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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-372]

Exempt Chemical Preparations Under the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Order with opportunity for comment.

SUMMARY: The applications for exempt chemical preparations received by the Drug Enforcement Administration (DEA) between January 1, 2016, and March 31, 2016, as listed below, were accepted for filing and have been approved or denied as indicated.

DATES: Interested persons may file written comments on this order in accordance with 21 CFR 1308.23(e). 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.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-372" on all correspondence, including any attachments. The Drug Enforcement Administration (DEA) encourages that all comments be submitted 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 that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, 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 are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA'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.

Comments containing personal identifying information and confidential business information identified as directed above will generally 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 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. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled

Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. 21 U.S.C. 801–971. The DEA published 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.

Section 201 of the CSA (21 U.S.C. 811) authorizes the Attorney General, by regulation, to exempt from certain provisions of the CSA certain compounds, mixtures, or preparations containing a controlled substance, if she finds that such compounds, mixtures, or preparations meet the requirements detailed in 21 U.S.C. 811(g)(3)(B).[1] The DEA regulations at 21 CFR 1308.23 and 1308.24 further detail the criteria by which the DEA Deputy Assistant Administrator may exempt a chemical preparation or mixture from certain provisions of the CSA. The Deputy Assistant Administrator may, pursuant to 21 CFR 1308.23(f), modify or revoke the criteria by which exemptions are granted and modify the scope of exemptions at any time.

Exempt Chemical Preparation Applications Submitted Between January 1, 2016, and March 31, 2016

[1] This authority has been delegated from the Attorney General to the Administrator of the DEA by 28 CFR 0.100, and subsequently redelegated to the Deputy Assistant Administrator pursuant to Section 7 of 28 CFR 0.104, appendix to subpart R.

The Deputy Assistant Administrator received applications between January 1, 2016, and March 31, 2016, requesting exempt chemical preparation status detailed in 21 CFR 1308.23. Pursuant to the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23, the Deputy Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart I below is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or animal and either: (1) contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse; or (2) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration that the preparation or mixture does not present any potential for abuse; if the preparation or mixture contains a narcotic controlled substance, it must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects if abused, and so that the narcotic substance cannot in practice be removed.

Accordingly, pursuant to 21 U.S.C. 811(g)(3)(B), and in accordance with 21 CFR 1308.23 and 21 CFR 1308.24, the Deputy Assistant Administrator has determined that each of the chemical preparations or mixtures generally described in Chart I below and specifically described in the application materials received by the DEA, are exempt, to the extent described in 21 CFR 1308.24, from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003, and 1004 (21 U.S.C. 822-823, 825-829, and 952-954) of the

CSA, and 21 CFR 1301.74, as of the date that was provided in the approval letters to the individual requesters.

Chart I

Supplier	Product Name	Form	Application Date
Cayman Chemical Company	Δ9-THC Metabolite Mixture CRM; 1 mg/mL each in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Δ9-THC Metabolite Mixture CRM; 100 µg/mL each in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Δ9-THC Metabolite Mixture CRM; 250 µg/mL each in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Δ9-THC Metabolite Mixture CRM; 500 µg/mL each in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Δ9-THC/Cannabidiol/Cannabinol Mixture CRM; 1 mg/mL each in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Δ9-THC/Cannabidiol/Cannabinol Mixture CRM; 100 µg/mL each in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Δ9-THC/Cannabidiol/Cannabinol Mixture CRM; 250 µg/mL each in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Δ9-THC/Cannabidiol/Cannabinol Mixture CRM; 500 µg/mL each in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabicitran CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabicitran CRM; 1 mg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabicitran CRM; 100 µg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabicitran CRM; 100 µg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabinodiol CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016

Cayman Chemical Company	Cannabinodiol CRM; 1 mg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabinodiol CRM; 100 µg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabinodiol CRM; 100 µg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabinol monomethyl ether CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabinol monomethyl ether CRM; 1 mg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabinol monomethyl ether CRM; 100 µg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Cannabinol monomethyl ether CRM; 100 µg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Clonazepam-d4 CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Clonazepam-d4 CRM; 100 µg/mL each in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zaleplon CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zaleplon CRM; 1 mg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zaleplon CRM; 100 µg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zaleplon CRM; 100 µg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zolpidem CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zolpidem CRM; 1 mg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zolpidem CRM; 100 µg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zolpidem CRM; 100 µg/mL in Methanol	Glass vial: 1 mL	2/10/2016

Cayman Chemical Company	Zopiclone CRM; 1 mg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zopiclone CRM; 1 mg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zopiclone CRM; 100 µg/mL in Acetonitrile	Glass vial: 1 mL	2/10/2016
Cayman Chemical Company	Zopiclone CRM; 100 µg/mL in Methanol	Glass vial: 1 mL	2/10/2016
Cerilliant Corporation	delta9-Tetrahydrocannabinolic acid A (1.0 mg/mL)	Glass vial: 1 mL	2/5/2016
Cerilliant Corporation	m-Hydroxycocaine (1 mg/mL)	Glass ampule: 1 mL	2/16/2016
Cerilliant Corporation	NIST SRM-971 Extract	Glass ampule: 0.3 mL	1/4/2016
Cerilliant Corporation	Norhydromorphone HCl (1 mg/mL)	Glass ampule: 1 mL	3/17/2016
Cerilliant Corporation	o-Hydroxycocaine (1 mg/mL)	Glass ampule: 1 mL	2/16/2016
Cerilliant Corporation	p-Hydroxycocaine (1 mg/mL)	Glass ampule: 1 mL	2/16/2016
Cerilliant Corporation	T-096 Extract	Glass ampule: 0.2 mL	1/4/2016
Cerilliant Corporation	T-097 Extract	Glass ampule: 0.3 mL	1/4/2016
Cerilliant Corporation	Thebaine (1 mg/mL)	Glass ampule: 1 mL	3/17/2016
Cerilliant Corporation	VAC-10-1	Glass ampule: 0.3 mL	1/4/2016
Cerilliant Corporation	VAC-10-2	Glass ampule: 0.3 mL	1/4/2016
Cerilliant Corporation	VAC-10-3	Glass ampule: 0.3 mL	1/4/2016
Cerilliant Corporation	VAC-10-4	Glass ampule: 0.3 mL	1/4/2016
Cerilliant Corporation	VAC-10-5	Glass ampule: 0.3 mL	1/4/2016
Cerilliant Corporation	VAC-10-6	Glass ampule: 0.3 mL	1/4/2016
Cerilliant Corporation	Zolpidem (1 mg/mL)	Glass ampule: 1 mL	3/17/2016
IsoSciences, LLC	(±)- Amphetamine-[13C6] • HCl, 0.1 mg/mL in methanol	Glass ampule: 1 mL	2/18/2016
IsoSciences, LLC	(±)- Amphetamine-[13C6] • HCl, 1.0 mg/mL in methanol	Glass ampule: 1 mL	2/18/2016
IsoSciences, LLC	(±)- Methamphetamine-[13C6] • HCl, 0.1 mg/mL in methanol	Glass ampule: 1 mL	2/18/2016
IsoSciences, LLC	(±)- Methamphetamine-[13C6] • HCl, 1.0 mg/mL in methanol	Glass ampule: 1 mL	2/18/2016

IsoSciences, LLC	(±)- Methylenedioxyamphetamine-[13C6] • HCl ((±)- MDA-[13C6] • HCl), 0.1 mg/mL in methanol	Glass ampule: 1 mL	2/18/2016
IsoSciences, LLC	(±)- Methylenedioxyamphetamine-[13C6] • HCl ((±)- MDA-[13C6] • HCl), 1.0 mg/mL in methanol	Glass ampule: 1 mL	2/18/2016
IsoSciences, LLC	(±)- Methylenedioxyethylamphetamine-[13C6] • HCl ((±)- MDEA-[13C6] • HCl), 0.1 mg/mL in methanol	Glass ampule: 1 mL	2/18/2016
IsoSciences, LLC	(±)- Methylenedioxyethylamphetamine-[13C6] • HCl ((±)- MDEA-[13C6] • HCl), 1.0 mg/mL in methanol	Glass ampule: 1 mL	2/18/2016
Lipomed Inc.	Chlordiazepoxide-D5 (0.1 mg/1 mL acetonitrile)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	Chlordiazepoxide-D5 (1 mg/1 mL acetonitrile)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	Clotiazepam (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	d,l-Methamphetamine-D14.HCl (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	d,l-Methamphetamine-D14.HCl (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	d,l-threo-Methylphenidate-D10.HCl (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	d,l-threo-Methylphenidate-D10.HCl (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	Oxycodone-OCD3.HCl (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	Oxycodone-OCD3.HCl (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	Oxymetholone (1 mg/1 mL acetonitrile)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	Prazepam-D5 (0.1 mg/1 mL acetonitrile)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	Prazepam-D5 (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	Tapentadol.HCl (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
SPEX CertiPrep Group, LLC	(-)-delta8-THC, 1000 µg/mL in Methanol	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	(-)-delta9-THC, 1000 µg/mL in Methanol	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	(-)-delta9-THC-D3, 100 µg/mL in Methanol	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	(-)-delta9-THC-D3, 1000 µg/mL in Methanol	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	(±)-11-Hydroxy-delta9-THC, 100 µg/mL in Methanol	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	(±)-11-nor-9-Carboxy-delta9-THC-D3, 100 µg/mL in Methanol	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	(±)-11-nor-9-Carboxy-delta9-THC-D3, 1000 µg/mL in Methanol	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	(±)-delta8-THC (Qualitative use only), 100 µg/mL in Heptane	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	(±)-delta9-THC (Qualitative use only), 100 µg/mL in Heptane	Glass ampule: 2 mL	2/25/2016
SPEX CertiPrep Group, LLC	exo-THC, 1000 µg/mL in Methanol	Glass ampule: 2 mL	2/25/2016

Ultra Scientific, Inc.	Custom Standard –Quote# 032116-099	Glass ampule: 5 mL	3/29/2016

The Deputy Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart II below is not consistent with the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23. Accordingly, the Deputy Assistant Administrator has determined that the chemical preparations or mixtures generally described in Chart II below and specifically described in the application materials received by DEA, are not exempt from application of any part of the CSA or from application of any part of the CFR, with regard to the requested exemption pursuant to 21 CFR 1308.23, as of the date that was provided in the determination letters to the individual requesters.

Chart II

Supplier	Product Name	Form	Application Date
Lipomed Inc.	Naloxone N-Oxide (1 mg/1 mL ACN/H2O 1:1)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	HU-210 (1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016
Lipomed Inc.	HU-210 (0.1 mg/1 mL methanol)	Glass ampule: 1 mL	1/28/2016

Scope of Approval

The exemptions are applicable only to the precise preparation or mixture described in the application submitted to DEA in the form(s) listed in this order and only for those sections of the CSA and the CFR that are specifically identified. In accordance with 21 CFR 1308.24(h), any change in the quantitative or qualitative composition of the preparation or mixture, or change in the trade name or other designation of the

preparation or mixture after the date of application requires a new application. In accordance with 21 CFR 1308.24(g), the DEA may prescribe requirements other than those set forth in 1308.24(b)–(e) on a case-by-case basis for materials exempted in bulk quantities. Accordingly, in order to limit opportunity for diversion from the larger bulk quantities, the DEA has determined that each of the exempted bulk products listed in this order may only be used in-house by the manufacturer, and may not be distributed for any purpose, or transported to other facilities.

Additional exempt chemical preparation requests received between January 1, 2016, and March 31, 2016, and not otherwise referenced in this order may remain under consideration until the DEA receives additional information required, in accordance with 21 CFR 1308.23(d), as detailed in separate correspondence to individual requesters. The DEA's order on such requests will be communicated to the public in a future *Federal Register* publication.

The DEA also notes that these exemptions are limited to exemption from only those sections of the CSA and the CFR that are specifically identified in 21 CFR 1308.24(a). All other requirements of the CSA and the CFR apply, including registration as an importer as required by 21 U.S.C. 957.

Chemical Preparations Containing Newly Controlled Substances

The statutory authority for exempt chemical preparations is based on the control status of substances contained within a preparation, the intended administration of a preparation, and the packaged form of a preparation. The DEA conducts a case-by-case analysis of each application for exemption to determine whether exemption of a

preparation from certain provisions of the CSA is appropriate pursuant to the specified statutory and regulatory requirements.

Most exempt chemical preparations have remained effective until the holder of a specific exempt chemical preparation specifically requested that the exemption be terminated. The CSA allows for modifications to the controlled substances schedules to add, remove, or change the schedule of substances thus resulting in periodic modifications to the control status of various substances. 21 U.S.C. 811(a). Since the CSA was enacted in 1970, the DEA has on several occasions added to, removed from, or modified the schedules of controlled substances in accordance with the CSA. Such changes may result in the non-compliance of exempt chemical preparations with current statutes or regulations if chemical preparations that have already obtained exempt status contain newly controlled substances. For example, although an exempt chemical preparation may continue to be packaged in the same manner as when it was approved, non-controlled substances in the preparation may become controlled, thus prompting the need for a new application for exemption of the chemical preparation to ensure continued compliance. Other preparations that previously contained no controlled substances may contain newly controlled substances and thus would require an application for exemption.

The DEA reviews applications for chemical preparation exemptions based on the statutes and regulations that are in place at the time of the application, including the control status of substances included in the preparation. The DEA must remain vigilant to ensure that exempt chemical preparations remain consistent with the standards set forth in the CSA and its implementing regulations. As such, the DEA reminds the public that

any chemical preparation, regardless of whether it was previously exempt, that contains a newly controlled substance will require a new application for exemption pursuant to 21 U.S.C. 811(g)(3)(B) and 21 CFR 1308.23–1308.24.

Opportunity for Comment

Pursuant to 21 CFR 1308.23, any interested person may submit written comments on or objections to any chemical preparation in this order that has been approved or denied as exempt. If any 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 will immediately suspend the effectiveness of any applicable part of this order until he may reconsider the application in light of the comments and objections filed.

Approved Exempt Chemical Preparations are Posted on DEA's Web site

A list of all current exemptions, including those listed in this order, is available on the DEA's Web site at http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf. The dates of applications of all current exemptions are posted for easy reference.

Dated: May 16, 2016.

Louis J. Milione,
Deputy Assistant Administrator.
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