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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1413L]

Adjustment to the Aggregate Production Quota for Lisdexamfetamine and d-Amphetamine (for conversion) 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 lisdexamfetamine and d-amphetamine (for conversion). 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. Lisdexamfetamine is a drug that is intended for use in the prevention or treatment of a debilitating disease or condition and therefore falls 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 7, 2025, DEA received a request from a DEA registered manufacturer of the Schedule II controlled substance lisdexamfetamine for an increase to its 2025 individual manufacturing quota pertaining to lisdexamfetamine. DEA reviewed the FDA drug shortage list and found multiple manufacturers reported a domestic shortage of lisdexamfetamine capsules and chewable tablets. The 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).

The manufacturing of lisdexamfetamine active pharmaceutical ingredient (API) requires the synthesis of an intermediate, d-amphetamine, a schedule II-controlled substance, and thus requires the DEA to additionally review whether an adjustment to the APQ of d-amphetamine (for conversion) is necessary.

Analysis for the Adjustment to the 2025 Lisdexamfetamine and d-Amphetamine (for conversion) Aggregate Production Quota

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 lisdexamfetamine and d-amphetamine (for conversion) APQs.

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 lisdexamfetamine is necessary. The increase is intended to address the rising global demand for lisdexamfetamine products and to allow domestic manufacturers of FDA-approved lisdexamfetamine drug products to replenish their inventories to levels

authorized by DEA regulations. DEA reviewed the most recent domestic usage data from IQVIA and export data from DEA's internal database and Multi International Data Analysis System (MIDAS). Extrapolation of the data predicts global consumption will increase 15.16 percent in 2025. The increase is due to the approval of the brand name product, Vyvanse, to treat patients suffering from attention-deficit/hyperactivity disorder (ADHD) in 29 countries in addition to the United States, with additional countries in the process of granting approval of this product for treatment of ADHD. Furthermore, other U.S. dosage manufacturers have also begun exporting lisdexamfetamine finished dosage-form products according to the data extracted from DEA's internal databases. Extrapolation utilizing previous years' reported data suggests the export requirements for lisdexamfetamine API and finished dosages likely will continue to increase in 2025 and beyond. An increase in domestic manufacturing of the API and finished dosages is necessary to supply lisdexamfetamine products to both the domestic and foreign markets.

Additionally, DEA reviewed internal databases and determined that bulk manufacturers started 2025 with less than the 40 percent inventory allowance permitted by 21 CFR 1303.24. Increasing the lisdexamfetamine APQ would allow the manufacturers to approach the 40 percent inventory allowance permitted by 21 CFR 1303.24 while meeting the estimated increasing legitimate domestic and global demands.

As a result of the increase to the APQ of lisdexamfetamine, DEA must make a corresponding increase to the APQ of d-amphetamine (for conversion) because this substance is used by some manufacturers as part of the synthesis pathway to manufacture lisdexamfetamine products. Without this corresponding increase, manufacturers of lisdexamfetamine API would not be able to utilize the entire amount of the increased lisdexamfetamine APQ.

After considering these factors, DEA determined that it is necessary to increase the established 2025 APQ for the schedule II controlled substances lisdexamfetamine and

d-amphetamine (for conversion) to be manufactured in the United States to provide for the estimated needs of the United States and export requirements to meet domestic and global demand. These adjustments are necessary to ensure that the United States has an adequate and uninterrupted supply of lisdexamfetamine 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 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(c) 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 Lisdexamfetamine and d-Amphetamine (for conversion) Aggregate Production Quota

In determining the adjustment of the 2025 lisdexamfetamine and d-amphetamine (for conversion) APQ, 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 APQ for lisdexamfetamine and d-amphetamine (for conversion).

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

Controlled Substance	Current APQ (g)	Adjusted APQ (g)
Schedule II		
lisdexamfetamine	32,736,000	39,907,536
d-amphetamine (for conversion)	23,688,235	27,906,786

The APQ for all other schedule I and II controlled substances included in the 2025 established APQ remain at this time as previously established.[2]

Signing Authority

This document of the Drug Enforcement Administration was signed on September 16, 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,
Federal Register Liaison Officer,
Drug Enforcement Administration.

[FR Doc. 2025-18110 Filed: 9/18/2025 8:45 am; Publication Date: 9/19/2025]

[2] 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).