PART 768—[AMENDED]

■ 22. The authority citation for 15 CFR part 768 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

PART 770—[AMENDED]

■ 23. The authority citation for 15 CFR part 770 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

PART 772—[AMENDED]

■ 24. The authority citation for 15 CFR part 772 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

PART 774—[AMENDED]

■ 25. The authority citation for 15 CFR part 774 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

Dated: August 30, 2010.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2010–21957 Filed 9–1–10; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–334F]

RIN 1117–AB29

Additions to Listing of Exempt Chemical Mixtures

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

ACTION: Direct final rule.

SUMMARY: Under this Direct Final Rule, the Drug Enforcement Administration (DEA) is updating the Table of Exempt Chemical Mixtures. This action is in response to DEA's review of new applications for exemption. Having reviewed applications and relevant information, DEA finds that these 21 preparations meet the applicable exemption criteria. Therefore, these products are exempted from the application of certain provisions of the Controlled Substances Act (CSA).

DATES: This Direct Final Rule is effective November 1, 2010 without further action, unless adverse comment is received by DEA no later than October 4, 2010. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until she has reconsidered the application in light of the comments and objections filed.

Written comments must be postmarked and electronic comments must be submitted on or before October 4, 2010. 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–334" on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to the 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 formats 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: Any interested person may file comments or objections to this order, on or before November 1, 2010. If any such comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Deputy Administrator may suspend the effectiveness of the order until she has reconsidered the application in light of the comments and objections filed. Thereafter, the Deputy Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

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.* 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 on *http://www.regulations.gov.*

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.

New Exempt Chemical Mixtures

Pursuant to provisions of 21 CFR 1310.13 discussed further below, the manufacturers of 21 chemical mixtures listed below, in the form and quantity listed in the application submitted (indicated as the "date") have applied for exemption pursuant to 21 CFR 1310.13. DEA has reviewed the applications received, as well as any additional information that may have been requested. It has been determined that (1) each of these chemical mixtures is formulated in such a way that they cannot be easily used in the illicit production of a controlled substance; and (2) the listed chemical(s) contained in these chemical mixtures cannot be readily recovered. Therefore, each of these manufacturers has received a DEA letter granting exempted status on the date shown in the attached table. This regulatory action conforms DEA regulations to the exemptions previously issued.

Background

21 CFR 1310.13 provides that the Administrator of DEA may, by publication of a Final Rule in the **Federal Register**, exempt from the application of all or any part of the CSA a chemical mixture consisting of two or more chemical components, at least one of which is not a List I or List II chemical, if:

(1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.

Any manufacturer seeking an exemption for a chemical mixture, not automatically exempt under 21 CFR 1310.12, may apply to the Administrator by submitting an application for exemption which contains the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The date of the application;

(3) The exact trade name(s) of the applicant's chemical mixture;

(4) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non-listed chemicals); or if a group of mixtures, the concentration range for the listed chemical and a listing of all non-listed chemicals with respective concentration ranges.

(5) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals; and if a group of mixtures, how the group's properties differ from the properties of the listed chemical.

(6) A statement that the applicant believes justifies an exemption for the chemical mixture or group of mixtures. The statement must explain how the chemical mixture(s) meets the exemption criteria.

(7) A statement that the applicant accepts the right of the Administrator to terminate exemption from regulation for the chemical mixture(s) granted exemption under 21 CFR 1310.13.

(8) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.

The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

21 CFR 1310.13 further specifies that within 30 days after the receipt of an application for an exemption, the Administrator will notify the applicant of acceptance or rejection of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to 21 CFR 1310.13 is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of this section.

If the exemption is granted, the applicant shall be notified in writing and the Administrator shall issue, and publish in the **Federal Register**, an order on the application. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until she has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

The Administrator may, at any time, terminate or modify an exemption for any product (21 CFR 1310.13(e)). In terminating or modifying an exemption, the Administrator shall issue, and publish in the **Federal Register**, notification of the removal of an exempt product or group of exempt products for which evidence of diversion has been found. This order shall specify the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the **Federal Register**. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

A manufacturer of an exempted chemical mixture shall notify DEA, in writing, of any change in the quantitative or qualitative composition of a chemical mixture that has been granted an exemption by application (21 CFR 1310.13(g)). Changes include those greater than the range of concentration given in the application or that remove non-listed chemical(s) given in the application as part of the formulation. A new application will be required only if reformulation results in a new product having a different commercial application or can no longer be defined as part of a group of exempted chemicals. DEA must be notified of reformulation at least 30 days in advance of marketing the reformulated mixture. For a change in name or other designation, code, or any identifier, a written notification is required. DEA must be notified of any changes at least 60 days in advance of the effective date for the change.

Each manufacturer seeking exemption must apply for such an exemption (21 CFR 1310.13(h)) to ensure that each manufacturer's product warrants an exemption and is not subject to diversion. A formulation granted exemption by publication in the **Federal Register** will not be exempted for all manufacturers.

Redelegation of Authority

The Administrator has redelegated the authority to change the listing of exempt chemical mixtures to the Deputy

Administrator, Drug Enforcement Administration, pursuant to 28 CFR 0.104, Appendix to Subpart R. The current Table of Exempt Chemical Mixtures lists those products that have been granted exempt status prior to this update. That table can be viewed online at: *http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_list.htm.*

Regulatory Action

Therefore, each of the 21 chemical mixtures for which DEA has received applications for exemptions from their manufacturers are designated as exempt chemical mixtures for the purposes set forth in 21 CFR 1310.13 and are exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822, 823, 830, 957 and 958).

DEA is updating the table in 21 CFR 1310.13(i) to include each of these exempt chemical mixtures.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. This regulation will not have a significant impact upon firms who distribute these products. In fact, the approval of Exempt Chemical Mixture status for these products reduces the regulatory requirements for distribution of these materials.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). It has been determined that this is not a significant regulatory action. Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988

The Deputy Administrator further certifies that this regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

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 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 costs 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 prior public notice provisions of the Administrative Procedure Act (5 U.S.C. 553(b)(B)), if it is determined to be unnecessary, impracticable, or contrary to the public interest. DEA finds that it is contrary to the public interest to seek public comment prior to making the exemption of these 21 chemical mixtures from the requirements of the CSA effective. Each of these manufacturers has received a DEA letter granting exempted status for the specific products on the date shown in the attached table. This regulatory action conforms DEA regulations to the exemptions previously issued.

List of Subjects in 21 CFR Part 1310

Administrative practice and procedure, Drug traffic control, Listed chemicals.

■ Under the authority vested in the Attorney General by section 202(d) of the Act (21 U.S.C. 811(g)(3)(B)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR 0.100), and redelegated to the Deputy Administrator, Drug Enforcement Administration, the Deputy Administrator hereby amends 21 CFR part 1310 as set forth below.

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

■ 1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

■ 2. In § 1310.13(i), the table is revised to read as follows:

§ 1310.13 Exemption of chemical mixtures; application.

* * * * *

(i) * * *

EXEMPT CHEMICAL MIXTURES

Manufacturer	Product name [1]	Form	Date
Cerilliant Corporation	1R,2S(-)-Ephedrine hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥ 50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation	1S,2R(+)-Ephedrine-D_3 hydrochloride 0.1 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007

EXEMPT CHEMICAL MIXTURES—Continued

Manufacturer	Product name [1]	Form	Date
Cerilliant Corporation	1S,2R(+)-Ephedrine-D_3 hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation	1S,2R(+)-Ephedrine hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation	Pseudoephedrine-D_3 hydrochloride 0.1 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation	R,R(-)-Pseudoephedrine 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20) methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation	S,S(+)-Pseudoephedrine 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
E.I. DuPont deNemours & Co.	RC–5156	Liquid	4/22/2005
E.I. DuPont deNemours & Co.	VH–6037	Liquid	4/22/2005
Hawthorne Products, Inc	Sole Pack Hoof Dressing	Paste	8/14/2007
Hawthorne Products, Inc	Sole Pack Hoof Packing	Paste	8/14/2007
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of ephedrine in blood, serum, or urine	Liquid	9/26/2007
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of pseudoephedrine in blood, serum, or urine	Liquid	9/26/2007
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of phenylpropanolamine in blood, serum, or urine	Liquid	9/26/2007
Reichhold, Inc	Beckosol® 12021–00 AA–200, IA–441, P531–T	Liquid	5/05/2005
Reichhold, Inc	Urotuf® L06–30S, F78–50T	Liquid	5/05/2005
Reichhold, Inc	Beckosol AA–220	Liquid	6/14/2005
Waterbury Companies, Inc	Waterbury 332500	Liquid	4/11/2005
Waterbury Companies, Inc	Waterbury 332762	Liquid	4/11/2005
Waterbury Companies, Inc	Waterbury 332400	Liquid	4/11/2005
Waterbury Companies, Inc	Waterbury 346201	Liquid	4/11/2005

[1] Designate product line if a group.

Dated: August 20, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–21778 Filed 9–1–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0790]

Security Zone, Mackinac Bridge, Straits of Mackinac, Michigan

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Mackinac Bridge Walk security zone on the Straits of Mackinac from 6 a.m. through 11:59 p.m. on September 6, 2010. This action is necessary to protect pedestrians during the event from an accidental or intentional allision between a vessel and the bridge. During the enforcement period, navigational and operational restrictions will be placed on all vessels and persons transiting through the Straits area, under and around the Mackinac Bridge, located between Mackinaw City, MI, and St. Ignace, MI. All vessels and persons must obtain permission from the Captain of the Port (COTP) or a designated representative to enter or move within the security zone.

DATES: The regulations in 33 CFR 165.928 will be enforced from 6 a.m. through 11:59 p.m. on September 6, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail BMC Gregory Ford, Marine Event Coordinator, U.S. Coast Guard Sector Sault Sainte Marie; telephone 906–635–3222, e-mail *Gregory.C.Ford@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the security zone for the annual Labor Day Mackinac Bridge Walk in 33 CFR 165.928 on September 6, 2010, from 6 a.m. to 11:59 p.m.

Under provisions of 33 CFR 165.928, a vessel or person may not enter or move within the regulated area, unless permission is received from the COTP or a designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under the authority of 33 CFR 165.928 and 5 U.S.C. 552(a). In addition to this notice