DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1228F]

Final Adjusted 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 2024

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2024 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective December 17, 2024.

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SUPPLEMENTARY INFORMATION:

Legal Authority

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

Background

DEA published the 2024 established aggregate production quotas (APQs) for controlled substances in schedules I and II and for the assessment of annual needs (AAN) for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the **Federal Register** (FR) on January 3, 2024.[1] This notice stated that the Administrator would adjust, as needed, the established APQ in 2024 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. DEA is committed to preventing and limiting diversion by enforcing laws and regulations regarding controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, while meeting the legitimate medical, scientific, and export needs of the United States.

The 2024 proposed adjusted APQ for controlled substances in schedules I and II and AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the **Federal Register** on September 25, 2024 [2] after consideration of the criteria outlined in that notice. All interested persons were invited to comment on or object to the proposed APQs and AANs on or before October 25, 2024. Prior to this notice, DEA also published a final order to increase the 2024 APQ for lisdexamfetamine and d-amphetamine (for conversion).[3] Therefore, DEA proposed no additional changes for those substances.

Comments Received

DEA received 20 timely comments in response to the September **Federal Register** notice, from chronic pain patients and DEA-registered entities. The comments included requests to ensure sufficient availability in the APQ for select schedule I and schedule II controlled substances including increasing specific APQs if necessary; requests that DEA utilize its regulatory authority in additional ways; opioid shortage concerns; and comments outside the scope of this final order. DEA restricted three comments from public view due to confidential business information and/or confidential personal identifying information.

DEA's Regulatory Authority

Issue: DEA-registered manufacturers requested the APQs for 4-Anilino-N-Phenethyl-4-Piperidine, fentanyl, hydromorphone, morphine (for conversion), oxymorphone (for conversion), and sufentanil be reviewed for sufficiency and adjusted if necessary.

DEA Response: DEA sets the APQs in a manner to meet the estimated medical, scientific, research, industrial needs of the United States, lawful export requirements, and for the establishment and maintenance of reserve stocks. As of the date the comment period closed for the proposed adjusted 2024 APQ and AAN, DEA believes that the proposed adjusted 2024 APQs are sufficient to meet the current estimated 2024 legitimate medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and to provide for adequate reserve stock.

Issue: A DEA-registered manufacturer suggested several changes that it believes are necessary to deter companies from using the quota process to gain competitive advantage and to ensure that quota is available when supply chain circumstances change. Among these, the commenter suggested that DEA needs to obtain authority to reallocate manufacturing quota from one registered bulk manufacturer to another in the event that a finished dosage form manufacturer wishes, midyear, to procure bulk material from a different bulk manufacturer than originally planned.

DEA Response: This comment is outside the scope of the current action, but DEA notes the commenter's suggestion for future consideration. DEA currently can reallocate or revoke quotas in specific circumstances as discussed in 21 CFR 1303.26 and 1303.36.

Issue: The same commenter who raised the immediately preceding issue also suggested that DEA should change the procurement quota application form (DEA Form 250) so that applicants can specify multiple suppliers from which they may procure a basic class of bulk controlled substance, as well as the estimated timeframe for receipt of the basic class from each supplier.

DEA Response: The current procurement quota application form (DEA Form 250) allows for the applicants to specify multiple suppliers from which they may procure a basic class of bulk controlled substance, as well as the estimated timeframe for receipt of the basic class from each supplier.

Issue: The same commenter who raised the two immediately preceding issues suggested that DEA specify, when granting quota, to which specific finished dosage forms the quota is to be applied and the proportion of the authorized amount that is to be used toward each identified dosage form. The manufacturer further requested that DEA verify during DEA inspections the manufacturer's compliance with the details specified in the quota grant.

DEA Response: In 21 U.S.C. 826(a)(2), Congress granted DEA the authority to delineate quota by pharmaceutical dosage form (tablets, capsules, oral

[1] Established 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 2024, 89 FR 407.

[2] 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 2024, 89 FR 78764 (September 25, 2024).

[3] Adjustment to the Aggregate Production Quota for Lisdexamfetamine and d-Amphetamine (for Conversion) for 2024, 89 FR 72424 (Sept. 5, 2024).

liquids, etc.) if DEA determines it will assist in avoiding overproduction, shortages, or diversion of a controlled substance. DEA currently believes the designation of quota by dosage forms at the bulk manufacturing level could lead to unforeseen circumstances such as interference with production schedules or hindrance of the supply chain. Moreover, in compliance with Congress's directive, DEA would need to consider whether the application of such detail to quotas would assist in avoiding overproduction, shortages, or diversion.

When a manufacturer has several customers that use the same active pharmaceutical ingredient (API) to manufacture similar dosage forms (*i.e.* brand and generic formulations), the terms of the contractual agreements govern the transaction in normal circumstances. DEA does not grant quota to fulfill specific business contracts between registrants; rather, DEA grants quota to meet the legitimate medical, scientific, research, and export requirements while ensuring the ability to maintain adequate reserve stock.

Issue: The same commenter who raised the three immediately preceding issues suggested that DEA assess ''quota usage'' on a quarterly or semi-annual basis to verify that manufacturers timely distribute materials that they are authorized under quota to manufacture, and to require companies to surrender unused quotas so that those unused amounts can be reassigned to others who can then supply the market.

DEA Response: DEA has in the past and will continue to ask manufacturers to surrender quota that they will not be able to utilize in a timely manner (*e.g.,* due to production scheduling issues, malfunctioning of manufacturing lines, etc.). While DEA will note for potential future consideration the commenter's suggestion that DEA periodically assess quota usage, in a series of meetings held in the spring of 2024, numerous API and dosage form manufacturers informed DEA that a requirement to utilize quota quarterly would not be feasible because of limited capacity of production lines and manufacturers' strict adherence to production schedules. As a result of the discussion, DEA is allotting commercial manufacturing procurement quotas for Schedule II non-injectable products on a semi-annual basis.

Opioid Shortage Concerns

Issue: Nine commenters expressed general concerns regarding a perceived nationwide shortage of opioid medication due to patients experiencing intermittent out-of-stock or back-ordered situations at pharmacies while attempting to fill their prescriptions.

DEA Response: DEA utilizes the available, reliable data and information received by the agency in advance of publication; however drug shortages may occur due to factors outside of DEA's control such as manufacturing and quality problems, processing delays, supply chain disruptions, or discontinuations. In such circumstances, if the drug manufacturer notifies the U.S. Food and Drug Administration (FDA) Drug Shortage Staff, FDA will coordinate with DEA to address and minimize the impact of drug shortages if both agencies believe action is warranted. Currently, FDA has not issued notice of any nationwide shortages of the type of opioid medications mentioned by these commenters.

Out of Scope Comments: DEA received other comments that were general in nature and raised issues with respect to specific medical illnesses and medical treatments. All of the issues raised are outside of the scope of this final order for 2024 and do not impact the analysis involved in finalizing the 2024 APQs.

Analysis for Final Adjusted 2024 Aggregate Production Quotas and Assessment of Annual Needs

In determining the final adjusted 2024 APQs and AANs, DEA has considered the above comments relevant to this final order for calendar year 2024, along with the factors set forth in 21 CFR 1303.13 and 21 CFR 1315.13, in accordance with 21 U.S.C. 826(a). DEA has also considered other relevant factors, including the 2023 year-end inventories, initial 2024 manufacturing and import quotas, 2024 export requirements, actual and projected 2024 sales, research and product development requirements, additional applications received, and the extent of any diversion of the controlled substance in the class. Based on all of the above, the Administrator is finalizing the adjusted APQs in the same amounts as proposed.

On July 29, 2024, DEA published a temporary scheduling order placing N-desethyl isotonitazene and N-piperidinyl etonitazene in schedule I of the CSA,[4] and on October 25, 2024, DEA published a final rule placing ethylphenidate in schedule I of the CSA,[5] making all regulatory controls pertaining to schedule I controlled substances applicable to the manufacture of these substances, including the requirement to establish an APQ pursuant to 21 U.S.C. 826 and 21 CFR part 1303. This final order establishes an APQ for these substances for the first time.

Pursuant to the above, the Administrator hereby finalizes the 2024 APQs for the following schedule I and II controlled substances and the 2024 AANs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

BILLING CODE 4410–P

[4] Schedules of Controlled Substances: Temporary Placement of N-Desethyl Isotonitazene and N-Piperidinyl Etonitazene in Schedule I, 89 FR 60817.

[5] Schedules of Controlled Substances: Placement of Ethylphenidate in Schedule I, 89 FR 84281.

Basic Class	Final Adjusted 2024 Quotas (g)
Schedule I	
-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	30
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2'-fluoro 2-fluorofentanyl	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	100
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	30
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
2-Methyl AP-237	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	12,000
3,4-Methylenedioxymethamphetamine (MDMA)	12,000
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	5,200
3,4-Methylenedioxypyrovalerone (MDPV)	35

3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylmethcathinone	30
3-Methylthiofentanyl	30
4,4′-Dimethylaminorex	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	5,100
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
4-CN-Cumyl-Butinaca	25
4-Fluoroisobutyryl fentanyl	30
4F-MDMB-BINACA	30
4F-MDMB-BUTICA	30
4-FMC; Flephedrone	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (alpha-PiHP)	30
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-alpha-ethylaminopentiophenone (4-MEAP)	25
4-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4′-Methyl acetyl fentanyl	30
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40
5F-AB-PINACA ; (1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	25
5F-CUMYL-P7AICA; 1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3carboximide	25
5F-CUMYL-PINACA	25
5F-EDMB-PICA	30
5F-EDMB-PINACA	25
5F-MDMB-PICA	25
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	25
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	25
5-Fluoro-PB-22; 5F-PB-22	25

5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	11,000
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-4en-PINACA	30
ADB-BUTINACA	30
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH-7921	30
All other tetrahydrocannabinol	1,166,130
Allylprodine	25
Alphacetylmethadol	25
alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-pyrrolidinoheptaphenone (PV8)	25
alpha-pyrrolidinohexabophenone (alpha-PHP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Amineptine	30
Aminorex	25
Anileridine	20
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	25
beta-Hydroxy-3-methylfentanyl	30
beta-Hydroxyfentanyl	30

beta-Hydroxythiofentanyl	30
beta-Methyl fentanyl	30
beta′-Phenyl fentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Brorphine	30
Bufotenine	15
Butonitazene	30
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonazolam	30
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl Fentanyl	25
CUMYL–PEGACLONE	30
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
d-9-THC	1,523,040
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diclazepam	30
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,300
Dihydromorphine	639,954
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	11,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Ethylphenidate	30
Etizolam	30
Etodesnitazene	30
Etonitazene	25
Etorphine	30
Etoxeridine	25

Eutylone	30
Fenethylline	30
Fentanyl carbamate	30
Fentanyl related substances	600
Flualprazolam	30
Flubromazolam	30
Flunitazene	30
FUB-144	25
FUB-AKB48	25
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	29,417,000
Heroin	150
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	150
Isobutyryl Fentanyl	25
Isotonitazine	25
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Ketobemidone	30
Levomoramide	25
Levophenyacylmorphan	25
Lysergic acid diethylamide (LSD)	1,200
MAB-CHMINACA; ADB-CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30
MDMB-4en-PINACA	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB-CHMICA-(AMB-CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-	25

methylbutanoate	
MMB-FUBICA	30
Marijuana	6,675,000
Marijuana extract	1,000,000
Mecloqualone	30
Mescaline	1,200
Mesocarb	30
Methaqualone	60
Methcathinone	25
Methiopropamine	30
Methoxetamine	30
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Metodesnitazene	30
Metonitazene	30
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT-45	30
Myrophine	25
NM2201: Naphthalen-1-yl 1-(5-fluorpentyl)-1H-indole-3-carboxylate	25
N,N-Dimethylamphetamine	25
Naphyronc	25
N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Nicocodeine	25
Nicomorphine	25
N-Desethyl Isotonitazene	30
N-methyl-3-piperidyl benzilate	30
N-Piperidinyl Etonitazene	30
N-Pyrrolidino Etonitazene	30
Noracymcthadol	25
Norlevorphanol	2,550
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
ortho-Fluoroacryl fentanyl	30

ortho-Fluorobutyryl fentanyl	30
ortho-Fluorofentanyl,2-Fluorofentanyl	30
ortho-Fluoroisobutyryl fentanyl	30
ortho-Methyl acetylfentanyl	30
ortho-Methyl methoxyacetyl fentanyl	30
Para-Chlorisobutyrl fentanyl	30
Para-flourobutyryl fentanyl	25
Para-fluorofentanyl	25
para-Fluoro furanyl fentanyl	30
Para-Methoxybutyrl fentanyl	30
Para-methoxymethamphetamine	30
para-Methylfentanyl	30
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphan	25
Phenoperidine	25
Phenyl fentanyl	30
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Protonitazene	30
Psilocybin	30,000
Psilocyn	36,000
Racemoramide	25
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrofuranyl fentanyl	15
Thebacon	25
Thiafentanil	25
Thiofentanyl	25
Thiofuranyl fentanyl	30
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	25
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
U-47700	30

Valeryl fentanyl	25
Zipeprol	30
Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	937,874
Alfentanil	5,000
Alphaprodine	25
Amobarbital	20,100
Bezitramide	25
Carfentanil	20
Cocaine	60,492
Codeine (for conversion)	942,452
Codeine (for sale)	19,262,957
d-amphetamine (for sale)	21,200,000
d,l-amphetamine	21,200,000
d-amphetamine (for conversion)	23,688,235
Dexmethylphenidate (for sale)	6,200,000
Dexmethylphenidate (for conversion)	5,374,683
Dextropropoxyphene	35
Dihydrocodeine	115,227
Dihydroctorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	60,492
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	731,341
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	27,121,498
Hydromorphone	1,951,508
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	20,000
Lisdexamfetamine	32,736,000
Meperidine	681,184
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	25,619,700

Methadone Intermediate	27,673,600
d,l-Methamphetamine	150
d-methamphetamine (for conversion)	485,020
d-methamphetamine (for sale)	47,000
l-methamphetamine	587,229
Methylphenidate (for sale)	53,283,000
Methylphenidate (for conversion)	19,975,468
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,393,200
Morphine (for sale)	20,805,957
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	24,756,979
Noroxymorphone (for sale)	1,000
Oliceridine	25,100
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	37,721,950
Oxycodone (for conversion)	437,827
Oxycodone (for sale)	53,584,449
Oxymorphone (for conversion)	31,773,105
Oxymorphone (for sale)	464,464
Pentobarbital	40,000,000
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	100
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	10,390,226
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	41,100
Ephedrine (for sale)	3,933,336
Phenylpropanolamine (for conversion)	14,878,320
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	186,617,466

BILLING CODE 4410–C

The Administrator also establishes that APQs for all other schedule I and II controlled substances included in 21

CFR 1308.11 and 1308.12 remain at zero.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 13, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–30019 Filed 12–16–24; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1413E]

Established 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 2025

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2025 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective December 17, 2024.

FOR FURTHER INFORMATION CONTACT: Heather E. Achbach, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

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

II. Background

The 2025 aggregate production quotas (APQ) and assessment of annual needs (AAN) represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2025, in order to provide for the estimated medical, scientific, research, and industrial needs of the U.S., lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

On September 25, 2024, a notice titled ''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 2025'' was published in the **Federal Register**.[1] This notice proposed the 2025 APQs for each basic class of controlled substance listed in schedules I and II and the 2025 AANs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed APQs and the proposed AANs on or before October 25, 2024.

III. Comments Received

Within the public comment period, DEA received 1,882 comments from DEA registrants, chronic pain patients, patients with attention deficit/hyperactivity disorder (ADHD), pain advocacy associations, U.S. professional associations, U.S. doctors and nurses, and others. The comments included concerns about potential domestic opioid drug shortages due to further quota reductions; patient difficulty filling authorized opioid prescriptions; increases in drug overdose deaths despite a continued decrease in production quotas; requests for an extension to the comment period; stimulant drug shortages in the United States; concerns that medical professionals might be impeded from exercising their medical expertise regarding opioid prescriptions; requests for a public hearing; and comments not pertaining to DEA-regulated activities. While all comments were posted to regulations.gov, DEA restricted the attachments to 10 comments from public view due to confidential business information and/or confidential personal identifying information.

Opioid Adequacy

Issue (National Production Levels of Proposed APQs for Opioids Compared to 2024 levels): DEA received a significant number of comments from pain advocacy groups, hospital associations, health professionals, and others who raised concerns over the proposed APQs for certain opioids in 2025, which were proposed at a level lower than the established production levels for 2024. The commenters suggested that the proposed APQ levels could exacerbate shortages experienced in 2024.

DEA Response: DEA considers numerous factors in determining an APQ, including total net disposal of the class by all manufacturers during the current and two preceding years, trends in the national rate of net disposal of the class, total actual or estimated inventories of the class and of all substances manufactured from the class, information obtained from the Food and Drug Administration (FDA), and changes in the currently accepted medical use in treatment. 21 U.S.C. 826(a); 21 CFR 1303.11(b). Additional factors considered can be found in 21 CFR 1303.11(b). After considering all of the relevant factors, DEA has determined that the proposed APQs for the five covered controlled substances—fentanyl, hydrocodone, hydromorphone, oxycodone and oxymorphone—are sufficient to meet the forecasted legitimate domestic and foreign needs and allow for maintenance of reserve stocks. These considerations also lead DEA to conclude that U.S. manufacturers will need to manufacture approximately the same amount of those opioids in 2025 as in 2024 in order to meet legitimate needs.

Accordingly, DEA proposed the 2025 APQs for those five substances at the same level as in DEA's proposed revised APQs for 2024 published on September

[1] 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 2025, 89 FR 78772 (September 25, 2024).