched in a known system-failure condition that affects structural performance, or affects the reliability of the remaining system to maintain structural performance, then the provisions of § 25.302 must be met for the dispatched condition and for subsequent failures. Flight limitations and expected operational limitations may be taken into account in establishing Q_j as the combined probability of being in the dispatched failure condition and the subsequent failure condition for the safety margins in Figures 2 and 3. These limitations must be such that the probability of being in this combined failure state, and then subsequently encountering limit-load conditions, is extremely improbable. No reduction in these safety margins is allowed if the subsequent system-failure rate is greater than 10^{-3} per hour.

Issued in Renton, Washington, on August 20, 2009.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9–20697 Filed 8–27–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–329I]

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: Interim rule with request for comments.

SUMMARY: Under this Interim 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 (21 U.S.C. 301), is excluded from provisions of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811(g)(1).

Any interested person may file comments or objections to this order on or before October 27, 2009. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Deputy Assistant Administrator shall immediately suspend the effectiveness of this order until he may reconsider the application in light of the comments or objections filed. Thereafter, the Deputy Assistant Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

DATES: This rulemaking shall become effective on August 28, 2009. Written comments must be postmarked and electronic comments must be submitted on or before October 27, 2009. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after Midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–329I'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to *dea.diversion.policy@usdoj.gov*. Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in time zones other than Eastern time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

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: *Posting of public comments:* Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, *etc.*) voluntarily submitted by the commenter.

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 posted online or made available in the public docket, you must include the phrase ''Personal Identifying Information'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket 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 posted online or made available in the public docket, you must include the phrase ''Confidential Business Information'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION** paragraph.

Background

The Controlled Substances Act (CSA) under 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, OH). 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 result in the possession of a schedule II controlled substance.

This rulemaking adds 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. Effective August 28, 2009 this product is excluded from CSA regulatory provisions. Any interested person may file written comments or objections to this order on or before October 27, 2009. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Deputy Assistant Administrator shall immediately suspend the effectiveness of this order until he may reconsider the application in light of the comments or objections filed. Thereafter, the Deputy Assistant Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

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

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. DEA finds that it is unnecessary and impracticable to seek public comment prior to making the exclusion of this nonnarcotic product from the requirements of the CSA effective. DEA has no discretion in its determination of whether the product may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

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, 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.

■ For the reasons set out above, 21 CFR Part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. Section 1308.22 is amended by adding to the table, in alphabetical order, the product listed below:

§ 1308.22 Excluded substances.

* * * * *

EXCLUDED NONNARCOTIC PRODUCTS

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
*	*	*	*	*	*
Classic Pharmaceuticals LLC	Nasal Decongestant Inhaler/ Vapor Inhaler.		IN	Levmetamfetamine (l-Desoxy-ephedrine).	50.00
*	*	*	*	*	*

Dated: August 21, 2009.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Deputy Chief of Operations, Office of Diversion Control.

[FR Doc. E9–20768 Filed 8–27–09; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 5

[Docket No. FR–5331–F–01]

RIN 2501–AD47

Use of Project Labor Agreements for Federal Construction Projects

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule removes a HUD regulation that prohibits the use of project labor agreements in HUD-assisted construction contracts. Executive Order 13502, entitled ''Use of Project Labor Agreements for Federal Construction Projects,'' and signed by President Obama on February 6, 2009, revoked Executive Order 13202, which had prohibited federal agencies from requiring or prohibiting project labor agreements as a condition for award of any federally funded contract or subcontract for construction. Executive Order 13502, which applies to direct federal procurement of construction, encourages federal agencies to consider requiring the use of project labor agreements in connection with federally procured large-scale construction projects. The Executive Order also allows the use of project labor agreements in circumstances not covered by the Order, including projects receiving federal financial assistance.

In a previously published **Federal Register** notice pertaining to HUD's Fiscal Year 2009 (FY 2009) funding, participants in HUD programs and prospective recipients of HUD funds were notified of the issuance of Executive Order 13502, of its removal of the restrictions on the use of project labor agreements, and of the invalidity of the HUD regulation promulgated to enforce the earlier Executive Order. With the revocation of Executive Order 13202, there is no longer a legal basis for HUD's regulation that implemented that executive order with respect to HUD-assisted projects. Therefore, this rule removes the regulation from the Code of Federal Regulations.

DATES: *Effective Date:* September 28, 2009.

FOR FURTHER INFORMATION CONTACT: Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street, SW., Room 10282, Washington, DC 20410; telephone number 202–402–5132 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background—Executive Order 13502, ''Use of Project Labor Agreements for Federal Construction Projects''

Executive Order 13502, entitled ''Use of Project Labor Agreements for Federal Construction Projects,'' and signed by President Barack Obama on February 6, 2009, while directed to federal agency procurement of construction, also allows federal agencies to consider requiring the use of project labor agreements in connection with large-scale federally assisted construction projects. (Executive Order 13502 was subsequently published in the **Federal Register** on February 11, 2009 (74 FR 6985).) The Executive Order revokes Executive Order 13202, ''Preservation of Open Competition and Government Neutrality towards Government Contractors' Labor Relations on Federal and Federally Funded Construction Projects,'' which prohibited federal agencies from requiring or prohibiting project labor agreements as a condition for award of any federally funded contract or subcontract for construction.[1] In order to bind participants in HUD programs to the provisions of Executive Order 13202, HUD established regulations at 24 CFR 5.108 that barred recipients of HUD funds from requiring or prohibiting project labor agreements in their procurements using HUD funds. The HUD regulations applied to HUD-assisted construction contracts. Construction contracts awarded directly by HUD were covered separately by provisions in the government-wide Federal Acquisition Regulation (FAR).

Executive Order 13502 restores to federal agencies the discretion to determine when project labor agreements may be appropriate and beneficial in federally assisted construction projects, through the revocation of Executive Order 13202. As a result of the revocation, Executive Order 13502 also removes the prohibition on recipients of HUD funds from requiring the use of project labor agreements in their procurements. Because the foundation for HUD's regulation in 24 CFR 5.108 was the prior Executive Order, which has been revoked, the rule no longer has effect. Accordingly, in an update of requirements applicable to HUD funding for FY 2009, published in the **Federal Register** on April 16, 2009 (74 FR 17685), HUD notified prospective recipients and participants in HUD programs that the new Executive Order revoked Executive Order 13202 and that the regulation in 24 CFR 5.108 was no longer in effect.

Executive Order 13502 was issued to address the challenges to efficient and timely procurement presented to the federal government by large-scale construction projects. Because construction employers often do not have a permanent workforce, it can be difficult for them to predict labor costs when bidding on contracts and to ensure a steady stream of labor on contracts being performed. Often, multiple employers are involved at a single location, and a labor dispute concerning even one employer can delay an entire project. A lack of coordination between employers or uncertainties about the terms and conditions of employment of various groups of workers can create friction and disputes in the absence of an agreed-upon resolution mechanism. Project labor agreements can present a means for addressing these problems by providing structure and stability to large-scale construction projects, thereby promoting the efficient and expeditious completion of federal construction contracts.

Executive Order 13502 declares that it is the policy of the federal government to encourage the executive agencies to consider requiring the use of project labor agreements in connection with large-scale construction projects in order to promote economy and efficiency in federal procurement. The Executive Order, however, does not require an executive agency to use a project labor agreement on any construction project, nor does it preclude the use of a project labor agreement in circumstances not covered by the Order, including leasehold arrangements and projects receiving federal financial assistance. The Executive Order also does not require contractors or subcontractors to enter into a project labor agreement with any particular labor organization.

[1] (Executive Order 13202 was signed by President George W. Bush on February 17, 2001 (published in the **Federal Register** on February 22, 2001 (66 FR 11225)) and later amended by Executive Order 13208, signed by President Bush on April 6, 2001 (published in the **Federal Register** on April 11, 2001 (66 FR 18717)).