

VIII. Notification

Unless such transaction is otherwise subject to the reporting and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, 15 U.S.C. 18a (the "HSR Act"), during the term of this Final Judgment, Defendants, without providing advance notification to the Antitrust Division, shall not directly or indirectly: (a) Acquire any assets of or any interest (including, but not limited to, any financial, security, loan, equity, or management interest) in, any company in the business of designing, developing, producing, marketing, servicing, distributing, and/or selling bonded insulated rail joints and/or polyurethane-coated insulated rail joints, or any company in the business of producing, marketing, distributing, and/or selling Friction Management Products; or (b) enter into any relationship with another company that involves the distribution of Friction Management Products in North America.

Such notification shall be provided to the Antitrust Division in the same format as, and per the instructions relating to the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended, except that the information requested in Items 5 through 9 of the instructions must be provided only about bonded insulated rail joints, polyurethane-coated insulated rail joints, and Friction Management Products. Notification shall be provided at least thirty (30) calendar days prior to acquiring any such interest, and shall include, beyond what may be required by the applicable instructions, the names of the principal representatives of the parties to the agreement who negotiated the agreement, and any management or strategic plans discussing the proposed transaction. If within the 30-day period after notification, representatives of the Antitrust Division make a written request for additional information, Defendants shall not consummate the proposed transaction or agreement until thirty (30) calendar days after submitting all such additional information. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted in the same manner as is applicable under the requirements and provisions of the HSR Act and rules promulgated thereunder. This Section shall be broadly construed and any ambiguity or uncertainty regarding the filing of notice under this Section shall be resolved in favor of filing notice.

IX. No Reacquisition

Defendants may not reacquire any part of the Divestiture Assets during the term of this Final Judgment.

X. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XI. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten (10) years from the date of its entry.

XII. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States's responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and responses to comments filed with the Court, entry of this Final Judgment is in the public interest.

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. § 16 United States District Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA #343E]

Controlled Substances: Established Initial Aggregate Production Quotas for 2011

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2011.

SUMMARY: This notice establishes initial 2011 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: *Effective Date:* December 20, 2010.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Springfield, Virginia 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The 2011 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2011 to provide

adequate supplies of each substance for: the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. 826(a) and 21 CFR 1303.11). These quotas do not include imports of controlled substances for use in industrial processes.

On September 15, 2010, a notice of the proposed initial 2011 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (75 FR 56137). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before October 15, 2010.

Seven responses (six from DEA registered manufacturers, and one from a non-DEA registrant) were received within the published comment period, offering comments on a total of 31 schedules I and II controlled substances. The commenters stated that the proposed aggregate production quotas for 3,4-methylenedioxyamphetamine, 3,4-methylenedioxy-N-ethylamphetamine, 3,4-methylenedioxymethamphetamine, 4-anilino-N-phenethyl-4-piperidine, amphetamine (for sale), cathinone, codeine (for sale), dihydromorphine, fentanyl, gamma hydroxybutyric acid, heroin, hydrocodone, hydromorphone, marihuana, meperidine, methaqualone, methylphenidate, morphine (for conversion), morphine (for sale), nabilone, noroxymorphone (for conversion), opium (tincture), oxycodone (for sale), pentobarbital, phencyclidine, remifentanyl, secobarbital, tapentadol, tetrahydrocannabinols, thebaine and tilidine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

In arriving at the aggregate production quotas, DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11(b) and other relevant 2010 factors, including 2010 manufacturing quotas, current 2010 sales and inventories, 2011 export requirements, additional applications received, as well as research and product development requirements. Based on this information, DEA has adjusted the initial aggregate production quotas for 3,4-methylenedioxyamphetamine, 3,4-methylenedioxy-N-ethylamphetamine, 3,4-methylenedioxymethamphetamine, amobarbital, cathinone, dimethyltryptamine, ibogaine, lysergic

acid diethylamide, metazocine, methaqualone, nabilone, normorphine, noroxymorphone (for sale), phenazocine, phencyclidine, secobarbital, and tetrahydrocannabinols to meet the legitimate needs of the United States.

Regarding 4-anilino-N-phenethyl-4-piperidine, amphetamine (for sale), codeine (for sale), dihydromorphine, fentanyl, gamma hydroxybutyric acid, heroin, hydrocodone, hydromorphone, marijuana, meperidine, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion),

opium (tincture), oxycodone (for sale), pentobarbital, remifentanyl, tapentadol, thebaine and tilidine DEA has determined that the proposed initial 2011 aggregate production quotas are sufficient to meet the current 2011 estimated medical, scientific, research, and industrial needs of the United States.

Pursuant to 21 CFR 1303, the Deputy Administrator of DEA will, in 2011, adjust aggregate production quotas and individual manufacturing quotas allocated for the year based upon 2010 year-end inventory and actual 2010 disposition data supplied by quota

recipients for each basic class of schedule I or II controlled substance.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. 826), and delegated to the Administrator of DEA by 28 CFR 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby orders that the 2011 initial aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic class—Schedule I	Established 2011 quotas
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	22 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	2 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	4 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	3,000 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	7 g
Gamma-hydroxybutyric acid	3,000,000 g
Heroin	20 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g

Basic class—Schedule I	Established 2011 quotas
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic class—Schedule II	Established 2011 quotas
1-Phenylcyclohexylamine	2 g
1-piperidinocyclohexanecarbonitrile	2 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,500,000 g
Alfentanil	8,000 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	7,500,000 g
Amphetamine (for sale)	18,600,000 g
Cocaine	247,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	92,000,000 g
Dihydrocodeine	800,000 g
Diphenoxylate	827,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	55,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	11 g
Levo-alphaacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	10,000 g
Lisdexamfetamine	9,000,000 g
Meperidine	6,600,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	5 g
Methadone (for sale)	20,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g

[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]

Methylphenidate	50,000,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	10,502 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	401,000 g
Opium (powder)	230,000 g
Opium (tincture)	1,500,000 g
Oripavine	15,000,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	105,500,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	3,070,000 g
Pentobarbital	28,000,000 g
Phenazocine	5 g

Basic class—Schedule II	Established 2011 quotas
Phencyclidine	24 g
Phenmetrazine	2 g
Phenylacetone	8,000,000 g
Racemethorphan	2 g
Remifentanyl	2,500 g
Secobarbital	260,002 g
Sufentanyl	7,000 g
Tapentadol	1,000,000 g
Thebaine	126,000,000 g

The Deputy Administrator further orders that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR 1308.11 and 1308.12 be established at zero.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$126,400,000 or more in any one year, and 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.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: December 10, 2010.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-350E]

Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2011

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of Assessment of Annual Needs for 2011.

SUMMARY: This notice establishes the initial 2011 Assessment of Annual Needs for certain List I chemicals in accordance with the Combat Methamphetamine Epidemic Act of 2005 (CMEA).

DATES: *Effective Date:* December 20, 2010.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Section 713 of the Combat Methamphetamine

Epidemic Act of 2005 (Title VII of Pub. L. 109-177) (CMEA) amended Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) by adding ephedrine, pseudoephedrine, and phenylpropanolamine to existing language to read as follows: “The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.” Further, section 715 of the CMEA amended 21 U.S.C. 952 “Importation of Controlled Substances” by adding the same List I chemicals to the existing language in paragraph (a), and by adding a new paragraph (d) to read as follows:

(a) Controlled substances in schedule I or II and narcotic drugs in schedule III, IV, or V; exceptions

It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of subchapter I of this chapter, or any narcotic drug in schedule III, IV, or V of subchapter I of this chapter, or ephedrine, pseudoephedrine, and phenylpropanolamine, except that—

(1) such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves, and of ephedrine, pseudoephedrine, and phenylpropanolamine, as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes * * * may be so imported under such regulations as the Attorney General shall prescribe.

* * * * *

(d)(1) With respect to a registrant under section 958 who is authorized under subsection (a)(1) to import ephedrine, pseudoephedrine, or phenylpropanolamine, at any time during the year the registrant may apply for an increase in the amount of such chemical that the registrant is authorized to import, and the Attorney General may