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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:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration (DEA) is publishing this proposed rule to strengthen 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:** Written comments must be postmarked, and electronic comments must be sent, on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail will be considered timely if they are postmarked on or before the last day of the comment period. The electronic Federal Docket Management System will accept electronic comments until Midnight Eastern Time at the end of that day.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-480" on all correspondence, including any attachment. 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 to 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 the electronic submission are not necessary and are discouraged. Should you, however, 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/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**POSTING OF PUBLIC COMMENTS:** Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov> and in DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket 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 posted online or made available in the public docket, 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. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "FOR FURTHER INFORMATION" paragraph.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-8953.

**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 proposed 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 proposed 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**

#### *Section 1303.11 – Aggregate production quotas*

Section 1303.11 in the existing regulations 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, and for the establishment and maintenance of reserve stocks. Section 1303.11(b)(1)-(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 proposed rule would make two additions to the list of factors that must regularly be considered in setting the aggregate production quotas because of their importance.

First, it would add to the list the extent of any diversion of the controlled substance in the class. This is relevant to ensure that the allowed aggregate production quota is limited to that needed to provide adequate supplies for the United States' legitimate needs.

Second, the proposed rule would amend 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. Pursuant to 42 U.S.C. 242(a), HHS studies the use and misuse of controlled substances and provides, through the FDA, an annual report to the Attorney General concerning the quantities of controlled substances necessary to support the medicinal needs of the United States. The CDC and the CMS may also have relevant information, including information about the prevalence and patterns of drug abuse and the diversion of controlled substances to

illicit use. The amendment would ensure that information will be requested from the relevant HHS components and will be considered in setting the aggregate production quotas.

Regarding the states, the proposed rule would provide 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, 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 proposed 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 in the regulations 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 proposed rule would amend § 1303.12(b) to clarify that the Administrator may require additional comparable 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 proposed rule would make amendments to § 1303.13 that parallel 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 attorney 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 proposed rule would amend § 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 proposed rule would amend § 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 proposed 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 proposed rule would correct a number of typographic errors in the current regulations.

**Request for Comments**

Some of the proposed rule's provisions, including those relating to seeking information from other federal agencies and the states, and those relating to the holding of hearings based on state objections, are exempt from the notice and comment requirements of the Administrative Procedure Act as "rules of agency organization, procedure, or practice." 5 U.S.C. 553(b)(A). Regarding the other matters addressed in the proposed rule, DEA particularly seeks comments on the provisions regarding the factors the Administrator shall 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).



Insofar as soliciting public comment is necessary or useful, DEA publishes this proposed rule with a 15-day public comment period. This shortened period for public comment is necessary as an element in addressing the largest drug crisis in the nation's history. HHS and DEA have developed extensive information concerning the nature and magnitude of the crisis. See [www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html](http://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html); [www.cdc.gov/drugoverdose/data](http://www.cdc.gov/drugoverdose/data) (CDC Epidemic Data); [www.cdc.gov/nchs/products/databriefs/db294.htm](http://www.cdc.gov/nchs/products/databriefs/db294.htm) (CDC Overdose Data); [www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf](http://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf) (SAMHSA Data); [www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis](http://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis) (NIDA Data); Drug Enforcement Administration, 2017 National Drug Threat Assessment (Oct. 2017), at v, 25-43 (2017 DEA Data). Salient facts include the following:

Drug overdoses are now the leading cause of injury-related death in the United States, eclipsing deaths from motor vehicle accidents, firearms, homicide, or suicide. There were more than 63,600 overdose deaths in 2016, with opioids as the main driver of such deaths. Overdoses involving opioids killed more than 42,000 people in 2016, with prescription opioids accounting for 40% of the total. Opioid overdose deaths were more than five times higher in 2016 than 1999. 2017 DEA Data at v, 25; CDC Overdose Data; CDC Epidemic Data.

The misuse of controlled prescription drugs, and particularly prescription opioids, has been central to this deadly epidemic. In 2016, of Americans aged 12 or older, an estimated 3.3 million had misused prescription pain relievers during the preceding month and approximately 11.8 million had misused opioids in the past year. Prescription opioid misuse

is more common than use of any category of illicit drug in the United States except for marijuana. SAMHSA Data at 14, 16, 20-21.

Users may be initiated into a life of substance abuse and dependency after first obtaining these drugs from their health care providers or without cost from the family medicine cabinet or from friends. Once ensnared, dependency on potent and dangerous street drugs may ensue. About 80% of heroin users first misused prescription opioids. Thus, it may be inferred that current users of heroin and fentanyl largely entered the gateway as part of the populations who previously misused prescription opioids. See NIDA Data.

Street prices for controlled prescription opioids are typically 5 to 10 times their retail value, with steady increases with the relative strength of the drug, fueling the market for prescription medications diverted into illegal channels. For example, hydrocodone combination products – a schedule II prescription drug and also the most prescribed controlled prescription drug in the country – can be purchased for \$5 to \$7 per tablet on the street. Slightly stronger drugs like oxycodone combined with acetaminophen (e.g., Percocet) can be purchased for \$7 to \$10 per tablet on the street. Even stronger prescription drugs are sold for as much as \$1 per milligram (mg). For example, 30 mg oxycodone (immediate release) and 30 mg oxymorphone (extended release) cost \$30 to \$40 per tablet on the street. Due in part to the large number of people who abuse licit controlled prescription drugs, other opioids are now being disguised and sold as controlled prescription drugs.

The economic impact of prescription drug abuse was estimated to be \$78.5 billion in 2013. Specific costs included increased health care and substance abuse treatment costs, criminal justice costs, and employment-related costs including lost earnings from premature death, reduced compensation, and lost employment. These costs, largely reflecting

prescription opioid abuse, represent a substantial and growing economic burden on society. 2017 DEA Data at 40.

This proposed rule's reforms, which will help to control the diversion of controlled substances feeding the crisis described above, must be implemented without delay to permit timely action by the Drug Enforcement Administration, informed by adequate input from manufacturers, other federal agencies, and the states. The affected determinations include the following:

Section 1303.11 in the regulations requires the DEA Administrator to publish notice of the proposed aggregate production quotas for 2019 well in advance in 2018. The proposed rule's amendments to § 1303.11 would expand the factors to be considered by the Administrator to include the extent of diversion and enhance the input and role of other federal agencies and the states in the quota-setting process. Having these reforms in place expeditiously will facilitate the sound proposal and determination of aggregate production quotas for 2019.

Section 1303.12 requires the Administrator to set manufacturers' procurement quotas for 2019 well in advance in 2018; manufacturers' applications were due by April 1, 2018. The proposed rule would amend § 1303.12 to allow the Administrator to require procurement quota applicants to provide additional information that may help to detect or prevent the diversion of controlled substances ostensibly obtained for legitimate dosage form manufacturing. Having this reform in place expeditiously will facilitate the sound determination of procurement quotas for 2019 and help to ensure that controlled substances sought for dosage form manufacturing will not be diverted.

Section 1303.13 allows the Administrator to increase or reduce aggregate production quotas at any time. The proposed amendments would expand the factors to be considered by the Administrator in adjusting aggregate production quotas to include changes in the extent of diversion and make other changes to enhance the input and role of the states in the aggregate production quota adjustment process. Having these reforms in place expeditiously, as well as the amendments to other sections authorizing the requisition of more information from manufacturers bearing on the extent of diversion, will facilitate the sound determination of aggregate production quota adjustments by the Administrator, which may be undertaken at any time.

Sections 1303.22 and 1303.23 require the Administrator to set individual manufacturing quotas for 2019 well in advance in 2018, based on applications the manufacturers must submit by May 1, 2018. The proposed rule's amendments to these sections would authorize the Administrator to require applicants to provide additional information that may help to detect or prevent diversion, and add the extent and risk of diversion to the factors the Administrator may deem relevant in fixing individual manufacturing quotas. Having these reforms in place expeditiously will facilitate the sound determination of the individual manufacturing quotas for 2019.

In sum, the death of over 63,600 Americans from drug overdoses in 2016, and the other human, social, and economic costs detailed above, make imperative the immediate use of all available tools to prevent the diversion of controlled substances. Delay in the finalization and implementation of this proposed rule would impede putting into effect the diversion countermeasures it authorizes, which will help to stem a source of the flow of controlled substances with legitimate uses into illicit channels. Such delay would prevent in

the meantime the alleviation of the toll on human life and health, and the devastating social and economic costs, which shortfalls in the existing regulations facilitate.

### **Regulatory Flexibility Act**

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this proposed 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 proposed 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.” DEA has determined that this proposed 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 proposed rule. Section 1303.11 would be amended to make two additions to the list of factors to be considered by the Administrator in setting the aggregate production quotas. First, it would add the extent of any diversion of the controlled substance in the class. Second, it would add 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, sections 1303.11 and 1303.13 would be 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 attorney 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, sections 1303.11, 1303.13, and 1303.32 would be 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 amount 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 proposed 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 would be 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 would be amended to add the requirement that 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 proposed 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 proposed rule is not expected to be an EO 13771 regulatory action because this proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.

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

**PART 1303 – QUOTAS**

1. The authority citation for 21 CFR part 1303 continues to read as follows:



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

2. In § 1303.11(b), remove the word “and” at the end of paragraph (4), redesignate paragraph (5) as paragraph (7), and add new paragraphs (5) and (6). The revision reads as follows:

**§ 1303.11 Aggregate production quotas.**

\* \* \* \* \*

(b) In making his determinations, the Administrator shall consider the following factors:

\* \* \* \* \*

(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\* \* \*

\* \* \* \* \*3. In § 1303.11(c), add the phrase “and transmitted to each state attorney general” before the period in the second sentence, add the phrase “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 need” before the period in the fourth sentence, remove the word “such” in the fifth sentence, add the phrase “, the Administrator” before “shall issue” in the sixth sentence, and add the phrase “and transmitted to each state attorney general” before the period in the final sentence.

4. In § 1303.12(b), add after the fifth sentence the following sentence: “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.”

5. In § 1303.13(b), revise paragraph (1) to read as follows:

**§ 1303.13 Adjustments of aggregate production quotas.**

\* \* \* \* \*

(b) In determining to adjust the aggregate production quota, the Administrator shall consider the following factors:

(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;

\* \* \* \* \*

6. In § 1303.13(c), add the phrase “and transmitted to each state attorney general” before the period in the second sentence, add the phrase “, 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 need” before the period in the fourth sentence, remove the word “such” in the fifth sentence, and add the phrase “and transmitted to each state attorney general” before the period in the final sentence.

7. In § 1303.21(a), remove “§§” in the second sentence and add in its place “§”.

8. In § 1303.22, add at the end a flush left sentence as follows: “The Administrator may require additional information from an applicant which, in the Administrator’s

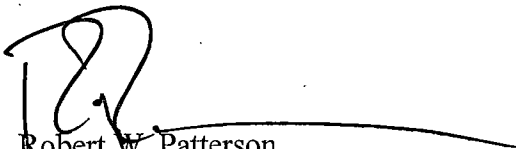
judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer.”

9. In § 1303.22(c)(2), remove the word “econolic” and add in its place the word “economic”.

10. 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).

11. In § 1303.32(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: 4-13-12

  
Robert W. Patterson,  
*Acting Administrator*