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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1303

[Docket No. DEA- 480]

RIN 1117-AB48

Controlled Substances Quotas

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is publishing this final rule to strengthen the process for setting controls over diversion of controlled substances and make other improvements in the quota management regulatory system for the production, manufacturing, and procurement of controlled substances.

DATES: This final rule is effective [insert date 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Legal Authority

Provisions of the Controlled Substances Act, 21 U.S.C. 801 et seq., authorize the Attorney General to issue rules and regulations relating to registration and control of the

manufacture, distribution, and dispensing of controlled substances and listed chemicals. 21 U.S.C. 821. Pursuant to this authority, the Attorney General, through the Drug Enforcement Administration (DEA), has issued and administers regulations setting aggregate production quotas for each basic class of controlled substances in schedules I and II, manufacturing quotas for individual manufacturers, and procurement quotas for manufacturers to produce other controlled substances or to convert the substances into dosage form. *See* 21 CFR part 1303.

The current regulations, issued initially in 1971, need to be updated to reflect changes in the manufacture of controlled substances, changing patterns of substance abuse and markets in illicit drugs, and the challenges presented by the current national crisis of controlled substance abuse. This final rule modifies the regulations to strengthen controls over diversion – that is, the redirection of controlled substances which may have lawful uses into illicit channels – and makes other improvements in the controlled substance regulatory quota system.

The quota process, in general terms, is a critical element of the Controlled Substances Act's regulatory system that seeks to prevent or limit diversion by preventing the accumulation of controlled substances in amounts exceeding legitimate need. The measures the final rule adopts to strengthen the system include authorizing the requisition from quota applicants of additional information helpful in detecting and preventing diversion, and ensuring that DEA's determinations regarding the appropriate quotas are adequately informed by input from other federal agencies, from the states, and from quota applicants.

Section-by-Section Analysis

The DEA is finalizing the rule as proposed without changes. Below are summaries of provisions contained in the final rule.

Section 1303.11 – Aggregate production quotas

Section 1303.11 currently directs the Administrator of DEA to determine the total quantity of each basic class of controlled substance listed in schedule I or II needed in the calendar year for the medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Section 1303.11(b)(1) through (4) identifies a number of factors that are categorically to be considered in determining aggregate production quotas – relating to total net disposal, net disposal trends, inventories and inventory trends, and demand – followed by a final catchall factor, (5), regarding factors to be considered as the Administrator finds relevant.

The final rule makes two additions to the list of factors that must regularly be considered in setting the aggregate production quotas because of their importance. First, it adds to the list the extent of any diversion of the controlled substance in the class, which will ensure that the allowed aggregate production quota is limited to that needed to provide adequate supplies for the United States' legitimate needs. Second, the final rule amends the list of factors to be considered in establishing these quotas to include relevant information from the Department of Health and Human Services (HHS) and its components, including the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS), as well as relevant information obtained from the states. The amendment will ensure that information will be requested from the relevant HHS components and will be considered in setting the aggregate production quotas.

The final rule provides that the Administrator will consider information from the states in setting the aggregate production quotas and make additional changes enhancing their role in § 1303.11(c). The states are critically situated to provide information about the extent of legitimate and illegitimate use of controlled substances because of their responsibilities for drug enforcement within their jurisdictions, including through the Prescription Drug Monitoring Programs (PDMP), their responsibilities for administration of their health care systems, and their responsibilities for dealing with the human and social costs of drug abuse and diversion. States may have relevant information indicating that individual procurement quota requests reflect quantities which will in fact be diverted to illicit use, which may in turn yield an exaggerated picture of the aggregate production quotas needed for legitimate purposes.

The final rule accordingly includes amendments to § 1303.11(c) which provide for (i) transmitting notices of proposed aggregate production quotas, and final aggregate production quota orders, to the state attorney general, and (ii) holding a hearing if necessary to resolve an issue of material fact raised by a state's objection to a proposed aggregate production quota as excessive in relation to legitimate United States need.

Section 1303.12 – Procurement quotas

Section 1303.12 currently directs the Administrator to issue procurement quotas for manufacturers that use controlled substances to put them into dosage form or to make other substances. The section requires applicants for procurement quotas to state what basic class of controlled substance is needed, the purpose or purposes for which the class is desired, the quantity desired for each purpose during the next calendar year, and the quantities used and estimated to be used for each purpose during the current and preceding two calendar years.

If the applicant's purpose is to manufacture another basic class of controlled substance, the applicant also must state the quantity of the other basic class that the applicant has applied to manufacture, and the quantity of the first basic class necessary to manufacture a specified quantity of the second basic class.

The final rule amends § 1303.12(b) to clarify that the Administrator may require additional information from applicants that may help to detect or prevent diversion, including customer identities and amounts of the controlled substance sold to each customer.

Section 1303.13 – Adjustments of aggregate production quotas

Section 1303.13 authorizes the Administrator, at any time, to increase or reduce the aggregate production quotas for basic classes of controlled substances that were previously fixed pursuant to § 1303.11. The final rule in § 1303.13 parallels some of the amendments made to § 1303.11. Specifically, it includes changes in the extent of any diversion of the controlled substance among the factors to be considered in adjusting the aggregate production quota, requires transmission of adjustment notices and final adjustment orders to the state attorneys general, and provides for a hearing if necessary to resolve an issue of material fact raised by a state's objection to a proposed adjusted quota as excessive for legitimate United States need.

Section 1303.22 – Procedure for applying for individual manufacturing quotas.

The final rules amends § 1303.22 to clarify that the Administrator may require additional information from individual manufacturing quota applicants that may help to detect or prevent diversion, including customer identities and amounts of the controlled substance sold to each customer.

Section 1303.23 – Procedures for fixing individual manufacturing quotas.

The final rule amends § 1303.23 to provide that the factors the Administrator may deem relevant in fixing individual manufacturing quotas include the extent and risk of diversion of controlled substances.

Section 1303.32 – Purpose of hearing

The final rule includes an amendment relating to hearings in § 1303.32(a), conforming to the amendments to §§ 1303.11(c) and 1303.13(c) concerning hearings based on state objections.

Other matters

In addition to the significant changes discussed above, the final rule corrects a number of typographic errors in the current regulations.

Notice of Proposed Rulemaking

On April 19, 2018, the DEA published a notice of proposed rulemaking (NPRM) in the *Federal Register*, which provided an opportunity for comment on the proposed rule. The comment period closed on May 4, 2018. 83 FR 17329. The DEA specifically sought comments on the provisions regarding the factors the Administrator should consider when adjusting the aggregate production quotas (21 CFR 1303.13(b)(1)), and the additional information the Administrator may require from applicants (21 CFR 1303.12(b) and 21 CFR 1303.22).

Discussion of Comments

DEA received a total of 1,561 written and electronic comments on the NPRM. In the NPRM, the DEA stated that some of the proposed rule's provisions relating to seeking information from other federal agencies and the states (21 CFR 1303.11(b)(6)) and those relating to the holding of hearings based on state objections (21 CFR 1303.11(c), 21 CFR

1303.13(c), and 21 CFR 1303.32(a)) were exempt from the notice and comment requirements of the Administrative Procedure Act as "rules of agency organization, procedure, or practice." 5 USC 553(b)(A). However, many commenters still addressed these two issues. While the DEA appreciates the interest commenters have shown in these areas, because they were exempt from the notice and comment requirements of the APA, the DEA has not considered these comments in its promulgation of this final rule.

After a review of the comments, DEA noted that there were six main issues that commenters raised, and that many commenters raised multiple issues in their comments. Each issue is summarized below, along with the DEA's responses. The DEA has also summarized the remainder of the comments which did not fit into one of the six main issues.

A. Causes for the increase in opioid deaths

Issue: Approximately 156 commenters raised the issue that the increase in opioid deaths was due to illicitly manufactured opioids coming in from Mexico and China and errors in reporting deaths involving multiple substances, not written prescriptions for controlled substances. Advocacy groups and the general public voiced concern about the accuracy of CDC death calculations that they believe led to more strict quotas on the pain pills they need to live, instead of focusing on the issue of illicitly manufactured substances like fentanyl and heroin.

One advocacy group noted that available data indicated that the large increase in overdose deaths was largely due to illicitly manufactured fentanyl, heroin, and synthetic opioids, not prescription opioids. The advocacy group stated that the data reinforced the need to address the growing threat posed by heroin, counterfeit fentanyl, and other counterfeit drugs.

An association representing physicians also noted that although the rate of prescription opioid mortality continues to rise, illicit fentanyl and heroin have become the main contributors to opioid-related mortality.

A coalition commented that a major issue with the proposed rule was that it would do nothing to solve the current opioid epidemic because illicit fentanyl and heroin cause most of the overdoses in the United States, not prescription opioids. The coalition referenced journal articles for statistics to support their argument. The coalition also noted that the vast majority of the illicit fentanyl that is arriving into the United States is coming from China through the U.S. Postal Service, and that the policies in the proposed rule would have no effect on the current number of overdose deaths.

One law firm noted that after a re-evaluation of CDC data and DEA's own analyses, it has become evident that the current opioid "crisis" is caused by illicit synthetic opioids, particularly fentanyl and deadlier fentanyl derivatives with no medical use.

DEA Response: This final rule does not establish specific quotas. Instead, this final rule revises and improves the process for DEA to follow in gathering information and taking other actions pertaining to quotas. The CDC has acknowledged that they have a new analysis confirming recent increases in drug overdose death[1], however, as stated in the NPRM, the CDC's data will not be the only source of information the DEA will be considering. The DEA will also consider relevant information from other components of HHS, as well as relevant information from the States.

The DEA believes that the misuse of controlled prescription drugs (CPDs) is inextricably linked with the threat the United States faces from the trafficking of heroin and illicit

[1] https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html

fentanyl and fentanyl analogues. In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain relievers within the past month.[2] Roughly 75 percent of heroin users reported nonmedical use of prescription opioids before using heroin (though the vast majority of individuals misusing opioid CPDs do not go on to use heroin).[3] Many stated that they first obtained these drugs for free from the family medicine cabinet or from friends[4] but then sought street or black market drugs to maintain their addiction. This illustrates the role that CPDs have played in the opioid epidemic and underscores the continued need for robust regulatory and enforcement measures to stop diversion of CPDs. Black-market sales for opioid CPDs are typically five to ten times their retail value, and DEA intelligence reveals the "street" cost of prescription opioids steadily increases with the relative strength of the drug.

B. The Injectable Shortage and Adjusting the Quota Process

Issue: The DEA received 23 comments concerning how manufacturing quotas may cause a shortage of injectable opioids. Commenters were concerned that injectable opioids that are used routinely for surgeries and cancer treatment, such as injectable morphine, hydromorphone, and fentanyl would not be available to hospitals and patients. Commenters attributed the perceived shortages of these drugs to manufacturing setbacks and a government effort to restrict the amount of opioids and other pain medicines to be manufactured.

[2] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[3] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. (2014). The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMA Psychiatry.71(7):821-826.

[4] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

Commenters stated that due to the alleged shortage of these drugs, hospitals are having a difficult time treating patients and finding alternatives for pain management.

Many commenters stated that the DEA is focusing on the wrong issues. A majority asserted that synthetic drugs are the cause of most of the overdose opioid deaths, and that the government should focus on those synthetic drugs instead of creating regulations that they feel lead to a reduction in injectable opioids.

Comments received from organizations and associations asserted that there is no risk of diversion for injectables. It was stated numerous times that the DEA should consider adding drug shortage information as a factor when establishing and adjusting quotas. It was also recommended that the DEA add the intent to resolve drug shortages to the relevant factors considered in adjusting quotas.

DEA Response: The DEA is committed to ensuring that quotas are set in such a way as to grant manufacturers the ability to provide FDA-approved drug products to meet the demand of the legitimate medical, scientific, and export needs of the United States. As required in 21 U.S.C. 826(h), when there is a shortage, the DEA will "increase the aggregate and individual production quotas and any ingredients therein to the level requested." When it is determined that the level requested is not necessary to address a shortage, the DEA provides a written response detailing the basis for the decision. 21 U.S.C. 826(h)(1)(B)(ii). Quotas granted to the dosage form manufacturers based on legitimate medical need will always be considered in the aggregate production quota. The DEA will always take into consideration any changes in market dynamics that may require allocation of individual manufacturers' quotas or revisions of the aggregate production quota. The DEA, however, cannot set quotas based on individual pharmaceutical dosage forms (21 U.S.C. 826(a)) nor

can DEA compel manufacturers to manufacture specific individual pharmaceutical dosage forms even though the latter may lead to manufacturer induced shortages based on their internal business decisions. Thus, independent of DEA's adjustment of quotas, manufacturers' business decisions and manufacturing practices may lead to a shortage of certain individual pharmaceutical dosage forms, despite the adequacy of the applicable aggregate production quota.

C. The DEA's methodology for quantifying diversion

Issue: The DEA received 16 comments regarding DEA's methodology for determining quantities of controlled substances being diverted. Three commenters recommended that the DEA obtain data from HHS, CDC, and CMS on topics such as patterns of drug abuse, and that such information be considered for calculating aggregate production quota. The same commenters suggested that the information from HHS, CDC, and CMS can contribute to appropriate methods for determining quantities of controlled substances being diverted. Another commenter stated that the DEA does not distinguish between diversion and abuse when considering the quota formula. Seven commenters stated that DEA does not have reliable measures to calculate diversion of controlled substances. One of these commenters stated that DEA did not provide any examples or explanations on how DEA will collect measureable data. Two commenters suggested that DEA obtain data from the FDA on controlled substances shortages (which can be broken down by dosage) to help the DEA quantify a clear picture of diversion risks by the specific dosage forms. Another commenter stated that DEA did not provide any scientific data that supports DEA claim that quota reductions decrease diversion of controlled substances.

One commenter suggested DEA work on anti-diversion legislation that will put requirements in place during the manufacturing process to prevent diversion of controlled substances so it will not affect quotas. Another commenter requested DEA to provide quantitative evidence to show the impact current reductions have had on diversion of controlled substances.

DEA Response: The DEA is committed to continuously developing sound and reliable methods for determining quantities of controlled substances being diverted. Currently, DEA's reliable method to measure the diversion of controlled substances occurs at the level of individual dosage manufacturers rather than at the aggregate production quota level. Selected opioid dispositions from these manufacturers are compared to known, completed regulatory and operation enforcement actions and counted toward diverted quantities for individual manufacturers and not the aggregate production quota itself.

Modifications to section 1303.11 would allow relevant information from appropriate HHS components to be considered in setting the aggregate production quota. HHS studies the use and misuse of controlled substances regarding the quantities of controlled substances necessary to support the medical needs in the United States pursuant to 42 U.S.C. 242(a). Furthermore, the CDC and the CMS may have relevant information related to the patterns of drug abuse and the diversion of controlled substances for illicit use which DEA will also consider when setting the aggregate production quota. The information collected from HHS through FDA, CDC, and CMS, and that collected from the states, will improve DEA's ability to distinguish diversion of controlled substances at a more geographically localized level. The information collected will enhance the DEA's ability to determine registrant's compliance with suspicious order monitoring regulations. The modifications to section

1303.22 will allow the Administrator to require additional information from manufacturing quota applicants that will assist the DEA in detecting or preventing diversion of controlled substances.

The Administrator of the DEA has the authority to determine the total quantity of each basic class of controlled substance listed in Schedule I or II needed in each calendar year for medical, scientific, research and industrial needs of the United States, for lawful export, and for the establishment and maintenance of reserve stocks. The DEA has observed a decline for certain prescriptions written for Schedule II opioids since 2014 which can be attributed to federal and state government activities and interventions, including the implementation of Prescription Drug Monitoring Programs, enforcement of current regulations, and guidance documents such as the CDC *Guideline for Prescribing Opioids for Chronic Pain* – United States March 2016.

D. Trend in the number of prescriptions written for controlled substances

Issue: The DEA received 36 comments from commenters stating that prescription data shows that there has been a downward trend in the prescribing of controlled substances for the last several years, therefore prescription opioids are not responsible for the current opioid epidemic. As such, the commenters believed there was no need for the regulations to be updated. There were comments received from patients describing their inability to receive prescriptions for pain medications; they stated that their doctors had placed blame on the DEA.

DEA Response: The DEA acknowledges that prescriptions for opioid drug products have decreased over the last several years due to the stepped up civil, criminal, and regulatory enforcement efforts of the agency. However, while there is a downward trend in

prescribing, these schedule II prescription opiates continue to have a high potential for abuse and dependence and require the annual assessment of quotas. These decreases can be attributed to DEA's 360 Strategy, which combines local, state, and federal activities and interventions, including creating new partnerships, enforcing current regulations, and dissemination of provider education and guidance documents, including the CDC *Guideline for Prescribing Opioids for Chronic Pain* released in March 2016. In addition, more states have enacted and are enforcing laws mandating the use of PDMPs by medical providers and pharmacists, which provides prescribers with valuable information to guide their medical decisions.[5] As such, this final rule will allow the downward trend to continue through the continued sharing of information from different HHS components and states.

E. Fifteen day comment period

Issue: The DEA received 5 comments from commenters who felt the proposed rule's comment period was too short. One commenter suggested that the comment period remain open for 180 days because of the complex issues being addressed in the document. Two commenters voiced displeasure with the length of the comment period stating that it made it seem like the average citizens' opinion was not being valued.

One national organization noted that the comment period provided by the DEA was unusual in its brevity. The national organization referenced Executive Order 13563, as well as guidance from the Administrative Conference of the United States, to suggest that the DEA comment period should have at least been 30 days since it was a rulemaking that was not considered "significant." The national organization stated that they were not certain that

[5] *Challenges and Solutions in the Opioid Abuse Crisis: Hearing Before the H. Comm. On the Judiciary*, 115th Cong. 6,10 (2018) (statement of Robert W. Patterson, Acting Administrator, Drug Enforcement Administration).

the additional 15 days necessary to achieve the 30-day period for review and input by experts outside of the agency would meaningfully "impede putting into effect the diversion countermeasures [the proposal] authorizes."

DEA Response: The APA does not specify a minimum time for submission of written comments. Agencies must provide the public with a "meaningful opportunity" to comment on a proposed notice. *Rural Cellular Ass'n v. FCC, 588 F.3d 1095* (D.C. Cir. 2009). While the length of the comment period is a factor in determining whether the public was afforded a "meaningful opportunity" to comment, courts have upheld comment periods of less than 30 days. *See, e.g. Omnipoint Corp. v. FCC, 78 F.3d 620* (D.C. Cir. 1996)(upholding 15-day comment period where there was "urgent necessity for rapid administrative action under the circumstances" and the public was not harmed).

Under Executive Order 13563, there is a presumption that a period of 60 days should be allotted for the comment period. The Administrative Conference of the United States' recommendations serve as guidance for the notice-and-comment period. While they recommend 30 to 60 days depending on the significance of a rule, they also recommend that agencies provide an explanation when they set a shorter comment period, as was done in the NPRM. 76 FR 48,791 (Aug. 9, 2011).

Here, the DEA received more than 1,500 comments, many of which included a thoughtful and detailed analysis. Due to the opioid epidemic as expressed in the proposed rule and the urgent need to finalize this rule, the 15-day comment period was sufficient.

F. Clarification of what additional data DEA may seek from registrants.

Issue: There were 11 comments received seeking clarification of what additional information the Administrator may require from registrants. The majority of the comments

received were from industry and advocacy groups. While they agreed that steps need to be taken to address the current opioid epidemic, the views were not completely in support of the possibility of having to turn in additional information.

One company felt the proposed changes seemed to codify the current practice of considering ARCOS (Automated Reporting and Consolidated Orders System) data when setting quotas. Many comments under this issue suggested that the DEA clearly detail what information would be required. A trade group also explained that knowing what the DEA could request beforehand would allow manufacturers the ability to ensure that systems are in place to collect and provide relevant data in a timely manner. The group felt that the DEA should determine whether additional data should be required beyond what is already required for schedule II controlled substances by way of the DEA Form 222. The group also requested that the DEA make sure that any additional requested information not place an undue burden on manufacturers or delay the issuance of initial quotas. They argued that DEA needs to include adequate protection of proprietary and sensitive commercial and financial information provided by the manufacturers, because the additional data allowed for the collection of trade secrets or confidential commercial information. One association asked for the additional data to be used in a timely fashion to help anticipate and address potential shortages in the future. Another organization strongly objected to the proposed rule, because they did not see how the additional information could be useful in reducing opioid abuse and overdose when the main source of the problem is illicit drugs.

A pharmaceutical company requested that the DEA provide opportunities for companies to receive guidance and training on how to best satisfy the additional information requirements. Another pharmaceutical company stated they contract with Contract

Manufacturing Organizations (CMO) for the manufacturing of their finished drug products, and that because of this the CMO would be the actual quota applicant but would not be equipped with the additional information to help in detecting and preventing diversion.

Two states commented on this issue and both applauded the DEA for taking action. West Virginia stated that obtaining additional information would be helpful because some of the legitimate demand may be double counted by way of multiple applicants relying on the same amounts of legitimate demand from the same customers. West Virginia's view was that the additional information will allow the DEA to prevent excess quota levels. Ohio also agreed with the proposed rule and encouraged the DEA to consider a more rigorous and information-driven quota application process.

DEA Response: The DEA acknowledges that the CSA's requirement for allotting quotas for manufacturers was enacted on the business model of a vertically integrated system. Since its enactment, manufacturers have determined new and innovative ways of conducting business, as a response to a more robust, competitive market. While the CSA allows for adequate domestic competition, it also limits this competition to the legitimate medical, scientific, and industrial needs of the United States. The DEA has always had the ability to request information to clarify and support a manufacturer's request for quota to ensure that any quota granted is limited to legitimate need. Detailed information about what may be requested for clarification or support cannot be provided because the request would be on a case-by-case basis. DEA does not provide a list of additional items needed to process quotas because they may not pertain to every registrant. Therefore, additional data will be determined in light of the information manufacturers provide to the DEA as justification for a quota.

Manufacturers of schedule I and II substances provide information needed to assist the DEA in making a quota determination. The information provided is based on their individual business activities. Regulations require manufacturers to utilize DEA Form 222[6] to document purchase and disposition information between DEA registrations; similar information is also transmitted to ARCOS. A limitation of ARCOS can be the reporting period a company opts to report their data (monthly or quarterly) and the timeliness of corrections to any errors in the reported data. There is no undue burden or cost to supply this information because it is already being captured in some form by the company per CSA regulations and good business practices.

The DEA communicates with registrants who have pending quota applications via telephone or email when necessary, to request clarification or additional information required to process their applications in a timely manner. The DEA also maintains an e-mail box that registrants may preemptively supply information and communicate concerns related to quota requirements. Appropriate safeguards are currently in place to protect confidential business information.

As stated above, requesting clarification or additional information is a current practice of DEA. The DEA provides training conferences annually, in strategic locations, to help registrants understand quota and reporting requirements. The agency also provides the presentations from the trainings on the DEA website. During these conferences, DEA explicitly states it never provides confidential and proprietary information supplied by registrants to outside sources. The additional information that may be requested is important

[6] 21 CFR 1305.11 -1305.19.

and an integral part of the analysis as it helps DEA determine the amount of quota a manufacturer should be granted.

G. Other Comments

Approximately 1,300 comments were received from the general public expressing concerns about the proposed regulations affecting their ability to get their prescriptions, and the possibility of drug shortages being created because of the proposed rule. The DEA understands and appreciates the nature of the comments. It is not the DEA's intent to create shortages or prevent a patient with a legitimate need from getting their prescription. The purpose of the proposed rule is to improve the process of setting the annual quota while ensuring an adequate supply is available for the United States' legitimate needs.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this final rule and by approving it certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The DEA estimates that 325 manufacturers may be affected by the final rule, of which 301 manufacturers (92.6% of the total) are small entities. There will not be a significant economic impact on a substantial number of these small entities or any others because, as the ensuing certifications discuss, any overall cost of the rule is not significant.

Executive Orders 12866, 13563, and 13771 – Regulatory Planning and Review, and Reducing Regulation and Controlling Regulatory Costs

This regulation has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review," section 1(b), Principles of Regulation, and Executive Order 13563, "Improving Regulation and Regulatory Review." The DEA has

determined that this final rule is not a "significant regulatory action" under Executive Order 12866, section 3(f). The DEA analyzed the economic impact of each provision of this final rule. Section 1303.11 is amended to make two additions to the list of factors to be considered by the Administrator in setting the aggregate production quotas. First, it adds the extent of any diversion of the controlled substance in the class. Second, it adds relevant information from HHS and its components, as well as from the states. The DEA has always considered any information obtained from other federal and state government agencies when fixing the aggregate production quotas for a controlled substance. While the DEA may receive additional information that is valuable in detecting and preventing diversion, the DEA has no reason to believe that there will be adverse economic impact or other consequences sufficient to implicate Executive Order (EO) 12866.

Additionally, §§ 1303.11 and 1303.13 are amended to require the DEA to transmit copies of aggregate production quotas and any adjustments to those quotas published in the *Federal Register* directly to state attorneys general. While the DEA anticipates some labor burden to transmit aggregate production quota notices and orders to each state attorney general, the DEA estimates that this activity will result in a minimal yearly cost to the DEA and that the DEA has sufficient resources to absorb this minimal cost.

Additionally, §§ 1303.11, 1303.13, and 1303.32 are amended to explicitly state that the DEA Administrator shall hold a hearing if he or she determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed quantity for the class as excessive for legitimate United States need. The estimated yearly cost of this revision will be dependent on the number of hearings the DEA Administrator determines to be necessary to resolve an issue of material fact raised by a state regarding the aggregate production quota.

Hearings regarding aggregate production quotas are infrequent and the DEA estimates that hearings of this type will continue to be infrequent under this final rule. For these reasons, the DEA does not expect a material increase in the number of hearings or in the associated costs to DEA or the states.

Sections 1303.12 and 1303.22 are amended to explicitly state that the Administrator may require additional information from an individual manufacturing or procurement quota applicant, including customer identities and amounts of controlled substances sold to each of their customers. Currently, the DEA can and does request additional information of this nature from quota applicants if deemed necessary. While affording the Administrator express regulatory authority to require such information may result in the receipt of additional information that is valuable in detecting and preventing diversion, it is not expected that the difference will have adverse economic impact or other consequences sufficient to implicate EO 12866.

Sections 1303.11, 1303.13, and 1303.23 are amended to add the requirement that the DEA consider diversion of a controlled substance when fixing aggregate production quotas, adjusting aggregate production quotas, and fixing individual manufacturing quotas. When fixing and adjusting the aggregate production quota, or fixing an individual manufacturing quota for a controlled substance, the DEA has always considered all available information regarding the diversion of that controlled substance. While the final rule's amendments, as discussed above, may result in the receipt and consideration of additional information relating to diversion, it is not expected that the difference will have adverse economic impact or other consequences sufficient to implicate EO 12866.

This final rule is not an EO 13771 regulatory action because this final rule is not significant under EO 12866.

Executive Order 13132 – Federalism

This regulation will not have substantial direct effects on the states, on the relationship between the national Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Executive Order 12988 – Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Paperwork Reduction Act

This final rule codifies current agency practice under existing approved information collections, and does not impose new information collection requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3521.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rulemaking is not a major rule as defined by section 251 of the Congressional Review Act. 5 U.S.C. 804. This final rule will not result in an annual effect on the economy

of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects in 21 CFR Part 1303

Administrative practice and procedure, Drug traffic control.

Accordingly, for the reasons stated in the preamble, part 1303 of title 21 of the Code of Federal Regulations is amended as follows:

PART 1303 – QUOTAS

1. The authority citation for part 1303 continues to read as follows:

Authority: 21 U.S.C. 821, 826, 871(b).

2. In § 1303.11:

a. Remove the word "and" at the end of paragraph (b)(4).

b. Redesignate paragraph (b)(5) as paragraph (b)(7).

c. Add new paragraph (b)(5) and paragraph (b)(6).

d. Revise paragraph (c).

The additions and revision read as follows:

§ 1303.11 Aggregate production quotas.

* * * * *

(b) * * *

(5) The extent of any diversion of the controlled substance in the class;

(6) Relevant information obtained from the Department of Health and Human Services, including from the Food and Drug Administration, the Centers for Disease Control

and Prevention, and the Centers for Medicare and Medicaid Services, and relevant information obtained from the states; and

* * * * *

(c) The Administrator shall, on or before May 1 of each year, publish in the FEDERAL REGISTER, general notice of an aggregate production quota for any basic class determined by him under this section. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made. The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him, except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed quantity for the class as excessive for legitimate United States' needs. In the event the Administrator decides to hold a hearing, he shall publish notice of the hearing in the FEDERAL REGISTER, which notice shall summarize the issues to be heard and shall set the time for the hearing, which shall not be less than 30 days after the date of publication of the notice. After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the FEDERAL REGISTER his final order determining the aggregate production quota for the basic class of controlled substances. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A copy of said order shall be mailed simultaneously to

each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general.

3. In § 1303.12, paragraph (b), add after the fifth sentence a new sentence to read as follows:

§1303.12 Procurement quotas.

* * * * *

(b) * * * The Administrator may require additional information from an applicant which, in the Administrator's judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer. * * *

* * * * *

4. In § 1303.13, revise paragraphs (b)(1) and (c) to read as follows:

§ 1303.13 Adjustments of aggregate production quotas.

* * * * *

(b) * * *

(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;

*** * * * ***

(c) The Administrator in the event he determines to increase or reduce the aggregate production quota for a basic class of controlled substance, shall publish in the FEDERAL REGISTER general notice of an adjustment in the aggregate production quota for that class determined by him under this section. A copy of said notice shall be mailed simultaneously

to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made. The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him, except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed adjusted quota as excessive for legitimate United States' needs. In the event the Administrator decides to hold a hearing, he shall publish notice of the hearing in the FEDERAL REGISTER, which notice shall summarize the issues to be heard and shall set the time for the hearing, which shall not be less than 10 days after the date of publication of the notice. After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, 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 order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A copy of said order shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general.

§ 1303.21 [Amended]

5. In § 1303.21, in paragraph (a), remove "§§" in the second sentence and add in its place "§".

6. In § 1303.22:

a. In paragraph (c)(2), remove the word “econolic” and add in its place the word “economic”.

b. Add paragraph (d).

The addition reads as follows:

§1303.22 Procedure for applying for individual manufacturing quotas.

* * * * *

(d) The Administrator may require additional information from an applicant which, in the Administrator’s judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer.

§ 1303.23 [Amended]

7. In § 1303.23, add the phrase “the extent of any diversion of the controlled substance,” after “strikes),” in paragraph (a)(2), and add the phrase “any risk of diversion of the controlled substance,” after “strikes),” in paragraph (b)(2).

§ 1303.32 [Amended]

8. In § 1303.32, in paragraph (a), add the phrase “and shall, if determined by the Administrator to be necessary under § 1303.11(c) or 1303.13(c) based on objection by a state,” before “hold a hearing”.

Dated: July 11, 2018

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Uttam Dhillon,
Acting Administrator.

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