



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1413M]

Adjustment to the Aggregate Production Quota for d-amphetamine (for sale) and methylphenidate (for sale) for 2025 Pursuant to 21 U.S.C. 826(h)

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Drug Enforcement Administration (DEA) is adjusting the 2025 aggregate production quota for the schedule II-controlled substances d-amphetamine (for sale) and methylphenidate (for sale). In making this determination, DEA has considered the factors set forth in 21 CFR 1303.13(b) in accordance with 21 U.S.C. 826(a) and is expediting publication of this determination to comply with the timeframes specified in 21 U.S.C. 826(h)(1).

DATES: This final order is effective [**INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

FOR FURTHER INFORMATION CONTACT: Heather E. Achbach, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration, Telephone: (571) 776-3882.

SUPPLEMENTARY INFORMATION:

Legal Authority

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

Under 21 U.S.C. 826(h), when a request for individual manufacturing quota is

submitted by a DEA-registered manufacturer pertaining to a schedule II-controlled substance that is contained in a drug on the Food and Drug Administration's (FDA's) list of drugs in shortage, DEA must complete review of such request not later than 30 days after receipt of the request. If, after the review is completed, DEA finds that an increase in the aggregate and individual production quotas is necessary to address a shortage of that controlled substance, DEA is to increase the aggregate and individual production quotas of that controlled substance and any ingredient therein to the level requested. 21 U.S.C. 826(h)(1)(B)(i). However, if it is determined that the level requested is not necessary to address the shortage, DEA is to provide a written response detailing the basis for the determination. 21 U.S.C. 826(h)(1)(B)(ii).

Background

DEA published the 2025 established APQ for controlled substances in schedules I and II in the *Federal Register* on December 17, 2024. 89 FR 102649. The 2025 established APQ represents those quantities of schedule I and II controlled substances that may be manufactured in the United States 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. The final order stipulated that all APQ are subject to an adjustment, in accordance with 21 CFR 1303.15.¹

Quotas Applicable to Drugs in Shortage Pursuant to 21 U.S.C. 826(h)

Under 21 U.S.C. 356c, manufacturers of drugs that are life-supporting, life-sustaining, or intended for the treatment or prevention of debilitating diseases or

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 2025, 89 FR 102649 (December 17, 2024).

conditions must notify FDA of any permanent discontinuation or interruption in manufacturing likely to result in a meaningful disruption of the drug's supply in the United States. d-Amphetamine (for sale) and methylphenidate (for sale) are drugs intended for use in the prevention or treatment of a debilitating disease or condition and therefore fall under the notification requirements of 21 U.S.C. 356c. This provision further requires FDA to assess whether the notifications received from manufacturers concern controlled substances that are subject to production quotas in accordance with 21 U.S.C. 826.

On August 15, 2025, DEA received a request from a DEA registered manufacturer of the schedule II-controlled substance d-amphetamine to increase its 2025 individual manufacturing quota pertaining to d-amphetamine (for sale). Also on August 15, 2025, DEA received a request from a separate DEA registered manufacturer of the schedule II-controlled substance methylphenidate to increase its 2025 individual manufacturing quota pertaining to methylphenidate (for sale). DEA reviewed the FDA drug shortage list and found manufacturers reported a domestic shortage of products containing d-amphetamine and products containing methylphenidate. Multiple manufacturers cited "shortage of an active ingredient" as the reason identified for the domestic shortages. Pursuant to this request, DEA began its review under the timeframes specified by 21 U.S.C. 826(h)(1).

Analysis for the Adjustment to the 2025 d-Amphetamine (For Sale) and Methylphenidate (For Sale) Aggregate Production Quotas

In conducting the review under 21 U.S.C. 826(h) in order to determine the necessity of this adjustment, the Administrator has considered the criteria in accordance with 21 CFR 1303.13 (adjustment of APQ for controlled substances). The Administrator is authorized to increase or reduce the APQ at any time. 21 CFR 1303.13(a). DEA regulations state that there are five factors that shall be considered in determining whether to adjust the APQ. 21 CFR 1303.13(b). Accordingly, the Administrator has

taken into account the following factors described below for 2025: (1) changes in the demand for that class, changes in the national rate of net disposal of the class, changes in the rate of net disposal of the class by registrants holding individual manufacturing quotas for that class, and changes in the extent of any diversion in the class; (2) whether any increased demand for that class, the national and/or individual rates of net disposal of that class are temporary, short term, or long term; (3) whether any increased demand for that class can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the APQ, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to 21 CFR 1303.24(b); (4) whether any decreased demand for that class will result in excessive inventory accumulation by all persons registered to handle that class (including manufacturers, distributors, practitioners, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to 21 CFR 1303.24(b) or abandoned pursuant to 21 CFR 1303.27; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, 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). Based on that review, DEA is increasing the current d-amphetamine (for sale) and methylphenidate (for sale) APQs.

DEA reviewed domestic and export data from DEA's internal databases, IQVIA, and Multi International Data Analysis System (MIDAS). Please note, IQVIA and MIDAS do not use the sub-categories of "for sale" and "for conversion." This is a U.S. concept to clarify how the substances are used domestically. Extrapolation of the data

predicts global consumption will increase 15.16 percent for d-amphetamine drug products and 7.59 percent for methylphenidate drug products in 2025 when compared to 2024. DEA also reviewed global production and consumption data of d-amphetamine and methylphenidate published in the 2024 Psychotropic Technical Report by the International Narcotics Control Board (INCB)². Please note, INCB also does not use the sub-categories of “for sale” and “for conversion.” The report stated global manufacturing of both d-amphetamine and methylphenidate increased in 2023 compared to 2022, with United States being the largest manufacturer of both substances. According to the INCB report, global imports of d-amphetamine have been increasing in the past decade, with forty-one countries and territories reporting imports in 2023. The volume of methylphenidate imports also increased in 2023 compared to 2022, with 120 countries and territories reporting.

Upon reviewing domestic and export data, along with the inventory reports provided by the bulk and dosage manufacturers, DEA has determined that although the current d-amphetamine (for sale) and methylphenidate (for sale) APQs are adequate to address both the domestic and foreign medical demand, they are insufficient to accommodate an unexpected rise of quota requests for product development activities. DEA is proposing to increase the APQs of d-amphetamine (for sale) and methylphenidate (for sale) to support the requests for product development activities by bulk and dosage form manufacturers submitted after the publication of the 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 2025.³ The proposed increases are to support manufacturers’

² INCB Psychotropics—Technical Report Psychotropic Substances 2024, Statistics for 2023, Assessments of Annual Medical Scientific Requirements for Substances for 2025.

³ 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, 89 FR 102649 (December 17, 2024).

product development activities toward obtaining FDA approval of new API manufacturing processes, as well as FDA approval of new drug products.

After considering these factors, DEA determined that it is necessary to increase the established 2025 APQ for the schedule II controlled substances d-amphetamine (for sale) and methylphenidate (for sale) to be manufactured in the United States to provide for the estimated legitimate medical needs of the United States, export requirements to meet foreign demand, the maintenance of reserve stocks, and to support estimated needs for product development activities. These adjustments are necessary to ensure that the United States has an adequate and uninterrupted supply of d-amphetamine (for sale) and methylphenidate (for sale) to meet legitimate patient needs both domestically and globally as well as to support product development requirements of both bulk and finished dosage form manufacturers.

Additional Legal Considerations

The procedures previously adopted by DEA for adjustment of APQ are set forth in DEA regulations in 21 CFR 1303.13. Under that provision, the Administrator, upon determining that an adjustment of the APQ of any basic class of controlled substance is necessary, shall publish in the Federal Register general notice of an adjustment in the APQ for that class. The regulation further directs that DEA will allow any interested person to file comments or objections to the adjusted APQ within the time specified by the Administrator in the notice. Section 1303.13 further provides that, “[a]fter consideration of any comments or objections . . . the Administrator shall issue and publish in the Federal Register his final order determining the APQ for the basic class of controlled substance.”

The statutory timeframe applicable to actions taken under 21 U.S.C. 826(h) was enacted by Congress after DEA established its regulations in 21 CFR 1303.13. DEA has determined that it is not possible to increase the APQ within the Congressionally-

mandated 30-day period while also complying with the procedures that DEA previously had laid out in 21 CFR 1303.13. Therefore, the Administrator has determined that, in order to comply with the 30-day timeframe in 21 U.S.C. 826(h), this final order must be published without opportunity for comment and made effective immediately.

Determination of 2025 d-Amphetamine (For Sale) and Methylphenidate (For Sale) Aggregate Production Quota

In determining the adjustment of the 2025 d-amphetamine (for sale) and methylphenidate (for sale) APQs, DEA has taken into consideration the factors set forth in 21 CFR 1303.13(b) in accordance with 21 U.S.C. 826(a) as well as 826(h). Based on all of the above, the Administrator is adjusting the 2025 APQs for d-amphetamine (for sale) and methylphenidate (for sale).

The Administrator hereby adjusts the 2025 APQ for the following schedule II-controlled substances expressed in grams of anhydrous acid or base, as follows:

Controlled Substance	Current APQ (g)	Adjusted APQ (g)
Schedule II		
d-amphetamine (for sale)	21,200,000	26,450,000
methylphenidate (for sale)	53,283,000	58,283,000

The APQ for all other schedule I and II controlled substances included in the 2025 established APQ remain at this time as established in other Notices.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on August 5, 2025, by Administrator Terrance Cole. 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,
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Drug Enforcement Administration.

[FR Doc. 2025-19335 Filed: 10/1/2025 8:45 am; Publication Date: 10/2/2025]