notifications disclosing all changes in membership.

On September 10, 2018, CONFERS filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on October 19, 2018 (83 FR 53106).

The last notification was filed with the Department on May 1, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 28, 2020 (85 FR 32049).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2020–26358 Filed 11–27–20; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Dynamic Spectrum Alliance, Inc.

Notice is hereby given that, on November 23, 2020, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Dynamic Spectrum Alliance, Inc. (''DSA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, The University of York, Heslington, UNITED KINGDOM; Amazon, Sunnyvale, CA; and Google, Mountain View, CA have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and DSA intends to file additional written notifications disclosing all changes in membership.

On September 1, 2020, DSA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on September 18, 2020 (85 FR 58390).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2020–26362 Filed 11–27–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on AC²AT–II

Notice is hereby given that, on November 19, 2020, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on Advanced Combustion Catalyst and Aftertreatment Technologies—II (''AC²AT–II'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Denso Corporation ''Client'', Aichi-ken, JAPAN, has withdrawn as a party to this venture. No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and AC²AT–II intends to file additional written notifications disclosing all changes in membership.

On February 6, 2019, AC²AT–II filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 28, 2019 (84 FR 6821).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2020–26361 Filed 11–27–20; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–688E]

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 2021

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2021 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: *Applicable Date:* Applicable November 30, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedule I and II and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

II. Background

The 2021 aggregate production quotas (APQ) and assessment of annual needs (AAN) represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2021 to provide for the estimated medical, scientific, research, industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled

substances for use in industrial processes.

On September 1, 2020, a notice titled ''Proposed 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 2021'' (hereinafter ''Proposed 2021 APQ'') was published in the **Federal Register**. 85 FR 54407. This notice proposed the 2021 APQ for each basic class of controlled substance listed in schedules I and II and the 2021 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed APQ and the proposed AAN on or before October 1, 2020.

III. Comments Received

Within the public comment period, DEA received 294 comments from DEA registrants, hospital associations, professional associations, doctors, nurses, health system organizations, State Attorneys General, and others. The comments included concerns over drug shortages due to further quota reductions from doctors and nurses, patients, and various health groups and hospital affiliations; requests for less interference in the doctor-patient relationship; concerns about the quota process with a request for public hearing; and comments not pertaining to DEA regulated activities.

The majority of the commenters expressed concerns regarding the potential adverse impact of the decrease to the APQ of controlled substances on the availability of pain-relieving prescription drugs for people with chronic pain. DEA received comments from four DEA-registered manufacturers regarding ten different schedule I and II controlled substances. Commenters stated the proposed APQ for ANPP, d-amphetamine (for conversion), fentanyl, hydrocodone (for sale), hydromorphone, lisdexamfetamine, morphine (for conversion), noroxymorphone (for conversion), oxycodone (for sale), and sufentanil be sufficient for manufacturers to meet medical and scientific needs. DEA has considered the comments for specific controlled substances in establishing the 2021 APQ.

DEA received no comments regarding the proposed established 2021 AAN for ephedrine, pseudoephedrine, and phenylpropanolamine.

A. Shortages

Issue: Some commenters expressed concerns about the decrease in certain APQ. These commenters alleged that decreases to the APQ have resulted in a shortage of injectable opioid medications and interfere with the treatment of patients. Some of these commenters also suggested that DEA separate quotas for solid oral controlled substances and injectable controlled substances, and urged DEA to utilize its discretionary authority under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act),[1] to establish APQ in terms of pharmaceutical dosage form for all schedule II controlled substances.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet the legitimate medical, scientific, and export needs of the United States. DEA sets APQ in a manner to provide for all dispensings authorized for legitimate medical purposes, and in turn, the APQ take into consideration both injectable opioids and solid oral opioids to meet the estimated medical needs of the United States. The SUPPORT Act allows, but does not require, DEA to grant quotas in terms of dosage forms if the agency determines that doing so will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. DEA believes that incorporating all dosage forms into the APQ, rather than allocating APQ by dosage form, allows the agency flexibility to adjust the individual quotas granted to manufacturers to alleviate any potential shortages and react to unforeseen emergencies. DEA believes the most accurate use of this authority would be in determining individual procurement quotas, if warranted under the circumstances. For example, if there was a shortage of any dosage form, the APQ would not need to be raised for manufacturers to produce that specific dosage form. Conversely, if multiple APQ for dosage forms were permitted, it is more likely that the APQ for that dosage form would need to be raised to respond to such a shortage before production could commence, thereby delaying the response time to the shortage.

Although DEA sets the APQ, it is possible that the business practices of manufacturers may lead to a shortage of controlled substances at the patient level, despite the adequacy of the APQ set by DEA. DEA can grant an individual quota to a manufacturer, and pursuant to the SUPPORT Act, also has the authority to grant individual manufacturing and/or procurement quotas for specific dosage forms; however, DEA cannot demand that the manufacturer utilize the quota immediately, nor does it have the authority to demand immediate production of dosage forms.

DEA and the Food and Drug Administration (FDA) are required to coordinate efforts to prevent or alleviate drug shortages pursuant to 21 U.S.C. 826(h) and maintain a collaborative working relationship. In addition, DEA and FDA have worked collaboratively. For example, in 2016 the domestic shortage of injectable controlled substances was alleviated by the importation of certain injectable controlled substances coordinated by the collaborated effort of FDA and DEA. The alleviation of this drug shortage did not require an adjustment to the APQ. Again in 2020, when hospitals informed DEA that there was a domestic shortage of injectable controlled substances due to the Coronavirus Disease of 2019 (COVID–19) health emergency, DEA collaborated with FDA to increase the appropriate APQ and individual quotas to allow for increased manufacturing of the specific drug products.

B. Pain Management Association Letters

Issue: DEA received comments that expressed concern that DEA's proposed reduction of opioids would adversely impact the availability of pain-relieving prescription drugs for people with chronic pain. The general concern is that lowering the APQ, which in turn decreases the amount available for physicians to write prescriptions, increases the probability that a physician cannot or will not prescribe such pain-relieving drugs.

DEA Response: DEA sets APQ in a manner to ensure that all prescriptions authorized for legitimate medical purposes can be filled. DEA does not set guidelines regarding patterns of prescribing medications, nor does DEA determine what dosage(s) are deemed ''medically necessary.'' Prescribers authorized to dispense controlled substances are responsible for adhering to the laws and regulations set forth under the CSA, which requires doctors to only write prescriptions for legitimate medical needs. Any practitioner issuing an invalid prescription for controlled substances and any pharmacy knowingly filling such a prescription would be in violation of the CSA.

C. Relevant Information Obtained From Health and Human Services (HHS) Agencies

Some commenters, including the State Attorneys General for West Virginia, Kentucky, Arkansas, and

[1] Public Law 115–271.

South Dakota, were concerned with DEA's use and/or analysis of relevant information from HHS, including: (1) Centers for Medicare and Medicaid Services (CMS) data on overprescribing; (2) FDA data; and (3) Centers for Disease Control and Prevention (CDC) data on overdose deaths.

CMS Data on Over-Prescribing

Issue: Some commenters expressed concern with DEA's use and interpretation of CMS data; particularly, in how such raw data would be used in the future to draw conclusions on the issue of overprescribing. Pain management associations questioned how DEA would distinguish between appropriate and inappropriate prescribing, and urged DEA to use ''nuanced and evidence-based means to draw distinctions between appropriate and inappropriate use.'' These associations also cautioned against misapplying dosage thresholds from CDC prescription guidance for schedule II substances to determine overprescribing rates.

DEA Response: As previously stated, DEA sets APQ in a manner to ensure that all prescriptions authorized for legitimate medical purposes can be filled. DEA does not set guidelines regarding patterns of prescribing medications, nor does DEA determine what dosage(s) can be deemed ''medically necessary.'' Prescribers authorized to dispense controlled substances are responsible for adhering to the laws and regulations set forth under the CSA, which require doctors to only write prescriptions for legitimate medical needs. Any practitioner issuing an invalid prescription for controlled substances and any pharmacy knowingly filling such a prescription would be in violation of the CSA.

As DEA discussed in the prior Proposed 2021 APQ, DEA contacted HHS and CMS, a component of HHS, to explore the possibility of using the agencies' data to estimate over prescribing. CMS informed DEA that the agency had reviewed its internal databases, and did not have the ability to systematically distinguish between appropriate and inappropriate prescriptions without investigating each prescription.

Issue: West Virginia, and joining state commenters, raised concerns that overprescribing, *i.e.,* opioids prescribed beyond actual medical needs, was not accounted for as part of diversion. The States noted that ''DEA has not accounted for illegitimate—but legal—demand for opioids through overprescribing.''

DEA Response: DEA sets APQ in a manner to ensure that all prescriptions authorized for legitimate medical purposes can be filled. Again, DEA does not set guidelines regarding patterns of prescribing medications, nor does DEA set guidelines as to what dosage(s) can be deemed ''medically necessary.'' Upon review of the studies cited in West Virginia's comment letter, DEA has determined that they are insufficient to support a reduction in the APQ. The studies cited found that for a variety of medical procedures, physicians prescribe more controlled substances for post-operative pain than patients utilize. While the referenced studies are concerning, DEA has concluded they are insufficient to support a determination on the level of overprescribing that occurs across the range of the medical procedures performed each year nationwide.

Prescribers authorized to dispense controlled substances are responsible for adhering to the laws and regulations set forth under the CSA, which require doctors to only write prescriptions for legitimate medical needs. Any practitioner issuing an invalid prescription for controlled substances and any pharmacy knowingly filling such a prescription would be in violation of the CSA. As DEA explores the possibility of using state Prescription Drug Monitoring Program (PDMP) data to estimate diversion, it may be possible to reliably discern over-prescribing on a national level and use this information to help determine the APQ. However, DEA does not currently have access to this data. Additionally, DEA previously attempted to use CMS data, but CMS did not have the ability to systematically distinguish between appropriate and inappropriate prescriptions without investigating each prescription.

FDA Data

Issue: West Virginia, and joining state commenters, took exception to DEA's response to FDA's projected levels of medical need for selected controlled substances, claiming that DEA outright rejected FDA recommendations.

DEA Response: DEA did not reject critical FDA ''recommendations.'' The term ''recommendation'' as used by the states appears to have been incorrectly interpreted; FDA only provided to DEA data that estimated legitimate domestic medical need. The data allowed DEA to estimate a collective decline in opioids to meet legitimate domestic medical need. Scientific, research, industrial needs, lawful export requirements, and the establishment and maintenance of reserve stocks are derived from information provided from quota applicants and research protocols submitted directly to DEA. On April 10, 2020, DEA published adjustments to the 2020 APQ for specific controlled substances identified by HHS COVID–19 treatment protocols, in order to allow manufacturers to meet the new and unforeseen medical need. 85 FR 20302. As explained in that notice, FDA's data was based on an analysis performed prior to the declaration of a national public health emergency due to COVID–19 by the HHS Secretary on January 31, 2020. DEA and HHS subsequently worked in concert to determine changes in legitimate medical need based on the unforeseen emergency posed by COVID–19, particularly the need of certain controlled substances required to treat patients on ventilators.

As stated in the Proposed 2021 APQ, DEA considered both the potential for diversion as well as the anticipated increase in demand for opioids used to treat patients with COVID–19, as previously identified by HHS, in proposing the 2021 APQ for those specific controlled substances.

Issue: Another commenter pointed out that while FDA's recommendation may have been made prior to the declaration of the COVID–19 emergency, DEA still did not provide any information about how it accounted for the impact of COVID–19 when arriving at its 2021 proposed APQ.

DEA Response: In the April 10, 2020 notice, DEA stated that DEA and HHS worked in concert to determine changes in legitimate medical need based on the unforeseen emergency posed by COVID–19, particularly the need of certain controlled substances required to treat patients on ventilators. DEA extended the projections provided by HHS to insure the relevant APQ were established to account for the predicted ''second wave'' of COVID–19 patients for the upcoming months.

CDC Data and Overdose Deaths

Issue: One commenter took issue with DEA's analysis of CDC data and DEA not differentiating between types of fentanyl overdoses, *i.e.,* overdoses that are the result of lawfully manufactured fentanyl versus illicit fentanyl.

DEA Response: CDC provided DEA with data from their National Vital Statistics System-Mortality files. DEA could not determine from CDC's data if the patient overdosed on an illicit opioid or a FDA-approved opioid product. Nor could DEA determine if the overdose was a result of accidental or intentional ingestion. As such, DEA is unable to determine the number of

overdose deaths resulting from fentanyl diverted from legitimate sources.

Whereas DEA is required to consider rates of overdose deaths pursuant to changes made by the SUPPORT Act, DEA concluded that the provided data on overdose deaths for 2015 through 2017 could not be reliably utilized to estimate the amount of diversion for the five covered controlled substances for the 2021 APQ.

D. Relevant Information Obtained From the States

Issue: Some commenters raised concerns that DEA did not adequately utilize data from the States. West Virginia, and joining state commenters, encouraged DEA to expand its methodology to enable better use of state data that does currently exist, despite not having a fulsome set of state data.

DEA Response: DEA solicited relevant information from the States and federal partners to be considered when setting the APQ pursuant to 21 CFR 1303.11. As DEA stated in the Proposed 2021 APQ, only 20 of the 56 State and Territory Attorneys General acknowledged receipt of DEA's letters requesting information on diversion, and of those 20, only nine states sent some form of Prescription Drug Monitoring Program (PDMP) data to DEA. The limited PDMP data that DEA received varied in form and content, and was ultimately determined to be insufficient to develop national estimates of diversion for each of the five covered controlled substances.

DEA is currently working with states and other federal agencies to obtain reliable data that will allow DEA to effectively estimate diversion. For example, DEA is seeking data from state PDMPs which can be evaluated to identify common diversion schemes such as ''doctor shopping,'' a scheme in which a patient obtains controlled substances from multiple treatment providers without the providers knowing of the other prescriptions. Information from PDMPs could assist in identifying additional ''red flags'' that may be evidence of diversion and misuse of covered controlled substances, such as: Over-prescribing; patients traveling long distances or across state lines to have prescriptions filled; early refills; and dangerous drug combinations.

E. The SUPPORT Act Mandates

Disparate Account of Diversion

Issue: West Virginia, and joining state commenters, raised concern over the disparate treatment of the five SUPPORT Act covered controlled substances and other regulated controlled substances in considering diversion.

DEA Response: Pursuant to 21 CFR 1303.11(b)(5), DEA considered the extent of diversion of the basic class as a factor in setting the APQ for each respective basic class, as well as the extent of diversion for all other schedule I and II controlled substances in proposing the estimated APQ. The regulation does not, however, mandate that DEA publish the diversion estimates for all controlled substances. As the state attorneys general comment notes, the SUPPORT Act specifically requires that DEA provide the diversion estimate only for the following five covered controlled substances: Fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone. In compliance with the SUPPORT Act, DEA published the estimated diversion for the five covered controlled substances.

F. Methodology for Determining the APQ and AAN Values

Issue: Some commenters wanted a more explicit explanation of DEA's methodology in determining the APQ and AAN values. West Virginia, and joining state commenters, for instance, called for DEA to adopt a ''specific, clear, and reproducible methodology developed and explained in advance'' to address the ''medically and scientifically necessary amount of controlled substances.'' Another commenter noted that DEA described one such methodology in the 2010 and 2011 AAN, but claimed that a more ''explicit discussion of how that methodology was applied would be beneficial.'' The same commenter also asked that DEA ''publicly provide and explicitly discuss the data it consulted to validate the need'' for APQ reductions.

DEA Response: As stated in the September 1, 2020, notice, DEA applies the factors listed in 21 CFR 1303.11 in determining the APQ and 21 CFR 1315.11 in determining the AAN. FDA is required to provide an estimate of the quantity of controlled substances together with reserves of such drugs that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States to DEA. 42 U.S.C. 242(a). Under this statute, HHS has delegated that responsibility to FDA, which provided the relevant information to DEA. DEA considered this information, including the observed and estimated domestic usage of marketed schedule II controlled substances, new drug applications and abbreviated drug application approvals, and clinical trials for schedule I and II controlled substances. The determination of scientifically necessary amounts of controlled substances occurs through the submission of business confidential and proprietary information from manufacturers. DEA also considered the impact of products entering and exiting the market, expected product development, expected exports, and inventory data.

Since 2014, FDA has observed a decline in the number of prescriptions written for schedule II opioids. DEA continues to set aggregate production quotas to meet the medical needs of the United States while combating the opioid crisis. These decreases take into account the combined efforts of DEA, FDA, and CDC enforcing regulations and issuing guidance documents, as well as many states enacting prescription monitoring database programs to stem the opioid epidemic.

G. Further Collaboration of Agencies and Stakeholders; Request for a Public Hearing

Issue: Some commenters suggested that DEA further or better collaborate with the states, other federal agencies, and other industry stakeholders. One commenter urged DEA to ''collaborate with a broad range of stakeholders'' to ''address the opioid crisis while ensuring an adequate supply of opioids for clinically appropriate care.'' The commenter further suggested that DEA should engage such stakeholders in roundtable discussions, listening sessions, or public hearings. West Virginia, and joining state commenters, urged DEA to work with states and other partners to develop methods to measure overprescribing and related forms of diversion. Another commenter asked that DEA work with ''HHS, Department of Defense, and others tasked with national security and emergency preparedness'' to ''address any emergent supply needs or preemptive supply preparation'' such as those arising from the pandemic.

DEA Response: DEA has and will continue to collaborate with federal agencies, industry, and medical associations to combat the opioid crisis, prevent diversion, and set appropriate manufacturing quantities of controlled substances and chemicals to meet legitimate need and preparedness for unforeseen circumstances within the United States. Additionally, the **Federal Register** comment period provides an opportunity for all stakeholders to make their issues known to DEA. Unfortunately, many of those issues revolve around prescribing practices for

specific medical conditions. As stated previously, DEA does not set guidelines regarding patterns of prescribing medications nor does DEA determine what dosages can be deemed ''medically necessary.''

Issue: One commenter stated that the DEA should have a hearing to gather stakeholder feedback on how DEA can help address the opioid epidemic while ensuring an adequate supply of opioids for clinically appropriate care and enable stakeholders to express their views about the proposed reductions.

DEA Response: Under DEA's regulations, the decision of whether to grant this type of a hearing on the issues raised by the commenter lies solely within the discretion of the Administrator. 21 CFR 1303.11(c) and 21 CFR 1303.13(c). The Administrator has considered the commenter's request and determined that a hearing is not necessary.

H. Comments From DEA-Registered Manufacturers

DEA received comments from four DEA-registered manufacturers regarding ten different schedule I and II controlled substances, requesting that the proposed APQ for ANPP, d-amphetamine (for conversion), fentanyl, hydrocodone (for sale), hydromorphone, lisdexamfetamine, morphine (for conversion), noroxymorphone (for conversion), oxycodone (for sale), and sufentanil be established to sufficient levels to allow for manufacturers to meet medical and scientific needs.

DEA considered the comments for specific controlled substances and made adjustments as needed which are described below in the section titled Determination of 2021 Aggregate Production Quotas and Assessment of Annual Needs.

I. Out of Scope Comments

DEA received several comments which addressed issues that are outside the scope of this final order. The comments were general in nature and raised issues of specific medical illnesses, medical treatments, and medication costs, as well as issues related to a separate **Federal Register** notice, and, therefore, were outside of the scope of this Final Order, and do not impact the original analysis involved in establishing the 2021 APQ.

IV. Determination of 2021 Aggregate Production Quotas and Assessment of Annual Needs

In determining the final 2021 aggregate production quotas and assessment of annual needs, DEA has considered the above comments along with the factors set forth in 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the 2020 manufacturing quotas, current 2020 sales and inventories, anticipated 2021 export requirements, industrial use, additional applications for 2021 quotas, as well as information on research and product development requirements.

DEA also considered the HHS Secretary's renewal of the public health emergency due to COVID–19 and worked with both FDA and the Assistant Secretary for Preparedness and Response (ASPR), including their revised estimated medical and Strategic National Stockpile requirements for fentanyl, hydromorphone, and morphine in establishing the 2021 APQ. Based on all of the above, the Administrator is adjusting the 2021 APQ for 4-anilino-N-phenethyl-4-piperadine (ANPP), 5-methoxy-n-n-dimethyltryptamine, Crotonyl fentanyl, D-methamphetamine (for sale), Fentanyl, Ethylone, Etonitazene, Gamma hydroxybutyric acid, Lisdexamfetamine, and Norlevorphanol.

Regarding D-amphetamine (for conversion), hydrocodone (for sale), hydromorphone, morphine (for conversion), noroxymorphone (for conversion), oxycodone (for sale), and sufentanil, DEA has determined the proposed APQ are sufficient to provide for the 2021 estimated medical, scientific, research, industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these APQ as well as the AAN at the same amounts as proposed.

Estimates of Diversion Pursuant to the SUPPORT Act

The SUPPORT Act (21 U.S.C. 826(i)(1)(a)) requires that ''in establishing any quota under this section . . . , for [the covered controlled substances], the Attorney General shall estimate the amount of diversion of the [covered controlled substances] that occurs in the United States.'' To estimate diversion as is required by the SUPPORT Act, DEA aggregated the active pharmaceutical ingredient (API) of each covered controlled substance by metric weight where the data was available in the aforementioned databases. Based on the individual entries into the aforementioned databases, DEA calculated the estimated amount of diversion by multiplying the strength of the API listed for each finished dosage form by the total amount of units reported to estimate the metric weight in kilograms of the controlled substance being diverted. The estimate of diversion for each of the covered controlled substances is reported below.

DIVERSION ESTIMATES FOR 2019

[kg]

Fentanyl	0.090
Hydrocodone	30.294
Hydromorphone	1.424
Oxycodone	60.959
Oxymorphone	1.311

In accordance with the SUPPORT Act, after estimating the amount of diversion for the foregoing five controlled substances, DEA made adjustments to the individual aggregate production quotas for each covered controlled substance by the corresponding quantities listed in the table. In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2021 APQ for the following schedule I and II controlled substances and the 2021 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Final 2021 quotas (g)
Schedule I	
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	15
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10

Basic class	Final 2021 quotas (g)
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	100
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36)	30
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5)	30
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-(n)-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine (DMA)	25
2-(4-Ethylthio-2,5-dimethoxyphenyl)ethanamine (2C–T–2)	30
2-(4-(Isopropylthio)-2,5-dimethoxyphenyl)ethanamine (2C–T–4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	40
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-N-methylcathinone (3–FMC)	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1 H-indazole-3-carboximide (4CN-Cumyl-Butinaca)	25
4-Fluoroisobutyryl fentanyl	30
4-Fluoro-N-methylcathinone (4–FMC; Flephedrone)	25
4-Methyl-N-ethylcathinone (4–MEC)	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-alpha-ethylaminopentiophenone (4–MEAP)	25
4-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4-Methyl-alpha-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)3-hydroxycyclohexyl-phenol (cannabicyclohexanol or CP–47,497 C8-homolog)	40
5F–CUMYL–PINACA	25
5F–EDMB–PINACA	25
5F–MDMB–PICA	25
5F–AB–PINACA; N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F–CUMYL–P7AICA; (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboximide)	25
5F–ADB; 5F–MDMB–PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
5F–AMB (methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate)	30
5F–APINACA; 5F–AKB48 (*N*-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	30
5-Fluoro-PB–22; 5F–PB–22	20
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	35
AB–CHMINACA	30
AB–FUBINACA	50
AB–PINACA	30
ADB–FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25
ADB–PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH–7921	30
All other tetrahydrocannabinols	1,000
Allylprodine	25
Alphacetylmethadol	25
Alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
Alphaprodine	25

Basic class	Final 2021 quotas (g)
Alpha-Methylfentanyl	30
Alpha-Methylthiofentanyl	30
Alpha-Methyltryptamine (AMT)	25
Alpha-Pyrrolidinobutiophenone (α-PBP)	25
Alpha-Pyrrolidinoheptaphenone (PV8)	25
Alpha-Pyrrolidinohexanophenone (α-PHP)	25
Alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Anileridine	20
APINACA, AKB48 (*N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	25
Beta-Hydroxy-3-methylfentanyl	30
Beta-Hydroxyfentanyl	30
Beta-Hydroxythiofentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Bufotenine	15
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl fentanyl	25
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
Delta 9–THC	384,460
Desomorphine	25
Dextromoramide	25
Diampromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,200
Dihydromorphine	753,500
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	50
Dioxaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Etonitazene	25
Etorphine	30
Etoxeridine	25
Fenethylline	30
Fentanyl related substances	600
FUB–144	25
FUB–AKB48	25
FUB–AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
Gamma Hydroxybutyric Acid	29,417,000
Heroin	45
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	30
Isobutyryl Fentanyl	25
Isotonitazene	25
JWH–018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH–019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH–073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH–081 (1-Pentyl-3-(1-(4-methoxynaphthoyl)indole)	30
JWH–122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH–200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH–203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH–250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH–398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30

Basic class	Final 2021 quotas (g)
Ketobemidone	30
Levomoramide	25
Levophenacylmorphan	25
Lysergic acid diethylamide (LSD)	40
MAB–CHMINACA; ADB–CHMINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide)	30
MDMB–CHMICA; MMB–CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB–FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB–CHMICA (AMB–CHMICA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Marihuana	1,500,000
Marihuana extract	200,000
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT–45	30
Myrophine	25
NM2201; Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate	25
N,N-Dimethylamphetamine	25
Naphyrone	25
N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
N-Methyl-3-Piperidyl Benzilate	30
Nicocodeine	25
Nicomorphine	25
Noracymethadol	25
Norlevorphanol	2,550
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
Ortho-fluorofentanyl, 2-fluorofentanyl	30
Para-chloroisobutyryl fentanyl	30
Para-fluorofentanyl	25
Para-fluorobutyryl fentanyl	25
Para-methoxybutyryl fentanyl	30
Parahexyl	5
PB–22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphan	25
Phenoperidine	25
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Psilocybin	30
Psilocyn	50
Racemoramide	25
SR–18 and RCS–8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR–19 and RCS–4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrofuranyl fentanyl	15
Thebacon	25
Thiafentanil	25
Thiofentanyl	25
THJ–2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	25
UR–144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25

Basic class	Final 2021 quotas (g)
U–47700	30
Valeryl fentanyl	25
Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	937,758
Alfentanil	3,260
Alphaprodine	25
Amobarbital	20,100
Bezitramide	25
Carfentanil	20
Cocaine	68,576
Codeine (for conversion)	1,612,500
Codeine (for sale)	27,616,684
D-amphetamine (for sale)	21,200,000
D-amphetamine (for conversion)	14,137,578
D-methamphetamine (for conversion)	485,02
D-methamphetamine (for sale)	40,000
D,L-amphetamine	21,200,000
D,L-methamphetamine	50
Dextropropoxyphene	35
Dihydrocodeine	156,713
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	68,576
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	731,452
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	30,821,224
Hydromorphone	2,827,940
Isomethadone	30
L-amphetamine	30
L-methamphetamine	587,229
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	26,495
Lisdexamfetamine	21,000,000
Meperidine	856,695
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	25,619,700
Methadone Intermediate	27,673,600
Methylphenidate	57,438,334
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	3,376,696
Morphine (for sale)	27,784,062
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	376,000
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750
Oxycodone (for conversion)	620,887
Oxycodone (for sale)	57,110,032
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	563,174
Pentobarbital	25,850,000
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Piminodine	25
Racemethorphan	5
Racemorphan	5

Basic class	Final 2021 quotas (g)
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	13,447,541
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	100
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,878,320
Phenylpropanolamine (for sale)	16,690,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

The Administrator also establishes APQ for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2021 APQ and AAN as needed.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–26289 Filed 11–27–20; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL SECURITY COMMISSION ON ARTIFICIAL INTELLIGENCE

[Docket No. 11–2020–01]

National Security Commission on Artificial Intelligence; Notice of Federal Advisory Committee Meeting

AGENCY: National Security Commission on Artificial Intelligence.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The National Security Commission on Artificial Intelligence (the ''Commission'') is publishing this notice to announce the following asynchronous Federal Advisory Committee meeting and paper review process. The meeting will be closed to the public.

DATES: Closed to the public, December 15, 2020 to February 14, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Angela Ponmakha, 703–614–6379 (Voice), *nscai-dfo@nscai.gov. Mailing address:* Designated Federal Officer, National Security Commission on Artificial Intelligence, 2530 Crystal Drive, Box 45, Arlington, VA 22202. *website: https://www.nscai.gov.*

SUPPLEMENTARY INFORMATION: The meeting and paper review process are being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The John S. McCain National Defense Authorization Act for Fiscal Year 2019 (FY19 NDAA), Sec. 1051, Public Law 115–232, 132 Stat. 1636, 1962–65 (2018), created the Commission to ''consider the methods and means necessary to advance the development of artificial intelligence, machine learning, and associated technologies by the United States to comprehensively address the national security and defense needs of the United States.'' The Commission will consider potential recommendations to Congress and the Executive Branch. According to the FY19 NDAA, the Commission ''may include a classified annex.''

Agenda: Due to the restrictions on in-person meetings imposed by the COVID–19 pandemic—including travel, social distancing, and other factors—the Commission will hold an asynchronous Federal Advisory Committee meeting beginning on or about December 15, 2020 and ending on or about February 14, 2020. For the asynchronous meeting, individual commissioners or small groups of commissioners will meet with Commission staff during this period of time to discuss and deliberate specifically on the Commission's draft classified annex. The Designated Federal Officer, Ms. Angela Ponmakha, or an alternate designated federal officer will convene and conclude all such meetings. Due to the restrictions from the COVID–19 pandemic, Commissioners may also deliberate and vote on the classified annex through a paper approval process managed by the Designated Federal Officer and relevant Commission staff. All materials and discussions in the asynchronous meeting and paper approval process will be classified.

Meeting Accessibility: In accordance with Section 10(d) of the FACA, NSCAI has determined the series of meetings and paper approval process will be closed to the public. Specifically, the Commission's Committee Management Officer, in consultation with the General Services Administration's Secretariat and Office of General Counsel, has determined in writing that the meetings will be closed to the public because they will consider matters covered by 5 U.S.C. 552b(c)(1). The determination is because it is expected that discussions throughout the course of the asynchronous meeting and the paper approval process will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material that it cannot be reasonably segregated into separate discussions without defeating the effectiveness and meaning of the overall meetings. To permit the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the Commission's findings and recommendations to the Congress and the President.

Written Statements: Written comments may be submitted to the Commission at any time regarding its mission or in response to the stated agenda of planned meetings via email to: *nscai-dfo@nscai.gov* in either Adobe Acrobat or Microsoft Word format. The DFO will compile all written submissions and provide them to the Commissioners for consideration. Please note that all submitted comments will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Commission's website.