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Sharon Bellamy,

Supervisory Hearings and Information Officer.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1228L]

Adjustment to the Aggregate Production Quota for Lisdexamfetamine and d-Amphetamine (for Conversion) for 2024

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Drug Enforcement Administration is adjusting the 2024 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 its regulations in accordance with the statutes and is expediting publication of this determination to comply with the timeframes specified in the statutes.

DATES: The final order is effective September 5, 2024.

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 the Drug Enforcement Administration (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 2024 established APQ for controlled substances in schedules I and II in the **Federal Register** on January 3, 2024. 89 FR 407. The 2024 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)

DEA received written correspondence from FDA on July 12, 2024, in accordance with 21 U.S.C. 356c, addressing the domestic drug shortage of lisdexamfetamine capsules and chewable tablets. In this letter, FDA advised DEA that ''shortage of an active ingredient'' is the reason identified for the shortages of all marketed generic lisdexamfetamine dimesylate capsules and chewable tablets. 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 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. That provision further requires FDA to assess whether notifications received from manufacturers concern controlled substances subject to production quotas in accordance with 21 U.S.C. 826.

FDA's July 12 letter requested that DEA increase the APQ and individual manufacturing quotas for lisdexamfetamine to a level that FDA deems necessary to address a shortage based on the best available market data.[2] FDA reiterated to DEA that lisdexamfetamine 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.

On August 2, 2024, DEA received a request from a DEA registered manufacturer of the Schedule II controlled substance lisdexamfetamine for an increase to its 2024 individual manufacturing quota pertaining to lisdexamfetamine. Pursuant to this request, and following the receipt of the letter from FDA on July 12, DEA began its review under the timeframes specified by 21 U.S.C. 826(h)(1).

D-amphetamine, another schedule II controlled substance, is used by some manufacturers as part of the synthesis pathway to manufacture lisdexamfetamine products.

Analysis for the Adjustment to the 2024 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 2024: (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

[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 (January 3, 2024).

[2] As the FDA's specific requested levels would reveal proprietary manufacturing data, DEA is not specifying the requested levels in this document.

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 proposing an increase to the current lisdexamfetamine and d-amphetamine (for conversion) APQ.

DEA reviewed domestic data from the latest IQVIA report on stimulant prescribing that reflected increases in prescribing of lisdexamfetamine products from 2022 to 2023. In addition, FDA's estimate of domestic medical need for lisdexamfetamine drug products predicted a 6 percent increase for 2024 domestic need when compared to 2023 observed need. Data reviewed by both agencies support an increase to the lisdexamfetamine APQ which is necessary to meet domestic demand.

Data shows an increase in the number of foreign countries that have approved drug products containing lisdexamfetamine for their patient populations. Vyvanse® is currently approved to treat patients suffering from attention-deficit/hyperactivity disorder (ADHD) in 29 countries besides the United States. According to a comment received in November 2023 from the Australian ADHD Foundation on the **Federal Register** notice that proposed the APQ and the assessment of annual needs (AAN) for 2024,[3] the Department of Health and Aged Care Therapeutic Goods Administration (TGA) of the Australian Government reported current shortages of lisdexamfetamine products with more shortages predicted for various strengths through April 2024. On June 18, 2024, TGA reported that certain strengths of lisdexamfetamine medications remain in shortage.[4] In February 2021, Australia extended a government subsidy of lisdexamfetamine medications to adults who are diagnosed with ADHD after the age of 18. There has since been an immediate and sustained increase in monthly dispensing.[5] In Europe, the consumption of lisdexamfetamine medications has been rapidly growing over the years. Additionally, Gimbach et al. conducted a study and reported the overall consumption of ADHD medications has increased in 26 of 28 countries in Europe.[6] According to those researchers, the growth in consumption can be attributed to an increase in the general awareness of ADHD among the public and medical practitioners, but more importantly, the broadening of diagnosis criteria in Europe.[7]

In addition to reviewing export data extracted from DEA's internal databases, DEA also obtained access to new data sources in 2024 that allow DEA to more accurately forecast foreign demand for domestically controlled substances that are not always internationally controlled,[8] such as lisdexamfetamine. The export data showed that exports of drug products containing lisdexamfetamine increased from 8,573.351 kg in 2022 to 11,502.175 kg in 2023. Extrapolation utilizing previous years' reported data suggests the export requirements for lisdexamfetamine active pharmaceutical ingredient and finished dosages likely will continue to increase in 2024 and beyond. An increase in domestic manufacturing of the active pharmaceutical ingredient and finished dosages is necessary to supply lisdexamfetamine products to foreign markets.

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's active pharmaceutical ingredient 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 2024 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. Of the 6,236 kg increase to the lisdexamfetamine APQ, 1,558 kg of the increase is to address increased domestic demand for finished dosage medications, while the other 4,678 kg addresses increases in foreign demand for finished dosage medications. 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 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 aggregate production 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.

[3] 88 FR 75312 (Nov. 2, 2023).

[4] *https://apps.tga.gov.au/Prod/msi/Search/Details/lisdexamfetamine-dimesilate.*

[5] Aust N Z J Psychiatry. 2023 Jul; 57(7): 1073–1076. Published online 2023 Apr 25.

[6] Gimbach, S., Vogel, D., Fried, R. *et al.* ADHD medicine consumption in Europe after COVID–19: catch-up or trend change?. BMC Psychiatry 24, 112 (2024).

[7] Gimbach, S., Vogel, D., Fried, R. *et al.* ADHD medicine consumption in Europe after COVID–19: catch-up or trend change?. BMC Psychiatry 24, 112 (2024).

[8] A controlled substance's placement in the 1961 UN Single Convention or the 1971 UN Psychotropic Convention determines whether a substance is internationally controlled. *https://www.incb.org/incb//conventions/index.html?lng=en.*

Determination of 2024 Lisdexamfetamine and d-Amphetamine (for Conversion) Aggregate Production Quota

In determining the adjustment of the 2024 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 2024 APQ for lisdexamfetamine and d-amphetamine (for conversion).

The Administrator hereby adjusts the 2024 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	26,500,000	32,736,000
d-amphetamine (for conversion)	20,000,000	23,688,235

The APQ for all other schedule I and II controlled substances included in the 2024 established APQ remain at this time as previously established.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 3, 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. 2024–20114 Filed 9–3–24; 4:15 pm]

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DEPARTMENT OF LABOR

[Agency Docket Number DOL–2024–0004]

Efforts by Certain Foreign Countries To Eliminate the Worst Forms of Child Labor; Child Labor, Forced Labor, and Forced or Indentured Child Labor in the Production of Goods in Foreign Countries; and Business Practices To Reduce the Likelihood of Forced Labor or Child Labor in the Production of Goods

AGENCY: Bureau of International Labor Affairs, Department of Labor.

ACTION: Notice of publication; request information and invitation to comment.

SUMMARY: This notice is a request for information and/or comment on three reports issued by the Bureau of International Labor Affairs (ILAB) regarding child labor and forced labor in certain foreign countries, as well as ILAB's Comply Chain knowledge tool for labor compliance in global supply chains. Relevant information submitted by the public will be used by the Department of Labor (DOL) in preparing its ongoing reporting as required under Congressional mandates and a Presidential directive.

DATES: Submitters of information are requested to provide their submission to DOL's Office of Child Labor, Forced Labor, and Human Trafficking (OCFT) at the email or physical address below by 11:59 p.m. on December 16, 2024.

ADDRESSES:

To Submit Information: Information should be submitted directly to OCFT, Bureau of International Labor Affairs, U.S. Department of Labor. Comments, identified as Docket No. DOL–2024–0004, may be submitted by any of the following methods:

Federal eRulemaking Portal: The portal includes instructions for submitting comments. Parties submitting responses electronically are encouraged not to submit paper copies.

Facsimile (fax): OCFT at 202–693–4830.

Mail, Express Delivery, Hand Delivery, and Messenger Service (1 copy): Matthew Fraterman, U.S. Department of Labor, OCFT, Bureau of International Labor Affairs, 200 Constitution Avenue NW, Room S–5315, Washington, DC 20210.

Email: Email submissions should be addressed to Matthew Fraterman (*Fraterman.matthew@dol.gov.*).

FOR FURTHER INFORMATION CONTACT: Matthew Fraterman, Office of Child Labor, Forced Labor, and Human Trafficking, U.S. Department of Labor at 202–693–4833 (this is not a toll-free number) or *Fraterman.matthew@dol.gov.*

Digital Accessibility: DOL is required to ensure that all its digital information is accessible to people with disabilities, including those who use assistive technology such as screen readers. Therefore, DOL requests that your submissions through the portal be as accessible as possible. If you are able to conform to the current Web Content Accessibility Guidelines (WCAG), then please do so. Otherwise, DOL requests that submissions be made in a Microsoft Word document, using the built-in styles for document formatting, including descriptive Alt Text on embedded images and graphics, and using the built-in Word Accessibility Checker for additional accessibility improvements. Although permissible, please avoid submitting scanned images, screen shots, or PDFs whenever possible.

SUPPLEMENTARY INFORMATION: The 2023 Findings on the Worst Forms of Child Labor (TDA report), published on September 5, 2024, assesses efforts of 131 countries to eliminate the worst forms of child labor in 2023 and whether countries made significant, moderate, minimal, or no advancement. It also suggests actions foreign countries can take to eliminate the worst forms of child labor through legislation, enforcement, coordination, policies, and social programs. The 2024 List of Goods Produced by Child Labor or Forced Labor (TVPRA List), published on September 5, 2024, makes available to the public a list of goods from countries that ILAB has reason to believe are produced by child labor or forced labor in violation of international standards, including, to the extent practicable, goods that are produced with inputs that are produced with forced labor or child labor. Finally, the List of Products Produced by Forced or Indentured Child Labor (E.O. 13126 List), provides a list of products, identified by country of origin, that DOL, in consultation and cooperation with the Departments of State (DOS) and Homeland Security (DHS), has a reasonable basis to believe might have been mined, produced, or manufactured with forced or indentured child labor. Relevant information