

Resideo Smart Homes Technology
(Tianjin), Building 21, Jinbin
Development Area, No. 156 Nanhai
Road, Teda, Tianjin 300457, China.

Resideo Technologies, Inc., 901 E. 6th
Street, Austin, TX 78702.

Xylem Inc., 1 International Drive, Rye
Brook, NY 10573.

(4) For the investigation so instituted,
the Chief Administrative Law Judge,
U.S. International Trade Commission,
shall designate the presiding
Administrative Law Judge.

The Office of Unfair Import
Investigations is not a party to this
investigation.

Responses to the amended complaint
and the notice of investigation must be
submitted by the named respondents in
accordance with section 210.13 of the
Commission's Rules of Practice and
Procedure, 19 CFR 210.13. Pursuant to
19 CFR 201.16(e) and 210.13(a), as
amended in 85 FR 15798 (March 19,
2020), such responses will be
considered by the Commission if
received not later than 20 days after the
date of service by the complainant of the
complaint and the notice of
investigation. Extensions of time for
submitting responses to the complaint
and the notice of investigation will not
be granted unless good cause therefor is
shown.

Failure of a respondent to file a timely
response to each allegation in the
complaint and in this notice may be
deemed to constitute a waiver of the
right to appear and contest the
allegations of the amended complaint
and this notice, and to authorize the
administrative law judge and the
Commission, without further notice to
the respondent, to find the facts to be as
alleged in the amended complaint and
this notice and to enter an initial
determination and a final determination
containing such findings, and may
result in the issuance of an exclusion
order or a cease and desist order or both
directed against the respondent.

By order of the Commission.

Issued: August 27, 2021.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2021-18929 Filed 9-1-21; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-688A]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2021

AGENCY: Drug Enforcement
Administration, Department of Justice.

ACTION: Notice with request for
comments.

SUMMARY: The Drug Enforcement
Administration proposes to adjust the
2021 aggregate production quotas for
several controlled substances in
schedules I and II of the Controlled
Substances Act and assessment of
annual needs for the list I chemicals
ephedrine, pseudoephedrine, and
phenylpropanolamine.

DATES: Interested persons may file
written comments on this notice in
accordance with 21 CFR 1303.13(c) and
1315.13(d). Electronic comments must
be submitted, and written comments
must be postmarked, on or before
October 4, 2021. 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.

Based on comments received in
response to this notice, the
Administrator may hold a public
hearing on one or more issues raised. In
the event the Administrator decides in
her sole discretion to hold such a
hearing, the Administrator will publish
a notice of any such hearing in the
Federal Register. After consideration of
any comments or objections, or after a
hearing, if one is held, the
Administrator will publish in the
Federal Register a final order
establishing the 2021 adjusted aggregate
production quotas for schedule I and II
controlled substances, and an adjusted
assessment of annual needs for the list
I chemicals ephedrine,
pseudoephedrine, and
phenylpropanolamine.

ADDRESSES: To ensure proper handling
of comments, please reference "Docket
No. DEA-688A" on all correspondence,
including any attachments. DEA
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 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 electronic
submissions 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, Attention: DEA Federal
Register Representative/DRW, 8701
Morrissette Drive, Springfield, Virginia
22152.

FOR FURTHER INFORMATION CONTACT:
Scott A. Brinks, Regulatory Drafting and
Policy Support Section, Diversion
Control Division, Drug Enforcement
Administration; Mailing Address: 8701
Morrissette Drive, Springfield, Virginia
22152, Telephone: (571) 776-2265.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments
received in response to this docket are
considered part of the public record.
They will, unless reasonable cause is
given, be made available by the Drug
Enforcement Administration (DEA) 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.

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 made publicly
available, 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 made publicly
available 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 made
publicly available, 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 or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying 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 and Background

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of DEA pursuant to 28 CFR 0.100.

DEA established the 2021 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on November 30, 2020 (85 FR 76604). That order stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Adjusted 2021 Aggregate Production Quotas and Assessment of Annual Needs

DEA proposes to adjust the established 2021 aggregate production quotas to be manufactured in the United States in 2021 to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. However, DEA's analysis does not suggest the need for adjustment of the 2021 assessment of annual needs for the List I chemicals.

Factors for Determining the Proposed Adjustments

In determining the proposed adjustments, the Administrator has taken into account the criteria in accordance with 21 CFR 1303.13 (adjustment of aggregate production quotas for controlled substances) and 21 CFR 1315.13 (adjustment of the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The Administrator is authorized to increase or reduce the aggregate production quota at any time. 21 CFR 1303.13(a) and 1315.13(a). DEA regulations state that there are five factors that shall be considered in determining to adjust the aggregate production quota and the assessment of annual needs. 21 CFR 1303.13(b) and 1315.13(b).

DEA determined whether to propose an adjustment of the aggregate production quotas and assessment of annual needs for 2021 by considering the factors summarized below:

(1) Changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, changes in the national rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for that class or chemical, and changes in the extent of any diversion in the class of controlled substance;

(2) whether any increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term;

(3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota or assessment of annual needs, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to Sec. 1303.24(b) and 1315.24(b);

(4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical (including manufacturers, distributors, practitioners, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to Sec. 1303.24(b) and 1315.24(b) or abandoned pursuant to Sec. 1303.27 and 1315.27; and

(5) other factors affecting medical, scientific, research, and industrial needs in the United States, lawful export requirements, and other factors affecting importation needs of listed chemicals in the United States as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes,

yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires. 21 CFR 1303.13(b) and 1315(b).

DEA considered the change in the extent of diversion of all controlled substances in proposing adjustments to the aggregate production quotas as required by 21 CFR 1303.13(b)(1). Pursuant to these factors, DEA has determined that any calculated changes from the previously determined initial calculations are slight and not statistically significant from the quantities originally calculated for the extent of diversion that were applied to the initial aggregate production quota valuations.

DEA also considered updated information obtained from 2020 year-end inventories, 2020 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information.

In evaluating whether there is a need for adjustment of the 2021 assessment of annual needs for List I chemicals, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively). However, DEA's analysis does not suggest the need for adjustment of the 2021 assessment of annual needs.

Considerations Based Upon the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act

Pursuant to 21 U.S.C. 826(a)(1), "production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance." However, the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act of 2018 (SUPPORT Act), (Pub. L. 115–271), provides an exception to that general rule by now giving DEA the authority to establish quotas in terms of pharmaceutical dosage forms if the

agency determines that doing so will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.

DEA has stated before that while there is the authority to set aggregate production quotas in terms of pharmaceutical dosage form, DEA will not be using that authority at this time. Furthermore, when DEA does utilize the authority, it will be doing so at the individual dosage-form manufacturing level, as that is where it is most appropriate to do so. As such, there are no adjustments to set any controlled substances in terms of pharmaceutical dosage forms.

Under the SUPPORT Act, when setting the aggregate production quota, DEA must estimate the amount of diversion of any substance that is considered a “covered controlled substance,” as defined by the SUPPORT Act. 21 U.S.C. 826(i)(1)(A). The covered controlled substances are fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone. The SUPPORT Act also requires DEA to “make appropriate quota reductions, as determined by the [Administrator],¹ from the quota the [Administrator] would have otherwise established had such diversion not been considered.” 21 U.S.C. 826(i)(1)(C). When estimating diversion, the “[Administrator]—(i) shall consider information the [Administrator], in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and (ii) may take into consideration whatever other sources of information the [Administrator] determines reliable.” 21 U.S.C. 826(i)(1)(B).

In February 2021, DEA sent letters to the Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), and the states requesting overdose death and overprescribing data that could be considered for estimating diversion. DEA did not receive information from CMS. However, DEA did receive information from the CDC in June 2021 and has started to receive information from the states. DEA has begun to receive Prescription Drug Monitoring Program (PDMP) data from the states in a format that will allow the Agency to develop a more robust methodology to assist in the determination of the diversion estimate in the future. This

information will be considered in determining the estimates of diversion for the five covered controlled substances in the Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2022.

To update the estimates of diversion, DEA used data from the Drug Theft and Loss Report, Statistical Management Analysis & Reporting Tools System (SMARTS), and System to Retrieve Information on Drug Evidence (STRIDE) databases to aggregate the active pharmaceutical ingredient (API) of each covered controlled substance by metric weight. From the databases, DEA gathered data involving employee theft, break-ins, armed robberies, and material lost in transit. DEA also used seizure data obtained from reports submitted by law enforcement agencies nationwide. This data was categorized by basic drug class and the amount of API in the dosage form was delineated with an appropriate metric for use in proposing the adjusted aggregate production quota values. Using the data, DEA calculated the estimates for the amount of diversion by multiplying the strength of the API listed for each finished dosage form by the total amount of units reported to estimate the metric weight in grams of the controlled substance being diverted. Below, DEA has updated the chart to include estimations of diversion for each of the covered controlled substances.

Diversion estimates for 2020 (g)	
Fentanyl	184
Hydrocodone	20,759
Hydromorphone	946
Oxycodone	47,316
Oxymorphone	534

DEA considered the change in the extent of diversion of all controlled substances in proposing adjustments to the aggregate production quotas as required by 21 CFR 1303.13(b)(1). Pursuant to these factors, DEA has determined that any calculated changes from the previously determined initial calculations are slight and not statistically significant from the quantities originally calculated for the extent of diversion that were applied to the initial aggregate production quota valuations.

Proposed Adjustments for the 2021 Aggregate Production Quotas and Assessment of Annual Needs

DEA is proposing significant increases to the APQs of the schedule I substances

psilocybin, psilocin, marihuana, and marihuana extract, which are directly related to increased interest by DEA registrants in the use of hallucinogenic controlled substances for research and clinical trial purposes. DEA firmly believes in supporting regulated research of schedule I controlled substances. Therefore, the APQ increases reflect the need to fulfill research and development requirements in the production of new drug products, and the study of marijuana effects in particular, as necessary steps toward potential Food and Drug Administration (FDA) approval of new drug products.

The DEA established the 2021 aggregate production quotas for substances in schedules I and II on November 30, 2020 (85 FR 76604). Subsequent to that publication, DEA published in the **Federal Register** two final rules to permanently schedule 14 specific fentanyl-related substances under the CSA (86 FR 22113, April 27, 2021, and 86 FR 23602, May 4, 2021). The specific fentanyl-related substances are 2'-fluoro 2-fluorofentanyl, 4'-Methyl acetyl fentanyl, beta-Methyl fentanyl, beta-Phenyl fentanyl, Fentanyl carbamate, ortho-Fluoroacryl fentanyl, ortho-Fluorobutyryl fentanyl, ortho-Fluoroisobutyryl fentanyl, ortho-Methyl acetylfentanyl, ortho-Methyl methoxyacetyl fentanyl, para-Fluoro furanyl fentanyl, para-Methylfentanyl, Phenyl fentanyl, and Thiofuranyl fentanyl. As a result, these substances will continue to be subject to the CSA schedule I controls and are now being assigned individual aggregate production quotas.

On March 1, 2021, DEA published a temporary scheduling order placing Brorphine in schedule I of the CSA (86 FR 11862), making all regulatory controls pertaining to schedule I controlled substances applicable to the manufacture of these substances, including the requirement to establish an aggregate production quota pursuant to 21 U.S.C. 826 and 21 CFR part 1303. This notice proposes to establish an aggregate production quota for this substance.

On May 7, 2021, DEA published an interim final rule placing serdexmethylphenidate, a component in a combination drug product recently approved by FDA for the treatment of ADHD in patients six years of age and older, in schedule IV of the CSA (86 FR 24487). Seroxmethylphenidate is manufactured from methylphenidate, a schedule II controlled substance. In order to more accurately estimate and manage the quantity of methylphenidate necessary for direct formulation into schedule II drug products versus the

¹ All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b).

quantity of methylphenidate necessary for the manufacturing of serdexmethylphenidate or other substances, DEA has delineated methylphenidate into methylphenidate (for sale) and methylphenidate (for conversion). This notice proposes to establish an aggregate production quota for methylphenidate (for conversion).

On June 20, 2021, DEA published the final rule to place oliceridine, a medication recently approved by FDA for medical use as an intravenous drug

for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate, in schedule II of the CSA effective July 12, 2021 (86 FR 30772). The placement of oliceridine in schedule II of the CSA, makes all regulatory controls pertaining to schedule II controlled substances applicable to the manufacture of this substance, including the requirement to establish an aggregate production quota

pursuant to 21 U.S.C. 826 and 21 CFR part 1303.

The Administrator, therefore, proposes to adjust the 2021 aggregate production quotas for certain schedule I and II controlled substances. The Administrator does not propose an adjustment to the assessments of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The proposed adjusted APQs, as expressed in grams of anhydrous acid or base, are as follows:

Basic class	Established 2021 quotas	Proposed revised 2021 quotas
	(g)	(g)
Temporarily Scheduled		
Brorphine	N/A	30.
Schedule I		
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20	no change.
1-(1-Phenylcyclohexyl)pyrrolidine	15	30.
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10	no change.
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30	no change.
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30	no change.
1-Benzylpiperazine	25	no change.
1-Methyl-4-phenyl-4-propionoxypiperidine	10	no change.
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change.
2'-fluoro 2-fluorofentanyl	N/A	30.
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	no change.
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30	no change.
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30	no change.
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30	no change.
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	100	no change.
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	30	no change.
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	no change.
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82) ...	25	no change.
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	no change.
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30	no change.
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change.
2,5-Dimethoxy-4-n-propylthiophenethylamine	25	no change.
2,5-Dimethoxyamphetamine (DMA)	25	no change.
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30	no change.
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30	no change.
3,4,5-Trimethoxyamphetamine	30	no change.
3,4-Methylenedioxyamphetamine (MDA)	55	no change.
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change.
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change.
3,4-Methylenedioxy-N-methylcathinone (methylone)	40	no change.
3,4-Methylenedioxypropylvalerone (MDPV)	35	no change.
3-FMC; 3-Fluoro-N-methylcathinone	25	no change.
3-Methylfentanyl	30	no change.
3-Methylthiofentanyl	30	no change.
4'-Methyl acetyl fentanyl	N/A	30.
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30	no change.
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	no change.
4-Chloro- α -pyrrolidinoveraloperone (4-chloro- α -PVP)	25	no change.
4CN-Cumyl-Butanica, 1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboximide	25	no change.
4-Fluoroisobutyryl fentanyl	30	no change.
4-FMC; Flephedrone	25	no change.
4-MEC; 4-Methyl-N-ethylcathinone	25	no change.
4-Methoxyamphetamine	150	no change.
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change.
4-Methylaminorex	25	no change.
4-Methyl-N-methylcathinone (mephedrone)	45	no change.
4-Methyl- α -ethylaminopentiophenone (4-MEAP)	25	no change.
4-Methyl- α -pyrrolidinohexiophenone (MPHP)	25	no change.
4-Methyl- α -pyrrolidinopropiophenone (4-MePPP)	25	no change.

Basic class	Established 2021 quotas	Proposed revised 2021 quotas
	(g)	(g)
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50	no change.
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40	no change.
5F-CUMYL-PINACA	25	no change.
5F-EDMB-PINACA	25	no change.
5F-MDMB-PICA	25	no change.
5F-AB-PINACA; N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25	no change.
5F-CUMYL-P7AICA; (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboximide)	25	no change.
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change.
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	30	no change.
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	30	no change.
5-Fluoro-PB-22; 5F-PB-22	20	no change.
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25	no change.
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change.
5-Methoxy-N,N-diisopropyltryptamine	25	no change.
5-Methoxy-N,N-dimethyltryptamine	35	no change.
AB-CHMINACA	30	no change.
AB-FUBINACA	50	no change.
AB-PINACA	30	no change.
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30	no change.
Acetorphine	25	no change.
Acetyl Fentanyl	100	no change.
Acetyl- <i>alpha</i> -methylfentanyl	30	no change.
Acetyldihydrocodeine	30	no change.
Acetylmethadol	25	no change.
Acryl Fentanyl	25	no change.
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50	no change.
AH-7921	30	no change.
All other tetrahydrocannabinol	1,000	no change.
Allylprodine	25	no change.
Alphacetylmethadol	25	no change.
<i>alpha</i> -Ethyltryptamine	25	no change.
Alphameprodine	25	no change.
Alphamethadol	25	no change.
Alphaprodine	25	no change.
<i>alpha</i> -Methylfentanyl	30	no change.
<i>alpha</i> -Methylthiofentanyl	30	no change.
<i>alpha</i> -Methyltryptamine (AMT)	25	no change.
<i>alpha</i> -Pyrrolidinobutiophenone (α -PBP)	25	no change.
<i>alpha</i> -Pyrrolidinoheptaphenone (PV8)	25	no change.
<i>alpha</i> -Pyrrolidinohexanophenone (α -PHP)	25	no change.
<i>alpha</i> -Pyrrolidinopentiophenone (α -PVP)	25	no change.
Aminorex	25	no change.
Anileridine	20	no change.
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25	no change.
Benzethidine	25	no change.
Benzylmorphine	30	no change.
Betacetylmethadol	25	no change.
<i>beta</i> -Hydroxy-3-methylfentanyl	30	no change.
<i>beta</i> -Hydroxyfentanyl	30	no change.
<i>beta</i> -Hydroxythiofentanyl	30	no change.
<i>beta</i> -Methyl fentanyl	N/A	30.
<i>beta</i> -Phenyl fentanyl	N/A	30.
Betameprodine	25	no change.
Betamethadol	4	no change.
Betaprodine	25	no change.
Bufotenine	15	no change.
Butylone	25	no change.
Butyryl fentanyl	30	no change.
Cathinone	40	no change.
Clonitazene	25	no change.
Codeine methylbromide	30	no change.
Codeine-N-oxide	192	no change.
Cyclopentyl Fentanyl	30	no change.
Cyclopropyl Fentanyl	20	no change.
Cyprenorphine	25	no change.
d-9-THC	384,460	no change.
Desomorphine	25	no change.
Dextromoramide	25	no change.
Diapromide	20	no change.
Diethylthiambutene	20	no change.

Basic class	Established 2021 quotas	Proposed revised 2021 quotas
	(g)	(g)
Diethyltryptamine	25	no change.
Difenoxin	9,200	no change.
Dihydromorphine	753,500	no change.
Dimenoxadol	25	no change.
Dimpheptanol	25	no change.
Dimethylthiambutene	20	no change.
Dimethyltryptamine	50	no change.
Dioxyaphetyl butyrate	25	no change.
Dipipanone	25	no change.
Drotebanol	25	no change.
Ethylmethylthiambutene	25	no change.
Etorphine	30	no change.
Etoxidine	25	no change.
Fenethylamine	30	no change.
Fentanyl carbamate	N/A	30.
Fentanyl related substances	600	no change.
FUB-144	25	no change.
FUB-AKB48	25	no change.
FUB-AMB, MMB-Fubinaca, AMB-Fubinaca	25	no change.
Furanyl fentanyl	30	no change.
Furethidine	25	no change.
<i>gamma</i> -Hydroxybutyric acid	29,417,000	no change.
Heroin	45	no change.
Hydromorphanol	40	no change.
Hydroxypethidine	25	no change.
Ibogaine	30	no change.
Isobutyryl Fentanyl	25	no change.
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35	no change.
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45	no change.
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45	no change.
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30	no change.
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30	no change.
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35	no change.
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30	no change.
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30	no change.
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30	no change.
Ketobemidone	30	no change.
Levomoramide	25	no change.
Levophenacetylmorphan	25	no change.
Lysergic acid diethylamide (LSD)	40	no change.
MAB-CHMINACA; ADB-CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1 <i>H</i> -indazole-3-carboxamide)	30	no change.
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change.
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change.
MMB-CHMICA-(AMB-CHMICA); Methyl-2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3-methylbutanoate	25	no change.
Marihuana	1,500,000	2,000,000.
Marihuana extract	200,000	500,000.
Mecloqualone	30	no change.
Mescaline	25	no change.
Methaqualone	60	no change.
Methcathinone	25	no change.
Methoxyacetyl fentanyl	30	no change.
Methyl-desorphan	5	no change.
Methyldihydromorphine	25	no change.
Morpheridine	25	no change.
Morphine methylbromide	5	no change.
Morphine methylsulfonate	5	no change.
Morphine-N-oxide	150	no change.
MT-45	30	no change.
Myrophine	25	no change.
NM2201; Naphthalen-1-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate	25	no change.
<i>N,N</i> -Dimethylamphetamine	25	no change.
Naphyrone	25	no change.
<i>N</i> -Ethyl-1-phenylcyclohexylamine	25	no change.
<i>N</i> -Ethyl-3-piperidyl benzilate	10	no change.
<i>N</i> -Ethylamphetamine	24	no change.
<i>N</i> -Ethylhexedrone	25	no change.
<i>N</i> -Ethylpentylone, ephylone	30	no change.
<i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine	24	no change.

Basic class	Established 2021 quotas	Proposed revised 2021 quotas
	(g)	(g)
N-Methyl-3-Piperidyl Benzilate	30	no change.
Nicocodeine	25	no change.
Nicomorphine	25	no change.
Noracymethadol	25	no change.
Norlevorphanol	2,550	no change.
Normethadone	25	no change.
Normorphine	40	no change.
Norpipanone	25	no change.
Ocfentanil	25	no change.
Ortho-fluorofentanyl, 2-fluorofentanyl	30	no change.
ortho-Fluoroacryl fentanyl	N/A	30.
ortho-Fluorobutyryl fentanyl	N/A	30.
ortho-Fluoroisobutyryl fentanyl	N/A	30.
ortho-Methyl acetylfentanyl	N/A	30.
ortho-Methyl methoxyacetyl fentanyl	N/A	30.
Para-chloroisobutyryl fentanyl	30	no change.
Para-fluorofentanyl	25	no change.
Para-fluorobutyryl fentanyl	25	no change.
para-Fluoro furanyl fentanyl	N/A	30.
para-Methylfentanyl	N/A	30.
Para-methoxybutyryl fentanyl	30	no change.
Parahexyl	5	no change.
PB-22; QUPIC	20	no change.
Pentdrone	25	no change.
Pentylone	25	no change.
Phenadoxone	25	no change.
Phenampromide	25	no change.
Phenomorphan	25	no change.
Phenoperidine	25	no change.
Phenyl fentanyl	N/A	30.
Pholcodine	5	no change.
Piritramide	25	no change.
Proheptazine	25	no change.
Properidine	25	no change.
Propiram	25	no change.
Psilocybin	30	1,500.
Psilocyn	50	1,000.
Racemoramide	25	no change.
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45	no change.
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30	no change.
Tetrahydrofuranlyl fentanyl	15	no change.
Thebacon	25	no change.
Thiafentanil	25	no change.
Thiofentanyl	25	no change.
Thiofuranlyl fentanyl	N/A	30.
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30	no change.
Tilidine	25	no change.
Trimeperidine	25	no change.
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25	no change.
U-47700	30	no change.
Valeryl fentanyl	25	no change.

Schedule II

1-Phenylcyclohexylamine	15	no change.
1-Piperidinocyclohexanecarbonitrile	25	no change.
4-Anilino-N-phenethyl-4-piperidine (ANPP)	937,758	no change.
Alfentanil	3,260	no change.
Alphaprodine	25	no change.
Amobarbital	20,100	no change.
Bezitramide	25	no change.
Carfentanil	20	no change.
Cocaine	68,576	no change.
Codeine (for conversion)	1,612,500	no change.
Codeine (for sale)	27,616,684	no change.
D-amphetamine (for sale)	21,200,000	no change.
D,l-amphetamine	21,200,000	no change.
D-amphetamine (for conversion)	14,137,578	16,068,789.
Dextropropoxyphene	35	no change.
Dihydrocodeine	156,713	no change.

Basic class	Established 2021 quotas	Proposed revised 2021 quotas
	(g)	(g)
Dihydroetorphine	25	no change.
Diphenoxylate (for conversion)	14,100	no change.
Diphenoxylate (for sale)	770,800	no change.
Ecgonine	68,576	no change.
Ethylmorphine	30	no change.
Etorphine hydrochloride	32	no change.
Fentanyl	731,452	no change.
Glutethimide	25	no change.
Hydrocodone (for conversion)	1,250	no change.
Hydrocodone (for sale)	30,821,224	no change.
Hydromorphone	2,827,940	2,743,101.
Isomethadone	30	no change.
L-amphetamine	30	no change.
Levo-alphaacetylmetadol (LAAM)	25	no change.
Levomethorphan	30	no change.
Levorphanol	26,495	no change.
Lisdexamfetamine	21,000,000	no change.
L-methamphetamine	587,229	no change.
Meperidine	856,695	no change.
Meperidine Intermediate-A	30	no change.
Meperidine Intermediate-B	30	no change.
Meperidine Intermediate-C	30	no change.
Metazocine	15	no change.
Methadone (for sale)	25,619,700	no change.
Methadone Intermediate	27,673,600	no change.
Methamphetamine	50	no change.
D-methamphetamine (for conversion)	485,020	no change.
D-methamphetamine (for sale)	40,000	no change.
Methylphenidate (for conversion)	0	15,300,000.
Methylphenidate (for sale)	57,438,334	no change.
Metopon	25	no change.
Moramide-intermediate	25	no change.
Morphine (for conversion)	3,376,696	no change.
Morphine (for sale)	27,784,062	26,505,995.
Nabilone	62,000	no change.
Norfentanyl	25	no change.
Noroxymorphone (for conversion)	22,044,741	no change.
Noroxymorphone (for sale)	376,000	no change.
Oliceridine	N/A	22,500.
Opium (powder)	250,000	no change.
Opium (tincture)	530,837	no change.
Oripavine	33,010,750	no change.
Oxycodone (for conversion)	620,887	no change.
Oxycodone (for sale)	57,110,032	no change.
Oxymorphone (for conversion)	28,204,371	no change.
Oxymorphone (for sale)	563,174	no change.
Pentobarbital	25,850,000	30,766,670.
Phenazocine	25	no change.
Phencyclidine	35	no change.
Phenmetrazine	25	no change.
Phenylacetone	40	no change.
Piminodine	25	no change.
Racemethorphan	5	no change.
Racemorphan	5	no change.
Remifentanyl	3,000	no change.
Secobarbital	172,100	no change.
Sufentanyl	4,000	no change.
Tapentadol	13,447,541	no change.
Thebaine	57,137,944	no change.
List I Chemicals		
Ephedrine (for conversion)	100	no change.
Ephedrine (for sale)	4,136,000	no change.
Phenylpropanolamine (for conversion)	14,878,320	no change.
Phenylpropanolamine (for sale)	16,690,000	no change.
Pseudoephedrine (for conversion)	1,000	no change.
Pseudoephedrine (for sale)	174,246,000	no change.

The Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2021 aggregate production quotas and assessment of annual needs as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will issue and publish in the **Federal Register** a final order establishing any adjustment of 2021 aggregate production quota for each basic class of controlled substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.13(c) and 1315.13(f).

Anne Milgram,

Administrator.

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DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

Rescission of Notice of Intention Not To Request, Accept or Use Employer Information Report (EEO-1) Component 2 Data, November 25, 2019

AGENCY: Office of Federal Contract Compliance Programs, Labor.

ACTION: Notice.

SUMMARY: The U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) and the Equal Employment Opportunity Commission (EEOC) collect workforce data through the Employer Information Report (EEO-1) under their Joint Reporting Committee. OFCCP is rescinding its previously issued notice, which stated that OFCCP did not intend to request, accept, or use EEO-1 Component 2 data. The agency has determined that it was premature to issue a notice stating OFCCP did not expect to find significant utility in the data.

DATES: This action is effective immediately.

FOR FURTHER INFORMATION CONTACT: Tina T. Williams, Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs, 200 Constitution Avenue NW, Room C-

3325, Washington, DC 20210. Telephone: (202) 693-0103 (voice) or (202) 693-1337 (TTY).

SUPPLEMENTARY INFORMATION:

Background

OFCCP administers and enforces Executive Order 11246, as amended (E.O. 11246), which applies to Federal contractors and subcontractors. E.O. 11246 prohibits employment discrimination and requires affirmative action to ensure equal employment opportunity regardless of race, color, religion, sex, sexual orientation, gender identity, or national origin. It also prohibits Federal contractors and subcontractors from discriminating against applicants and employees for inquiring about, discussing, or disclosing information about their pay or the pay of their co-workers, subject to certain limitations.

OFCCP and the EEOC have separate legal authority to collect EEO-1 data, and they coordinate collection to promote efficiency through their Joint Reporting Committee. The EEOC's legal authority to collect EEO-1 data from private employers derives from Title VII of the Civil Rights Act, and OFCCP's authority to collect data from certain Federal contractors derives from E.O. 11246 and its implementing regulations.¹ The EEO-1 data collection is a mandatory annual data collection that requires all private sector employers that are covered by Title VII and have 100 or more employees, and Federal contractors with 50 or more employees meeting certain criteria, to submit demographic workforce data, including data by sex, race, ethnicity, and job categories (Component 1) (Office of Management and Budget (OMB) Control No. 3046-0049). The EEO-1 Component 1 data has been shared between the two agencies for decades to avoid duplicative information collections and to minimize the burden on employers.

OFCCP had previously expressed interest in collecting summary compensation data for the purpose of informing its compliance and enforcement efforts. On August 8, 2014, OFCCP published a notice of proposed rulemaking in the **Federal Register** to amend the regulations that implement E.O. 11246 by adding a requirement that certain Federal contractors and subcontractors supplement their EEO-1 Report with summary information on compensation paid to employees, as contained in the Form W-2, Wage and Tax Statement, by sex, race, ethnicity,

¹ See 42 U.S.C. 2000e-8(c); 29 CFR 1602.7; 41 CFR 60-1.7.

and specified job categories, as well as other relevant data points such as hours worked and the number of employees.² The purpose of the proposed collection was to enable OFCCP to more effectively focus its enforcement resources to better identify potential pay inequities for further evaluations. Public comments submitted to OFCCP on the proposal argued for, among other things, improving interagency coordination and decreasing employer burden for reporting compensation data by using the EEO-1 data collection, rather than conducting a new OFCCP data collection. Ultimately, OFCCP determined that it would collaborate with the EEOC to collect compensation data as part of the EEO-1 filing rather than proceed with publishing a final rule.

On July 14, 2016, the EEOC published a 30-day notice in the **Federal Register** to obtain a three-year approval from OMB for the continued collection of Component 1 demographic data, as well as a new collection of summary compensation data, referred to as "Component 2" EEO-1 data.³ The notice stated that, although the EEOC is responsible for compliance with the Paperwork Reduction Act of 1995, the EEO-1 report is a joint data collection to meet the enforcement needs of both the EEOC and OFCCP while avoiding duplication. The Component 2 collection included aggregated data on employee pay and hours worked. On September 29, 2016, OMB approved the EEO-1 Components 1 and 2 information collection for calendar years 2017 and 2018.

On August 29, 2017, OMB stayed the EEOC's collection of Component 2 data, and the EEOC proceeded to collect only Component 1 data. Subsequently, the EEOC issued a **Federal Register** notice on September 15, 2017, suspending the Component 2 data collection.⁴ In response to a lawsuit challenging OMB and the EEOC's actions, on March 4, 2019, the United States District Court for the District of Columbia vacated OMB's stay of the Component 2 data collection and ordered that the previous approval of the EEO-1 Component 2 collection was in effect.⁵ The court further ordered the EEOC to collect the Component 2 data for calendar years 2017 and 2018 by September 30, 2019. On May 3, 2019, the EEOC published a **Federal Register** notice announcing the

² See 79 FR 46561 (Aug. 8, 2014).

³ See 81 FR 45479 (July 14, 2016).

⁴ See 82 FR 43362 (Sept. 15, 2017).

⁵ *National Women's Law Center, et al. v. Office of Management and Budget, et al.*, 358 F. Supp. 3d 66 (D.D.C. 2019).