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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1568M]

Adjustment to the 2026 Aggregate Production Quota for d,l-Amphetamine, d-Amphetamine (for sale), Hydromorphone and Methylphenidate (for sale) 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 2026 aggregate production quota for the schedule II controlled substances d,l-amphetamine, d-amphetamine (for sale), hydromorphone, 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 on the Food and Drug Administration's (FDA) list of drugs in shortage, DEA must complete review of such request no 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 2026 established APQ for controlled substances in schedules I and II in the *Federal Register* on January 5, 2026. 91 FR 287. The 2026 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 use in 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 2026, 91 FR 287 (January 5, 2026).

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. Schedule II controlled substances d,l-amphetamine, d-amphetamine (for sale), hydromorphone, 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.

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 calendar year 2026: (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,l-amphetamine, d-amphetamine (for sale), hydromorphone, and methylphenidate (for sale) APQs.

Analysis for the Adjustment to the 2026 d,l-Amphetamine and d-Amphetamine (For Sale) Aggregate Production Quota

On August 14 and August 24, 2026, DEA received two requests from two DEA registered manufacturers of the schedule II controlled substance d,l-amphetamine for an increase to their 2026 individual manufacturing quota pertaining to d,l-amphetamine. On August 14, 2026, DEA also received a request from a DEA registered manufacturer of the schedule II controlled substance d-amphetamine for an increase to its 2026 individual manufacturing quota pertaining to d-amphetamine (for sale). DEA reviewed the FDA drug shortage list and found multiple manufacturers reported a domestic shortage of amphetamine mixed salts tablets. Some manufacturers cited "shortage of an active ingredient" as the reason identified for the domestic shortages. Pursuant to these requests, DEA began its review under the timeframes specified by 21 U.S.C. 826(h)(1).

DEA reviewed the data provided by FDA in July 2026 on the domestic medical use of d,l-amphetamine and d-amphetamine (for sale), as well as export data and

inventory reports from both bulk and dosage manufacturers. FDA predicted the domestic medical need for d,l-amphetamine and d-amphetamine in 2026 will increase by 23.6 percent and 23.7 percent respectively when compared to the 2025 observed domestic medical need. DEA also reviewed the global consumption data from Multi International Data Analysis System (MIDAS). Extrapolation of the global sales of d,l-amphetamine and d-amphetamine predicts an increase of 4.36 percent and 4.07 percent respectively in 2026 when compared to 2025. While sufficient quota was granted to meet legitimate patient needs both domestically and globally, DEA has determined that due to the increase in domestic and global medical needs, an increase to the d,l-amphetamine and d-amphetamine (for sale) is necessary to allow for the adequate manufacturing of reserve stocks to start the next calendar year.

DEA also saw an increase in quota requests for product development activities by bulk and dosage form manufacturers of d,l-amphetamine and d-amphetamine (for sale) to synthesize engineering and validation batches to support the filing of new drug applications for FDA review. Year-to-date amounts approved for product development by bulk and dosage manufacturers have increased 173 percent for d,l-amphetamine and 32 percent for d-amphetamine (for sale) in 2026 when compared to 2025, respectively. DEA has determined that it is necessary to increase the 2026 d,l-amphetamine and d-amphetamine (for sale) APQs to allow for the maintenance of reserve stocks and increased product development needs after considering all estimated consumption data and projected product development needs.

Analysis for the Adjustment to the 2026 Hydromorphone Aggregate Production Quota

On July 24, 2026, DEA received a request from a DEA registered manufacturer of the schedule II controlled substance hydromorphone for an increase to its 2026 individual manufacturing quota pertaining to hydromorphone. DEA reviewed the FDA drug

shortage list and found multiple manufacturers reported a domestic shortage of hydromorphone hydrochloride injectable products. The manufacturers cited "demand increase for the drug or delay of manufacturing" as the reasons identified for the domestic shortages. Pursuant to this request, DEA began its review under the timeframe specified by 21 U.S.C. 826(h)(1).

DEA reviewed the most recent domestic usage data from IQVIA, as well as data provided by the FDA on the domestic medical use of hydromorphone. FDA predicted the domestic medical need for hydromorphone in 2026 will increase by 20.9 percent compared to the 2025 observed medical need. DEA also reviewed export information provided by bulk manufacturers, export data from DEA's internal database, and global consumption data from MIDAS. Export data shows that the 2026 exports of hydromorphone will increase 142 percent when compared to 2025 because one bulk manufacturer is planning to significantly increase its export of hydromorphone in 2026. DEA has determined that an increase to the hydromorphone APQ is necessary to support the estimated increase in domestic medical need and projected new export requirements.

Analysis for the Adjustment to the 2026 Methylphenidate (For Sale) Aggregate Production Quota

On July 31, August 1, and August 20, 2026, DEA received requests from DEA registered manufacturers of the schedule II controlled substance methylphenidate for an increase to their 2026 individual manufacturing quota pertaining to methylphenidate (for sale). DEA reviewed the FDA drug shortage list and found multiple manufacturers reported a domestic shortage of methylphenidate tablets and film. The manufacturers cited "demand increase for the drug" or "discontinuation of the manufacture of the drug" as the reasons identified for their portion of the domestic shortages. Pursuant to these requests, DEA began its review under the timeframes specified by 21 U.S.C. 826(h)(1).

Following a review of domestic and export data, as well as inventory reports from

both the bulk and dosage manufacturers, DEA has determined that an increase to the APQ of methylphenidate (for sale) is necessary to address the increasing global medical demand and to allow domestic manufacturers of FDA-approved methylphenidate drug products to replenish their inventories to levels authorized by DEA regulations. FDA predicted the domestic medical need for methylphenidate in 2026 will increase by 23.4 percent compared to the 2025 observed medical need. DEA also reviewed the methylphenidate export data from DEA's internal database, as well as global consumption data from MIDAS. Extrapolation of the sales data from MIDAS predicts global consumption will increase by 8.01 percent for methylphenidate drug products in 2026 when compared to 2025.

DEA also reviewed global production and consumption data of methylphenidate published in the 2025 Psychotropic Technical Report by the International Narcotics Control Board (INCB).[2] The INCB reported the United States as the leading manufacturer of methylphenidate, and although the total manufacturing of methylphenidate was reported to be at the highest level since INCB began receiving data, the global stocks of methylphenidate decreased by 11 tons, from 91.6 tons in 2023 to 80.6 tons in 2024. After considering all the domestic and global data, DEA has determined that an increase to the 2026 methylphenidate (for sale) APQ is necessary to allow for the adjustment of reserve stocks to support the increasing global medical demand.

After considering the factors set forth in 21 CFR 1303.13(b) in accordance with 21 U.S.C. 826(a) as well as 826(h), DEA determined that it is necessary to increase the established 2026 APQs for the schedule II controlled substances d,l-amphetamine, d-amphetamine (for sale), hydromorphone, and methylphenidate (for sale) to be manufactured in the United States to provide for the estimated legitimate medical needs

[2] INCB Psychotropics—Technical Report Psychotropic Substances 2025, Statistics for 2024, Assessments of Annual Medical Scientific Requirements for Substances for 2026.

of the United States and export requirements to meet foreign demand. These adjustments are necessary to ensure that the United States has an adequate and uninterrupted supply of d,l-amphetamine, d-amphetamine (for sale), hydromorphone, and methylphenidate (for sale) to meet legitimate patient needs both domestically and globally.

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* a 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 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 2026 d,l-Amphetamine, d-Amphetamine (For Sale), Hydromorphone, and Methylphenidate (for sale) Aggregate Production Quota

In determining the adjustment of the 2026 d,l-amphetamine, d-amphetamine (for sale), hydromorphone, 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 2026 APQs for d,l-amphetamine, d-amphetamine (for sale), hydromorphone, and methylphenidate (for sale).

The Administrator hereby adjusts the 2026 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,l-amphetamine	24,234,443	31,654,915
d-amphetamine (for sale)	26,450,000	37,108,041
hydromorphone	1,949,378	2,356,798
methylphenidate (for sale)	58,283,000	69,502,651

The APQ for all other schedule I and II controlled substances included in the 2026 established APQ remain at this time as previously established.[3]

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on November 4, 2026, by DEA Administrator Terrance C. 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,
Federal Register Liaison Officer,
Drug Enforcement Administration.

[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 2026, 91 FR 287 (January 5, 2026).

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