Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-505F]

RIN 1117-ZA05

Additions to Listing of Exempt Chemical Mixtures

AGENCY: Drug Enforcement Administration, 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 to include the listing of 15 additional preparations. This action is in response to DEA's review of new applications for exemption. Having reviewed applications and relevant information, DEA finds that these preparations meet the applicable exemption criteria. Therefore, these products are exempted from the application of certain provisions of the Controlled Substances Act.

DATES: This direct final rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] without further action, unless adverse comment is received by DEA no later than [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the DEA will publish a timely withdrawal of the rule in the Federal Register.

Written comments must be postmarked and electronic comments must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF 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.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-505F/ RIN 1117-ZA05" on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration 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 to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152. Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION: Any interested person may file comments or objections to this order, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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 DEA will publish a timely withdrawal of the rule in the Federal Register. The Acting Administrator may reconsider the application in light of the comments and objections filed and 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.

New Exempt Chemical Mixtures

The manufacturers of 15 chemical mixtures listed below have applied for an exemption pursuant to 21 CFR 1310.13. The Drug Enforcement Administration (DEA) has reviewed the applications, as well as any additional information submitted by the respective manufacturers. DEA has found that: (1) each of these chemical mixtures 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(s) contained in these chemical mixtures cannot be readily recovered. Therefore, DEA has determined that each of the applications should be granted, and previously issued a letter to this effect. This regulatory action conforms DEA regulations to the exemptions previously issued.

Background

Under 21 CFR 1310.13(a), the Acting Administrator may, by publication of a Final Rule in the *Federal Register*, exempt from the application of all or any part of the Controlled Substances Act a chemical mixture consisting of two or more chemical components, at least one of which is not a list I or list II chemical. Each manufacturer must apply for such an exemption (21 CFR 1310.13) to ensure that each manufacturer's product warrants an exemption by demonstrating that:

- The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and
- 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 Acting Administrator by submitting an application for exemption which contains the information required by 21 CFR 1310.13(c):

- The name, address, and registration number, if any, of the applicant;
- The date of the application;
- The exact trade name(s) of the applicant's chemical mixture;
- 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;

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

Title 21 CFR 1310.13 further specifies that within a reasonable period of time after the receipt of an application for an exemption, the Acting Administrator will notify the applicant of acceptance or rejection of the application for filing. If the application is not accepted for filing, an explanation will be provided. The Acting 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 Acting 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 Acting 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 DEA will publish a timely withdrawal of the rule in the Federal Register. The Acting Administrator may reconsider the application in light of the comments and objections filed and reinstate, terminate, or amend the original order as deemed appropriate.

A formulation granted exemption by publication in the Federal Register will not be exempted for all manufacturers. 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*.

Findings

Having considered the information provided in each of the below listed applications, I find that each of the referenced chemical mixtures meets the requirements for exemption under 21 CFR 1310.13(a). Therefore, each of these mixtures is exempt from the application of sections 302, 303, 310, 1007, and 1008 of the Controlled Substances 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 Analyses

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 unnecessary to engage in notice and comment procedures because this rulemaking grants exemptions for the below listed products in accordance with standards set by existing DEA regulations. Each of these manufacturers has previously received a letter from DEA granting exempted status for the specific products. This regulatory action hereby conforms DEA regulations to the exemptions previously considered and issued.

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This direct final rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) 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; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. DEA has determined that this direct final rule is not a "significant regulatory action" under Executive Order 12866, section 3(f).

This direct final rule is not an Executive Order 13771 regulatory action pursuant to Executive Order 12866 and the Office of Management and Budget (OMB) guidance.[1]

Executive Order 12988, Civil Justice Reform

The Acting Administrator further certifies that this rulemaking meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 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, Federalism

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 National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

[1] Office of Mgmt. & Budget, Exec. Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled "Reducing Regulation and Controlling Regulatory Costs" (Feb. 2, 2017).

This rule does not have tribal implications warranting the application of Executive Order 13175. It 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.

Regulatory Flexibility Act

The Acting 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.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action will 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 UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action does 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 the Congressional Review Act (CRA), 5 U.S.C. 804. This rule does 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 U.S.-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 direct final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1310

Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

Under the authority vested in the Attorney General by section 102(39)(A)(vi) of the Act (21 U.S.C. 802(39)(A)(vi)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR 0.100), the Acting Administrator hereby amends 21 CFR part 1310 as set forth below.

PART 1310--RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF 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 amended by:

a. Designating the table as table 1 to paragraph (i); and

b. Adding the entries “GFS Chemicals; WaterMark® Karl-Fisher Reagent, Pyridine-Free Single Solution, 5 mg/ml,” “GFS Chemicals; WaterMark® Karl-Fisher Reagent, 5 mg/ml Single Solution NON-HAZ,” “GFS Chemicals; WaterMark® Karl-Fisher Reagent, Pyridine-Free Single Solution, 2 mg/ml,” “GFS Chemicals; WaterMark® Karl-Fisher Reagent, 2 mg/ml Single Solution NON-HAZ,” “GFS Chemicals; WaterMark® Karl-Fisher Reagent, 5 mg/ml, Stabilized, Pyridine-Based,” “Lord Corporation; Chemlok TS701-52,” “Lord Corporation; Chemlok TS701-53,” “Sigma-Aldrich; Hydranal®-Composite 1,” “Sigma-Aldrich; Hydranal®-Composite 2,” “Sigma-Aldrich; Hydranal®-Composite 5K,” “Sigma-Aldrich; Hydranal®-Composite 5,” “Standard Homeopathic Co.; Baby Cough Syrup,” “Standard Homeopathic Co.; Defend Cough & Cold Night,” “Standard Homeopathic Co.; Defend Cough & Cold,” and “Standard Homeopathic Co.; Diarrex” in alphabetical order of Manufacturer.

The additions read as follows:

§ 1310.13 Exemption of chemical mixtures; application.

* * * * *

(i) * * *

Table 1 to Paragraph (i)--Exempt Chemical Mixtures

Manufacturer	Product name[1]	Form	Approval Date
* * * * * * *			
GFS Chemicals	WaterMark® Karl-Fisher Reagent, Pyridine-Free Single Solution, 5 mg/ml	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 5 mg/ml Single Solution NON-HAZ	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, Pyridine-Free Single Solution, 2 mg/ml	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 2 mg/ml Single Solution NON-HAZ	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 5 mg/ml, Stabilized, Pyridine-Based	Liquid	11/26/2018
* * * * * * *			
Lord Corporation	Chemlok TS701-52	Liquid	05/03/2018
Lord Corporation	Chemlok TS701-53	Liquid	05/03/2018
* * * * * * *			

Sigma-Aldrich	Hydranal®-Composite 1	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 2	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 5K	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 5	Liquid	5/29/2013
Standard Homeopathic Co.	Baby Cough Syrup	Liquid	9/28/2012
Standard Homeopathic Co.	Defend Cough & Cold Night	Liquid	9/28/2012
Standard Homeopathic Co.	Defend Cough & Cold	Liquid	9/28/2012
Standard Homeopathic Co.	Diarrex	Liquid	9/28/2012
* * * * * * *			

[1] Designate product line if a group.

Dated: January 3, 2020.

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Uttam Dhillon,
Acting Administrator.

[FR Doc. 2020-00667 Filed: 1/24/2020 8:45 am; Publication Date: 1/27/2020]