Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–411N]

Controlled Substances: Proposed Adjustments to the Aggregate Production Quotas for Difenoxin, Diphenoxylate (for conversion), and Marijuana

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration is proposing to adjust the established 2015 aggregate production quota for difenoxin, diphenoxylate (for conversion), and marijuana which are schedule I and II controlled substances under the Controlled Substances Act.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13. Electronic comments must be submitted, and written comments must be postmarked, on or before [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–411N" on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly

into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but

do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified and located as directed above will generally be made available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended.

21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

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

Background

The DEA established the initial 2015 aggregate production quotas and assessments of annual need on September 8, 2014 (79 FR 53216). That notice stipulated that, as provided for in 21 CFR 1303.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Based on unanticipated medical, scientific, research, and industrial needs of the United States the DEA proposes to adjust the established 2015 aggregate production quotas for the schedule I and II controlled substances difenoxin, diphenoxylate (for conversion), and marijuana to be manufactured in the United States in 2015. The

adjustment is necessary to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks.

In proposing the adjustment, the Administrator has taken into account the following criteria in accordance with 21 CFR 1303.13: (1) changes in demand for the basic class, changes in the national rate of net disposal for the class, and changes in the rate of net disposal by the registrants holding individual manufacturing quotas for the class; (2) whether any increased demand or changes in the national and/or individual rates of net disposal 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 aggregate production quota; (4) whether any decreased demand will result in excessive inventory accumulation by all persons registered to handle the class; and (5) other factors affecting the medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Administrator finds relevant.

Analysis for Adjusting the Established 2015 Aggregate Production Quota for Difenoxin and Diphenoxylate (for Conversion)

Since the establishment of the initial 2015 aggregate production quotas, the DEA has received requests from DEA registered manufacturers to manufacture difenoxin and diphenoxylate (for conversion) to support the manufacture of prescription drug products approved by the Food and Drug Administration (FDA) for the treatment of chronic diarrhea and for the treatment of diarrhea associated with irritable bowel syndrome

(IBS).[1] These FDA approved products have not been manufactured since 2009 due to FDA-regulated manufacturing issues and there is no existing generic or therapeutic equivalent.

Analysis for Adjusting the Established 2015 Aggregate Production Quota for Marijuana

Since the establishment of the initial 2015 aggregate production quotas, the DEA has received notification from DEA registered manufacturers that research and product development involving cannabidiol, is increasing beyond that previously anticipated for 2015. The associated product development activities are related to process validation and commercialization activities, including qualification activities related to potential U.S. Food and Drug Administration submission support.

Additionally, the DEA has also received notification from the National Institute on Drug Abuse (NIDA) that it required additional supplies of marijuana to be manufactured in 2015 to provide for ongoing and anticipated research efforts involving marijuana. NIDA is a component of the National Institutes of Health and the U.S. Department of Health and Human Services which oversees the cultivation, production and distribution of research-grade marijuana on behalf of the United States Government, pursuant to the Single Convention on Narcotic Drugs (March 30, 1961, 18 UST 1407).

The Administrator, therefore, proposes to adjust the 2015 aggregate production quotas for difenoxin, diphenoxylate (for conversion), and marijuana, expressed in grams of anhydrous acid or base, as follows:

[1] Difenoxin (schedule I) is the active pharmaceutical ingredient in the diarrhea preparation (schedule V).

Basic Class-Schedule I	Previously Established 2015 Quota	Adjusted 2015 Quota
Difenoxin	50 g	9,000 g
Marijuana	125,000 g	400,000 g

Basic Class-Schedule II	Previously Established 2015 Quota	Adjusted 2015 Quota
Diphenoxylate (for conversion)	Zero	75,000 g

Dated: April 1, 2015.

Michele M. Leonhart,
Administrator.
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