business proprietary information ("BPI") under administrative protective order. BPI referred to during the remand proceedings will be governed, as appropriate, by the administrative protective order issued in the investigations. The Secretary will maintain a service list containing the names and addresses of all persons or their representatives who are parties to the remand proceedings, and the Secretary will maintain a separate list of those authorized to receive BPI under the administrative protective order during the remand proceedings.

Written Submissions.—The Commission is not reopening the record and will not accept the submission of new factual information for the record. The Commission will permit the parties to file comments concerning how the Commission could best comply with the Court's remand instructions.

The comments must be based solely on the information in the Commission's record. The Commission will reject submissions containing additional factual information or arguments pertaining to issues other than those on which the Court has remanded this matter. The deadline for filing comments is August 1, 2016. Comments shall be limited to no more than fifteen (15) double-spaced and single-sided pages of textual material.

Parties are advised to consult with the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subpart A (19 CFR part 207) for provisions of general applicability concerning written submissions to the Commission. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's Web site at http:// edis.usitc.gov, elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list),

and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

By order of the Commission. Issued: July 18, 2016.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2016-17286 Filed 7-21-16; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-443N]

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 2017

AGENCY: Drug Enforcement Administration, Department of Justice. **ACTION:** Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2017 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

pates: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 22, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the Federal Register a final order establishing the 2017 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine,

pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-443N" on all correspondence, including any attachments. The Drug **Enforcement Administration encourages** that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to http://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for vour comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia

FOR FURTHER INFORMATION CONTACT:

Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information

you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

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

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

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

Legal Authority

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 schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

Analysis for Proposed 2017 Aggregate Production Quotas and Assessment of Annual Needs

The proposed year 2017 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances, and the list I chemicals

ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2017 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

In determining the proposed 2017 aggregate production quotas and assessment of annual needs, the Acting Administrator has taken into account the criteria pursuant to 21 U.S.C. 826(a) and in accordance with 21 CFR 1303.11 (aggregate production quotas for controlled substances) and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The DEA proposes the aggregate production quotas and assessment of annual needs for 2017 by considering: (1) Total net disposal of each class or chemical by all manufacturers and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for each class or chemical as indicated by procurement and import quotas requested in accordance with 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Acting Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

Other factors the Acting Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2017 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

During the calendar years 2013–2016, the DEA included an additional 25% of the estimated medical, scientific, and research needs for the United States as part of the amount necessary to ensure the establishment and maintenance of reserve stocks for all schedule II aggregate production quotas, and certain schedule I aggregate production quotas (difenoxin, gamma-hydroxybutyric acid, and tetrahydrocannabinols). Based on interagency discussions beginning in November 2015, and after reviewing all relevant quota applications received, published FDA drug shortage lists, and subsequent reports required under 21 U.S.C. 826a for those calendar years, the Acting Administrator has determined that inclusion of the additional 25% of the estimated medical, scientific, and research needs for the United States is unnecessary. Instead, the Acting Administrator determined that 21 U.S.C. 826(c) and 21 U.S.C. 952(a)(2)(A) provide sufficient ability for the DEA to mitigate adverse public effects should a natural disaster or other unforeseen event result in substantial disruption to the amount of controlled substances available for legitimate public need. As such, DEA proposes to remove the additional 25% from the aggregate production quotas. The resulting proposed established aggregate production quotas reflect these reduced amounts.

The Acting Administrator, therefore, proposes to establish the 2017 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Proposed 2017 quotas (g)
Schedule I	
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	35
1-Benzylpiperazine	25

Basic class	Proposed 201 quotas (g)
Butyl-3-(1-naphthoyl)indole (JWH-073)	
Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	
Hexyl-3-(1-naphthoyl)indole (JWH-019)	
Methyl-4-phenyl-4-propionoxypiperidine	
Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	
Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	
Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	
Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	
Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	
Pentýl-3-[1-(4-methóxynaphthóyl)]indòle (JWH-081) /	
(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	
(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	
2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	
2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	
(2,5-Dimethoxyphenyl)ethanamine (2C-H)	
(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	
4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	
(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	
4-lodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	
4-iodo-2,5-dimethoxyphenyi)-N-(2-methoxybenzyi)ethanamine (25i-NBOMe; 26-i-NBOMe; 25i; Cimbi-5)	
5-Dimethoxy-4-n-propylthiophenethylamine	
5-Dimethoxyamphetamine	
4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	
4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	
4,5-Trimethoxyamphetamine	
f-Methylenedioxyamphetamine (MDA)	
4-Methylenedioxymethamphetamine (MDMA)	
I-Methylenedioxy-N-ethylamphetamine (MDÉA)	
I-Methylenedioxy-N-methylcathinone (methylone)	
I-Methylenedioxypyrovalerone (MDPV)	
FMC; 3-Fluoro-N-methylcathinone	
Methylfentanyl	
Methylthiofentanyl	
Bromo-2,5-dimethoxyamphetamine (DOB)	
Bromo-2,5-dimethoxyphenethylamine (2-CB)	
FMC; Flephedrone	
Methoxyamphetamine	
Methylaminorex	
MEC; 4-Methyl-N-ethylcathinone	
Methyl-N-methylcathinone (mephedrone)	
Methyl-α-pyrrolidinopropiophenone (4-MePPP)	
(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	
(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	
Fluoro-UR144, XLR11	
Methoxy-3,4-methylenedioxyamphetamine	
Methoxy-N,N-diisopropyltryptamine	
Methoxy-N,N-dimethyltryptamine	
3-PINACA	
etyl-alpha-methylfentanyl	
etyldihydrocodeine	
etylmethadol	
l-7921	
ylproduce	
pha-Ethyltryptamine	
sha-Methylfentanyl	
pha-Methylthiofentanyl	
pha-Methyltryptamine (AMT)bha-Pyrrolidinobutiophenone (α-PBP)	
ha-Pyrrolidinopentiophenone (α-PVP)	
phacetylmethadol	
phameprodine	
phamethadol	
ninorex	
PINCA, AKB48	
enzylmorphine	
ta-Hydroxy-3-methylfentanyl	
eta-Hydroxyfentanyl	
ta-Hydroxythiofentanyl	
etacetylmethadol	
tameprodine	1

Basic class	Proposed 2017 quotas (g)
Betamethadol	4
Betaprodine	2
Bufotenine	3
Butylone	25
Butyryl fentanyl	30 24
Cathinone	5
Codeine-N-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	8,750
Dihydromorphine	1,566,000
Dimethyltryptamine	35 5
Fenethylline	5
gamma-Hydroxybutyric acid	56,200,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	10 472 000
Marihuana Mescaline	472,000 25
Methagualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N,N-Dimethylamphetamine	25 50
N-(1-Amino-3,3-difficity)-1-0xobutan-2-yl)-1-perityl-11-indazole-3-carboxamide (AB-FUBINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100
N-Ethyl-1-phénylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Naphyrone	25
Noracymethadol	2 52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Pentedrone	25
Pentylone	25
Phenomorphan	2
Pholocodine	5
PsilocybinPsilocyn	30 50
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	20
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	20
Tetrahydrocannabinols	409,000
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
UR-144	25
Schedule II	
1-Phenylcyclohexylamine	4
1-Piperidinocyclohexanecarbonitrile	4
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,000,000
Alphanadiaa	4,200
Alphaprodine	20 100
Amphetamine (for conversion)	20,100
Amphetamine (for conversion)	9,000,000 37,500,000
Carfentanil	37,500,000
Cocaine	94,000
Codeine (for conversion)	40,000,000

Basic class	Proposed 2017 quotas (g)
Dextropropoxyphene	
Dihydrocodeine	81,1
Dihydroetorphine	- ,
iphenoxylate (for conversion)	15,0
Diphenoxylate (for sale)	820,0
cgonine	90,0
thylmorphine	00,0
torphine hydrochloride	
entanyl	1,750,0
Slutethimide	1,730,0
lydrocodone (for conversion)	122,0
	58,410,0
lydrocodone (for sale)	, ,
lydromorphone	4,300,0
somethadone	
evo-alphacetylmethadol (LAAM)	
evomethorphan	4.0
evorphanol	4,9
isdexamfetamine	19,000,0
Meperidine	3,706,0
Meperidine Intermediate-A	
Meperidine Intermediate-B	
Meperidine Intermediate-C	
Metazocine	
Methadone (for sale)	23,700,0
Methadone Intermediate	25 600 0
	25,600,0
Methamphetamine	1,539,1
Methamphetamine	73,000,0 27,300,0 41,000,0 15,0
Methamphetamine	73,000,0 27,300,0 41,000,0 15,0 17,700,0
Methamphetamine	1,539, tamine mostly f 73,000, 27,300, 41,000, 15, 17,700, 400,
Methamphetamine	73,000, 27,300, 41,000, 15, 17,700, 400, 90,
Methamphetamine	73,000,0 27,300,0 41,000,0 15,0 17,700,0 400,0 90,0 300,0
Methamphetamine	73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000,
Methamphetamine	73,000, 27,300, 41,000, 15,0 17,700, 400, 90,0 300,0 20,000,0 2,610,0
Methamphetamine	1,539, tamine mostly for 73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510,
Methamphetamine	1,539, tamine mostly for 73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300,
Methamphetamine	1,539, tamine mostly for 73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300, 4,200,
Methamphetamine	73,000,0 27,300,0 41,000,0
Methamphetamine	73,000,0 27,300,0 41,000,0 15,0 17,700,0 400,0 90,0 300,0 20,000,0 2,610,0 108,510,0 22,300,0 4,200,0
Methamphetamine [900,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 600,000 grams for methamphet conversion to a schedule III product; and 39,100 grams for methamphetamine (for sale)] Methylphenidate Morphine (for conversion) Morphine (for sale) Idoroxymorphone (for conversion) Idoroxymorphone (for conversion) Idoroxymorphone (for sale) Idoroxymorphone (for sale) Idoroxymorphone (for sale) Idoroxymorphone (for conversion) Idoroxymorphone (for sale) Idoroxymorphone (for conversion)	1,539, tamine mostly for 73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300, 4,200,
Methamphetamine	1,539, tamine mostly for 73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300, 4,200,
[900,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 600,000 grams for methamphet conversion to a schedule III product; and 39,100 grams for methamphetamine (for sale)] Idethylphenidate	73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 4,200,
Sethamphetamine	73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300, 4,200,
Methamphetamine [900,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 600,000 grams for methamphet conversion to a schedule III product; and 39,100 grams for methamphetamine (for sale)] Methylphenidate	73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300, 4,200, 27,500,
Methamphetamine [900,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 600,000 grams for methamphet conversion to a schedule III product; and 39,100 grams for methamphetamine (for sale)] Methylphenidate Morphine (for conversion) Morphine (for conversion) Morphine (for sale) Morphine (for sale) Morphine (for conversion) Morphine (for sale) Morphine (for conversion) Morphine (for sale) Morphine (for conversion) Morphine (for sale) Morphine (for sale) Morphine (for conversion) Morphine (for sale) Morphine (for sale) Morphine (for sale) Morphine (for conversion) Morphine (for sale)	1,539, tamine mostly f 73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300, 4,200, 27,500,
Methamphetamine [900,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 600,000 grams for methamphet conversion to a schedule III product; and 39,100 grams for methamphetamine (for sale)] Methylphenidate Morphine (for conversion) Morphine (for sale) Morphine (for sale) Morpymorphone (for conversion) Morphine (for sale) Morphymorphone (for sale) Morphymorphone (for sale) Morphymorphone (for conversion) Morphymorphone (for conversion) Morphymorphone (for conversion) Morphymorphone (for sale) Morphymorphone (for sale) Morphymorphone (for sale) Morphymorphone (for conversion) Morphymorphone (for sale) Morphymo	1,539, tamine mostly to 73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300, 4,200, 27,500,
Methamphetamine [900,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 600,000 grams for methamphet conversion to a schedule III product; and 39,100 grams for methamphetamine (for sale)] Methylphenidate Morphine (for conversion) Morphine (for conversion) Morphine (for sale) Morphine (for sale) Morphine (for conversion) Morphine (for sale) Morphine (for conversion) Morphine (for sale) Morphine (for conversion) Morphine (for sale) Morphine (for sale) Morphine (for conversion) Morphine (for sale) Morphine (for sale) Morphine (for sale) Morphine (for conversion) Morphine (for sale)	73,000, 27,300, 41,000, 15, 17,700, 400, 90, 300, 20,000, 2,610, 108,510, 22,300, 4,200,

The Acting Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR

1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Acting Administrator may adjust the 2017 aggregate production quotas and assessment of annual needs as needed.

List I Chemicals

Thebaine

Ephedrine (for conversion)

Ephedrine (for sale)

Phenylpropanolamine (for conversion)

Phenylpropanolamine (for sale)

Pseudoephedrine (for sale)

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the **Federal Register** a final order establishing the

100.000.000

50,000

4,100,000

15,000,000

8,500,000

200,000,000

2017 aggregate production quota for controlled substances in schedules I and II and establishing an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.11(c) and 1315.11(f).

Dated: July 14, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016-17370 Filed 7-21-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mikhayl Soliman, M.D.: Decision and Order

On March 27, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Mikhayl Soliman, M.D. (hereinafter, Applicant), of both Wayne, Michigan and Los Angeles, California. The Show Cause Order proposed the denial of Applicant's applications for DEA Certificates of Registration in the States of Michigan and California on multiple grounds. GX 7, at 1.

First, the Show Cause Order alleged that Applicant had previously been registered to handle controlled substances in only Schedule III and IIIN, at the registered address of 3152 South Wayne Road, Wayne, Michigan. *Id.* The Show Cause Order alleged that on September 14, 2012, Applicant was issued an Order to Show Cause and Immediate Suspension of Registration and that he subsequently voluntarily surrendered his registration.

The Show Cause Order alleged that on September 24, 2012, Applicant applied for a new DEA practitioner's registration at his previous registered location in Wayne, Michigan, and that on October 2, 2012, he applied for a new practitioner's registration at a proposed location in Los Angeles, California. *Id.* The Order then alleged that on both applications, Applicant had failed to disclose that he had voluntarily surrendered his registration and had materially falsified both applications. *Id.* at 1–2 (citing 21 U.S.C. 843(a)(4)(A)).

Second, the Show Cause Order alleged that as a result of actions taken by the medical boards of California and Michigan, Applicant is "without authority to practice in the States . . . in which [he] applied for" DEA registrations. *Id.* at 2. Specifically, the Show Cause Order alleged that on January 15, 2014, the Michigan Board of Medicine issued a Consent Order which

found that he "had prescribed controlled substances . . . in a manner which demonstrated negligence, incompetence, and a lack of good moral character" and that he "prescribed, gave away or administered drugs for other than lawful diagnostic or therapeutic purposes." Id. The Order also alleged that the Michigan Board had suspended his medical license for six months and one day and required that he petition the Board for reinstatement; the Order then alleged that Applicant's Michigan medical license remains suspended. Id. The Order further alleged that based on the Michigan Board's findings, the Medical Board of California revoked his California license effective October 10, 2014. Id.

Finally, the Show Cause Order alleged that on May 16, 2012, DEA Investigators had seized 323 patient files which Applicant had discarded in the trash at his residence, and that the files showed that Applicant had prescribed both hydrocodone (then a Schedule III controlled substance) and alprazolam (a Schedule IV drug) "to the majority of these patients." Id. The Order then alleged that DEA Investigators obtained information from the Michigan Automated Prescriptions System which showed that "between January 1, 2007 and August 20, 1012, [Applicant] prescribed at least 19,409 dosage units of [s]chedule II [drugs], 725,760 dosage units of [s]chedule IV [drugs], and 246,397 dosage units of [s]chedule V [drugs], without the registered authority to do so." Id.1

Thereafter, the Government attempted to serve the Show Cause Order by FedEx delivered to the proposed business address Applicant used when he applied for a registration in Los Angeles. GX 9, at 1. The Government did not, however, require a signature. *Id.* at 1–2. Moreover, the Government does not point to any precedent of either the courts or this Agency which allows for the use of FedEx to serve a charging document or complaint (as opposed to post-service filings) on a person.² Thus, this attempt was deemed inadequate to accomplish service.

The Government also noted that it emailed a lawyer who was representing Applicant "in a pending criminal matter" and asked him if he could confirm Applicant's current address or accept service on Applicant's behalf. GX 10. The lawyer, however, did not respond. Request for Final Agency Action, at 3. Moreover, according to the Government, a Supervisory Diversion Investigator phoned the attorney and asked for Applicant's address in order to serve the Show Cause Order. *Id.* According to the Government, while the attorney stated that he would contact the Government's counsel, he did not.³ *Id.*

The Government then mailed the Show Cause Order by certified mail, return receipt requested, addressed to Applicant at his proposed business address in Wayne, Michigan. GX 11, 12, and 13. Several weeks later the mailing was returned unclaimed, with the Post Office indicating that it was "unable to forward" the mailing. GX 13. The Government did not, however, send the Show Cause Order to Applicant by First Class Mail. See Jones v. Flowers, 547 U.S. 220 (2006).

Subsequently, the Government submitted a Request for Final Agency Action along with the Investigative File. Upon review of the record, I found that service was inadequate and directed that the Request for Final Agency Action be returned.

On November 9, 2015, the Government again mailed the Show Cause Order by certified mail, return receipt requested, addressed to Applicant at his proposed registered location. Here again, several weeks later the mailing was returned by the Post Office as undeliverable. GX 18.

Also on November 9, 2015, the same day the Government had re-mailed the Show Cause Order, it emailed the Order to Applicant at the email address he had provided to the Agency on his applications. According to an affidavit submitted by the Government, it "did not receive any bounce-back email or other indication that the email . . . was undeliverable or otherwise not received." GX 19.

Upon re-submission of its Request for Final Agency Action, the Government advised that on September 24, 2015, Applicant was found guilty in the United States District Court for the Eastern District of Michigan on multiple counts of health care fraud and aiding and abetting the unlawful distribution of controlled substances. Request for Final Agency Action, at 4; see also GX 15, at 5). The Government further advised that on October 5, 2015,

¹ The Show Cause Order also notified Applicant of his right to either request a hearing on the allegations of the Order to Show Cause or to submit a written statement while waiving his right to a hearing, the procedure for electing either option, and the consequence of failing to elect either option. GX 7, at 3.

² Nor am I aware of any rules of procedure which allow for a charging document or complaint to be served in this manner.

³ Given that Applicant had been criminally charged and released on bond, the Pre-Trial Services Office would likely have been a more fruitful source for obtaining his residence address.