Square, 145 N Street NE, Mail Stop 3.E–405A, Washington, DC 20530.

Dated: January 14, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

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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 between April 1, 2021, and June 30, 2021, 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 March 22, 2022. 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.

Electronic comments: Drug Enforcement Administration 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: 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/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–8201.

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. The Freedom of Information Act 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 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

Section 201 of the Controlled Substances Act (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 he finds that such compounds, mixtures, or preparations meet the requirements detailed in 21 U.S.C. 811(g)(3)(B).[1] The Drug Enforcement Administration (DEA) regulations at 21 CFR 1308.23 and 1308.24 further detail the criteria by which the DEA Assistant Administrator may exempt a chemical preparation or mixture from certain provisions of the CSA. The 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 April 1, 2021, and June 30, 2021

The Assistant Administrator received applications between April 1, 2021, and June 30, 2021, 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 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 and, if the preparation or mixture contains a narcotic controlled substance, is formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or

[1] This authority has been delegated from the Attorney General to the DEA Administrator by 28 CFR 0.100, and subsequently redelegated to the Deputy Assistant Administrator pursuant to 28 CFR 0.104 and Section 7 of the appendix to subpart R of part 0.

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), 21 CFR 1308.23, and 21 CFR 1308.24, the 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 DEA is 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.

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 above mentioned sections of the CSA and the CFR. 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. The requirements set forth in 21 CFR 1308.24(b)–(e) apply to the exempted materials. In accordance with 21 CFR 1308.24(g), DEA may prescribe requirements other than those set forth in 21 CFR 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, 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 April 1, 2021, and June 30, 2021, and not otherwise referenced in this order, may remain under consideration until DEA receives additional information required, pursuant to 21 CFR 1308.23(d), as detailed in separate correspondence to individual requesters. DEA's order on such requests will be communicated to the public in a future **Federal Register** publication.

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.

CHART I

Supplier	Product name	Form	Application date
Aalto Scientific, Ltd	Immunoassay Base (Level A–E)	Glass or plastic bottle or flask: 500 mL–1 L.	4/13/2021
Aalto Scientific, Ltd	Immunoassay Base (Level A–E)	Glass or plastic bottle or flask: 100 mL–500 mL.	4/13/2021
Aalto Scientific, Ltd	Immunoassay Base (Level A–E)	Glass or plastic bottle or flask: 1 mL–100 mL.	4/13/2021
Aalto Scientific, Ltd	Immunoassy Base (Level A–E)	Glass vial, bottle, or flask: 1 mL	4/1/2021
Aalto Scientific, Ltd	TDM Base (Level A–E)	Glass vial, bottle, or flask: 500 mL–1L.	4/1/2021
Aalto Scientific, Ltd	TDM Base (Level A–E)	Glass vial, bottle, or flask: 100mL–500 mL.	4/1/2021
Aalto Scientific, Ltd	TDM Base (Level A–E)	Glass vial, bottle, or flask: 1 mL–100 mL.	4/1/2021
Aalto Scientific, Ltd	TDM Beckman AU Base (Level A–E)	Glass vial, bottle, or flask: 500 mL–1L.	4/1/2021
Aalto Scientific, Ltd	TDM Beckman AU Base (Level A–E)	Glass vial, bottle, or flask: 100mL–500 mL.	4/1/2021
Aalto Scientific, Ltd	TDM Beckman AU Base (Level A–E)	Glass vial, bottle, or flask: 1 mL–100 mL.	4/1/2021
ARK Diagnostics, Inc	DRI Fentanyl II Control	Kit: 4 Dropper vials, 10 mL each	4/15/2021
ARK Diagnostics, Inc	DRI Fentanyl II Cutoff Calibrator	Kit: 2 Dropper vials, 10 mL each	4/15/2021
Audit MicroControls	Linearity FD Fertility Siemens Atellica/Centaur	Kit: 5 vials; 3 mL each	4/29/2021
Audit MicroControls	Linearity FD Fertility Siemens Atellica/Centaur, Set 2 Level A	Glass vial: 3 mL	4/29/2021
Audit MicroControls	Linearity FD Fertility Siemens Atellica/Centaur, Set 2 Level B	Glass vial: 3 mL	4/29/2021
Audit MicroControls	Linearity FD Fertility Siemens Atellica/Centaur, Set 2 Level C	Glass vial: 3 mL	4/29/2021
Audit MicroControls	Linearity FD Fertility Siemens Atellica/Centaur, Set 2 Level D	Glass vial: 3 mL	4/29/2021
Audit MicroControls	Linearity FD Fertility Siemens Atellica/Centaur, Set 2 Level E	Glass vial: 3 mL	4/29/2021
Audit MicroControls	Linearity FD TDM Siemens Atellica/Centaur	Kit: 5 vials; 5 mL each	4/27/2021
Cayman Chemical Company	(S)-5-fluoro ADB (CRM); 100 µg/mL in Acetonitrile	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	2′-fluoro ortho-Fluorofentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4-ANPP (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4-ANPP (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4-ANPP-13C6 (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4-ANPP-d5 (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4-ANPP-d5 (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4′-chloro-α-Pyrrolidinovalerophenone (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4-cyano CUMYL-BUTINACA (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4′-methyl Acetyl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4′-methyl Acetyl fentanyl-d5 (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4-methyl-α-Ethylaminopentiophenone (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	4′-methyl-α-Pyrrolidinohexanophenone (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	5-fluoro CUMYL-PINACA; 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Acrylfentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Acrylfentanyl-d5 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Butyryl fentanyl-d5 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021

CHART I—Continued

Supplier	Product name	Form	Application date
Cayman Chemical Company	Cocaethylene (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Cyclohexyl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Cyclohexyl fentanyl-d5 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Cyclopentyl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Cyclopropyl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Cyclopropyl fentanyl-13C6 (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	D8-THCA-A (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D8-THCA-A (CRM) 100 µg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D8-THCH (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D8-THCH (CRM) 1 mg/ml, 1 mL in methanol	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D8-THCH (CRM) 100 µg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D8-THCH (CRM) 100 µg/ml, 1 mL in methanol	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCB (CRM) 100 µg/mL, 1 mL acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCB (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCB (CRM) 1 mg/ml, 1 mL methanol	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCB (CRM) 100 µg/mL, 1 mL methanol	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCBA-A (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCBA-A (CRM) 100 µg/mL, 1 mL acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCH (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCH (CRM) 1 mg/ml, 1 mL in methanol	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCH (CRM) 100 µg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCH (CRM) 100 µg/ml, 1 mL in methanol	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCHA–A (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCHA–A (CRM) 100 µg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCP (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCP (CRM) 1 mg/ml, 1 mL methanol	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCP (CRM) 100 µg/mL, 1 mL acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCP (CRM) 100 µg/mL, 1 mL methanol	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCPA-A (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	D9-THCPA-A (CRM) 100 µg/mL, 1 mL acetonitrile	Glass ampule: 1 mL	6/8/2021
Cayman Chemical Company	FIBF (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	FIBF-d7 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Furanyl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Furanyl fentanyl-13C6 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Furanyl fentanyl-d5 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Isobutyryl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Isobutyryl fentanyl-d5 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Lorcaserin (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	meta-Fluorobutyryl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	meta-Fluoroisobutyryl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Methoxyacetyl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	MMB-FUBINACA (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	MT-45-d11 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	N-ethyl Pentylone (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Ocfentanil (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Ocfentanil-d5 (hydrochloride); 100 µg/mL in Methanol (CRM)	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	ortho-Fluorobutyryl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	ortho-Fluoroisobutyryl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	para-Chloroisobutyryl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	para-Fluorobutyryl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	para-Fluorobutyryl fentanyl-13C6 (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	para-Fluorobutyryl fentanyl-d7 (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	para-Fluorofentanyl-d5 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	para-methoxy-Butyryl fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	para-methoxy-Butyryl fentanyl-d7 (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	PV8 (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Tetrahydrofuran fentanyl (hydrochloride) (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Valeryl fentanyl (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Valeryl fentanyl-13C6 (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	Valeryl fentanyl-d5 (CRM); 100 µg/mL in Methanol	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	α-Ethylaminohexanophenone (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cayman Chemical Company	α-Pyrrolidinohexanophenone (hydrochloride) (CRM); 100 µg/mL in Methanol.	Glass ampule: 1.0 mL	4/14/2021
Cerilliant Corporation	6-Acetylcodeine-D3	Glass ampule: 1.0 mL	4/15/2021
Cerilliant Corporation	Normorphine-D3	Glass ampule: 1.0 mL	4/15/2021
Cliniqa Corporation	TDM + MTX Control Level 1, Part: 43746	Bottle: 500 ml	4/27/2021
Cliniqa Corporation	TDM + MTX Control Level 1, Part: 83737	Vial: 5 ml	4/27/2021
Cliniqa Corporation	TDM + MTX Control Level 2, Part: 43747	Bottle: 500 ml	4/27/2021

CHART I—Continued

Supplier	Product name	Form	Application date
Cliniqa Corporation	TDM + MTX Control Level 2, Part: 83738	Vial: 5 ml	4/27/2021
Cliniqa Corporation	TDM + MTX Control Level 3, Part: 43747	Bottle: 500 ml	4/27/2021
Cliniqa Corporation	TDM + MTX Control Level 3, Part: 83739	Vial: 5 ml	4/27/2021
College of American Pathologists	2022 DMPM–01	HDPE bottle: 40 mL	4/19/2021
College of American Pathologists	2022 DMPM–02	HDPE bottle: 40 mL	4/19/2021
College of American Pathologists	2022 DMPM–03	HDPE bottle: 40 mL	4/19/2021
College of American Pathologists	2022 DMPM–05	HDPE bottle: 40 mL	4/19/2021
College of American Pathologists	2022 DMPM–06	HDPE bottle: 40 mL	4/19/2021
College of American Pathologists	2022 DMPM–07	HDPE bottle: 40 mL	4/19/2021
College of American Pathologists	2022 FTC–02	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–03	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–04	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–05	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–07	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–08	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–10	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–12	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–13	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 FTC–14	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 OFD–01	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–02	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–03	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–04	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–05	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–06	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–07	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–08	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–10	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–11	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–12	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–13	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–14	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–15	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–16	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–17	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–18	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–19	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 OFD–20	HDPE vial: 2 mL	4/19/2021
College of American Pathologists	2022 T–03	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 T–04	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 T–05	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 T–07	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 T–08	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 T–09	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 T–12	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 T–13	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022 THCB–01	Glass vial: 10 mL	4/19/2021
College of American Pathologists	2022 THCB–02	Glass vial: 10 mL	4/19/2021
College of American Pathologists	2022 THCB–03	Glass vial: 10 mL	4/19/2021
College of American Pathologists	2022 THCB–04	Glass vial: 10 mL	4/19/2021
College of American Pathologists	2022 THCB–05	Glass vial: 10 mL	4/19/2021
College of American Pathologists	2022 THCB–06	Glass vial: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–01	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–02	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–03	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–04	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–05	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–06	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–07	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–08	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–09	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–10	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–11	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–12	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–13	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–14	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UDS–15	HDPE bottle: 10 mL	4/19/2021
College of American Pathologists	2022 UT–01	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–02	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–03	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–04	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–05	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–06	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–07	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–08	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–09	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–10	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–11	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–12	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–13	HDPE bottle: 50 mL	4/19/2021

CHART I—Continued

Supplier	Product name	Form	Application date
College of American Pathologists	2022 UT–14	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UT–15	HDPE bottle: 50 mL	4/19/2021
College of American Pathologists	2022 UTCO–01	HDPE bottle: 40 mL	4/19/2021
College of American Pathologists	2022 ZE–01	Glass vial: 5 mL	4/19/2021
College of American Pathologists	2022 ZE–02	Glass vial: 5 mL	4/19/2021
College of American Pathologists	2022 ZE–03	Glass vial: 5 mL	4/19/2021
College of American Pathologists	2022 ZE–04	Glass vial: 5 mL	4/19/2021
College of American Pathologists	2022 ZE–05	Glass vial: 5 mL	4/19/2021
College of American Pathologists	2022 ZE–06	Glass vial: 5 mL	4/19/2021
College of American Pathologists	2022FTC–01	HDPE bottle: 20 mL	4/19/2021
College of American Pathologists	2022–OFD–09	HDPE vial: 2 mL	4/19/2021
CPI International	(-)-delta9-tetrahydrocannabinol (d9-THC) 1000 mg/L, 1 mL	Amber ampule: 1 mL	4/7/2021
LGC—Dr. Ehrenstorfer	Custom (-)-delta9-tetrahydrocannabinol (d9-HC) 1000 µg/mL in acetonitrile.	Amber ampule: 1 mL	4/12/2021
LGC—Dr. Ehrenstorfer	Custom Pharmaceutical Mix 6509 100–10000 µg/mL in methanol	Amber ampule: 1 mL	6/8/2021
LGC—Dr. Ehrenstorfer	Custom Pharmaceutical Mix 6509 100–10000 µg/mL in methanol	1 kit: 5 ampules × 1 mL each	4/12/2021
LGC—Dr. Ehrenstorfer	Δ11-Tetrahydrocannabinol (Δ11-THC) 100 µg/mL in Methanol	Amber ampule: 1 mL	6/14/2021
LGC—Dr. Ehrenstorfer	Δ11-Tetrahydrocannabinol (Δ11-THC) 100 µg/mL in Methanol	Amber ampule: 1 mL	4/20/2021
LGC—Dr. Ehrenstorfer	Δ11-Tetrahydrocannabinol (Δ11-THC) 1000 µg/mL in Methanol	Amber ampule: 1 mL	6/14/2021
LGC—Dr. Ehrenstorfer	Δ11-Tetrahydrocannabinol (Δ11-THC) 1000 µg/mL in Methanol	Amber ampule: 1 mL	4/20/2021
LGC—Dr. Ehrenstorfer	Δ9-Tetrahydrocannabivarinic acid (THCVA) 100 µg/mL in Methanol	Amber ampule: 1 mL	6/8/2021
LGC—Dr. Ehrenstorfer	Δ9-Tetrahydrocannabivarinic acid (THCVA) 1000 µg/mL in Methanol	Amber ampule: 1 mL	6/8/2021
LGC—Dr. Ehrenstorfer	Boldenone cypionate 100 µg/mL in Acetonitrile	Amber ampule: 1 mL	5/4/2021
Lin-Zhi International	LZI Norfentanyl (Q) Qualitative Calibrator (5 ng/mL), Ref# C68815	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	LZI Norfentanyl Level 1 Control (3.75 ng/mL), Ref# C68821	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	LZI Norfentanyl Level 2 Control (6.25 ng/mL), Ref# C68822	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	LZI Norfentanyl Qualitative Calibrator (5 ng/mL), Ref# C68810	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	LZI Norfentanyl Semi-Quantitative Calibrator Set, Ref# C68811	Kit: 4 dropper bottles; 15 mL each	6/9/2021
Lin-Zhi International	Norbuprenorphine DAU Calibrator, Norbuprcnorphinc, Intermediate Calibrator #2 (40 ng/mL), Ref# A68829.	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	Norbuprenorphine DAU Calibrator, Norbuprenorphine Level 2 Control (13 ng/mL), Ref# A68825.	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	Norbuprenorphine DAU Calibrator, Norbuprenorphine Low Calibrator (5 ng/mL), Ref# A68826.	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	Norbuprenorphine DAU Calibrator, Norbuprenorphine, Cutoff Calibrator (10 ng/mL), Ref# A68827.	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	Norbuprenorphine DAU Calibrator, Norbuprenorphine, High Calibrator (100 ng/mL), Ref# A68830.	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	Norbuprenorphine DAU Calibrator, Norbuprenorphine, Intermediate Calibrator #1 (20 ng/mL), Ref# A68828.	Dropper bottle: 5 mL	6/9/2021
Lin-Zhi International	Norbuprenorphine DAU Calibrator, Norbuprenorphine, Level 1 Control (7 ng/mL), Ref# A68824.	Dropper bottle: 5 mL	6/9/2021
Microgenics Corporation	Alinity c Benzodiazepines Qual Calibrator Kit, Catalog Number: 10027281/09P5201.	Kit: 1 vial, 2.9 mL	4/2/2021
Microgenics Corporation	Alinity c Cannabinoids Control 1 Kit, Catalog Number: 10024827/09P5410.	Kit: 2 LDPE, 5 mL each	4/2/2021
Microgenics Corporation	Alinity c Cannabinoids Control 2 Kit, Catalog Number: 10027212/09P5411.	Kit: 1 LDPE, 5 mL	4/2/2021
Microgenics Corporation	Alinity c Cannabinoids Qual Calibrator, Catalog Number: 10024821/09P5401.	Kit: 1 vial, 3.0 mL	4/2/2021
Microgenics Corporation	Alinity c Cannabinoids SemiQuant 100 Calibrator Kit, Catalog Number: 10026530/09P5402.	Kit: 3 vials, 3 mL each	4/2/2021
Microgenics Corporation	Alinity c Cannabinoids SemiQuant 200 Calibrator Kit, Catalog Number: 10026531/09P5403.	Kit: 3 vials, 3 mL each	4/2/2021
Microgenics Corporation	Alinity c Ecstasy Qual Calibrator Kit, Catalog Number: 10024822/09P5801.	Kit: 1 vial, 3.0 mL	4/2/2021
Microgenics Corporation	Alinity c Ecstasy Semiquant Calibrator Kit, Catalog Number: 10026532/09P5802.	Kit: 4 vials, 3.0 mL each	4/2/2021
Microgenics Corporation	Alinity c Opiates Qual Calibrator Kit, Catalog Number: 10024823/09P6501.	Kit: 1 vial, 3.0 mL	4/2/2021
Microgenics Corporation	Alinity c Opiates Semiquant Calibrator Kit, Catalog Number: 10026534/09P6502.	Kit: 4 vials, 3 mL each	4/2/2021
o2si Smart Solutions	Codeine monohydrate as codeine Solution, 2,000 mg/L—Parent Stock Solution—Not For Sale.	Glass cryule: 2 mL	5/28/2021
o2si Smart Solutions	Heroin Solution, 2,000 mg/L—Parent Stock Solution—Not For Sale	Glass cryule: 2 mL	5/28/2021
o2si Smart Solutions	Hydrocodone (+)-bitartrate salt as hydrocodone Solution, 2,000 mg/L—Parent Stock Solution—Not For Sale.	Glass cryule: 2 mL	5/28/2021
o2si smart solutions	ISO 17034—Custom Toxin/Poison Standard Kit, 45–46, 100 mg/L, 1 × 1 ml of Each Level (G34–140319–01, G34–140339–01, G34–140340–01).	Kit: 2 amber ampules, 1 mL each	5/28/2021
o2si smart solutions	ISO 17034 Custom Toxin/Poison Stock Standard Mix, 10–318, 100 mg/L, 1 mL.	Amber ampule: 1 mL	5/28/2021
o2si smart solutions	ISO 17034 Custom Toxin/Poison Stock Standard Mix, 10–319, 100 mg/L, 1 mL.	Amber ampule: 1 mL	5/28/2021
o2si smart solutions	ISO 17034 Custom Toxin/Poison Stock Standard Mix, 34–318, 100 mg/L, 1 mL.	Amber ampule: 1 mL	5/27/2021
o2si Smart Solutions	ISO 17034 Custom Toxin/Poison Stock Standard Mix, 34–318, 100 mg/L, 1 mL.	Amber ampule: 1 mL	4/26/2021
o2si smart solutions	Levorphanol (+)-tartrate salt dehydrate as levorphanol Solution, 2,000 mg/L—Parent Stock Solution—Not For Sale.	Glass cryule: 2 mL	5/28/2021

CHART I—Continued

Supplier	Product name	Form	Application date
o2si Smart Solutions	Oxycodone Solution, 2,000 mg/L—Parent Stock Solution—Not For Sale	Glass cryule: 2 mL	5/28/2021
o2si Smart Solutions	Pentazocine Solution, 2,000 mg/L—Parent Stock Solution	Glass cryule: 2 mL	5/28/2021
Restek Corporation	Custom D-Methamphetamine Standard	Glass Ampule: 1.3 mL	4/15/2021
UTAK Laboratories, Inc	DAU High Cutoff 1 Urine Control	Kit: 4 bottles, 10 mL each	4/16/2021
UTAK Laboratories, Inc	DAU High Cutoff 2 Urine Control	Kit: 4 bottles, 10 mL each	4/16/2021
UTAK Laboratories, Inc	DAU Low Cutoff 1 Urine Control	Kit: 4 bottles, 10 mL each	4/16/2021
UTAK Laboratories, Inc	DAU Low Cutoff 2 Urine Control	Kit: 4 bottles, 10 mL each	4/16/2021
UTAK Laboratories, Inc	Drugs of Abuse Level 1 Whole Blood Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	Fentanyl Analogues 2 NG/ML Whole Blood Control	Kit: 5 bottles, 3 mL each	4/16/2021
UTAK Laboratories, Inc	Fentanyl Analogues 5 NG/ML Urine Control	Kit: 5 bottles, 3 mL each	4/16/2021
UTAK Laboratories, Inc	PM 100 Urine Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	PM 100 Whole Blood Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	PM Plus High Urine Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	PM Plus Low Urine Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	SAMHSA Confirm Level 1 SMX Oral Fluid Control	Kit: 5 bottles, 3 mL each	4/16/2021
UTAK Laboratories, Inc	SAMHSA Confirm Level 2 SMX Oral Fluid Control	Kit: 5 bottles, 3 mL each	4/16/2021

The 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 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
Aalto Scientific, Ltd	Immunoassy Base (Level A–E)	Glass vial, bottle, or flask: 500 mL–1L.	4/1/2021
Aalto Scientific, Ltd	Immunoassy Base (Level A–E)	Glass vial, bottle, or flask: 100mL–500 mL.	4/1/2021
Aalto Scientific, Ltd	Immunoassy Base (Level A–E)	Glass vial, bottle, or flask: 100 mL ..	4/1/2021

Opportunity for Comment

Pursuant to 21 CFR 1308.23(e), 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 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. Thereafter, the Assistant Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

Approved Exempt Chemical Preparations Are Posted on the DEA's Website

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

* * * * *

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2022–01125 Filed 1–20–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Daniel R. Nevarre, M.D.; Decision and Order

On June 7, 2021, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Daniel R. Nevarre, M.D., (hereinafter, Applicant), of South Jordan, Utah. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the denial of Applicant's application No. H21079595C for a DEA Certificate of Registration, because the United States Department of Health and Human Services, Office of Inspector General (hereinafter, HHS/OIG) mandatorily excluded Applicant from participation in Medicare, Medicaid, and all Federal health care programs for a minimum period of 10 years pursuant to 42 U.S.C. 1320a–7(a); and such exclusion ''warrants denial of [Applicant's] application for DEA registration pursuant to 21 U.S.C. 824(a)(5).'' *Id.* at 2. The OSC also alleged that Applicant's application ''contains material false statements'' and thus forms an independent ground for denial. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)).

The OSC alleged that on May 25, 2018, Applicant ''pled guilty to one count of medical assistance fraud in violation of 62 P.S. § 1407(a)(1), and to one count of insurance fraud, in violation of 18 Pa.C.S. § 4117(a)(2).'' *Id.* at 1–2 (citing *Commonwealth of Pa.* v. *Daniel Raymond Nevarre,* No. CP–11–CR–0000717–2018 (Pa. Ct. Comm. Pl. May 25, 2018)). The OSC further alleged that, based on such conviction, HHS/OIG ''mandatorily excluded [Applicant] from participation in Medicare, Medicaid, and all Federal health care programs'' for a minimum period of 10 years pursuant to 42 U.S.C. 1320a–7(a), effective November 20, 2018. *Id.* The OSC therefore proposed denial of Applicant's application based on 21 U.S.C. 824(a)(5).