



Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

JAN 21 2015

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, #51-633
Silver Spring, Maryland 20993

Dear Dr. Woodcock:

The Drug Enforcement Administration (DEA), in accordance with part 1303 of Title 21 of the Code of Federal Regulations, Title 21, United States Code, Section 826 (21 U.S.C. § 826), and 42 U.S.C. § 242, requests that the Department of Health and Human Services (HHS) provide estimates of the quantities of schedules I and II controlled substances and three list I chemicals which will be required to meet the legitimate medical, scientific, and reserve stock needs of the United States in 2015 and 2016. Please provide the information by April 1, 2015, so that the DEA may use these figures to calculate revised 2015 and initial 2016 aggregate production quotas for publication in the Federal Register.

Each year, the DEA is required to determine the total quantity of schedules I and II controlled substances and three list I chemicals to be manufactured to provide for the estimated needs of the United States. In order to accomplish this, the DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific, and reserve stock needs in 2015 and 2016 for the following substances:

| | | |
|---------------------------|------------------|--|
| Alfentanil | Hydrocodone | Opium (tinctures, extracts, etc., expressed in terms of U.S.P. powdered opium) |
| Amobarbital | Hydromorphone | Oxycodone |
| Amphetamine | Levorphanol | Oxymorphone |
| Cannabidiol | Lisdexamfetamine | Pentobarbital |
| Cocaine | Marijuana | Phenylpropanolamine |
| Codeine | Meperidine | Pseudoephedrine |
| Difenoxin | Methadone | Remifentanil |
| Dihydrocodeine | Methamphetamine | Secobarbital |
| Diphenoxylate | Methylphenidate | Sufentanil |
| Etorphine | Morphine | Tapentadol |
| Ephedrine | Nabilone | Tetrahydrocannabinols |
| Fentanyl | Noroxymorphone | |
| Gamma-hydroxybutyric acid | | |

To a significant extent, the DEA relies on medical and scientific information unique to the Food and Drug Administration to estimate the amounts of these substances which will be required each year. In addition to estimates for the aggregate requirements of the above schedules I and II controlled substances and three list I chemicals, the DEA requests any product or company specific information which may assist in the establishment and revision of quotas. Such information includes anticipated new products, discontinued or recalled products, new indications for existing products, new dosage forms, new manufacturing processes, research requirements, and manufacturing problems. Please be assured that such information will be treated as confidential and proprietary. The DEA greatly appreciates your assistance in providing these estimates, along with any comments regarding legitimate medical needs.

The DEA also has certain reporting mandates under international treaties. In accordance with article 19 of the Single Convention on Narcotic Drugs, 1961, and article 16 of the Convention on Psychotropic Substances, 1971, the DEA must report the quantities of internationally controlled substances manufactured in the United States, the total quantities exported and imported, and the United States' assessment of the maximum quantity of controlled substances imported into the United States. Therefore, the DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific, and reserve stock needs in 2015 and 2016 for the following controlled substances and substances manufactured from controlled substances:

Alprazolam
Buprenorphine
Clobazam
Clonazepam
Diazepam
Diethylpropion

Lorazepam
Midazolam
Naloxone
Naltrexone
Temezepam
Zolpidem

My staff is available to provide any assistance you may need in fulfilling this request. In order to facilitate the exchange of information, Christine A. Sannerud, Ph.D., Chief, United Nations Reporting and Quota Section, Office of Diversion Control, will act as the DEA liaison for all exchanges concerning this matter. She may be reached by telephone at (b)(6). Should you require further information or assistance regarding this matter, please contact me at (b)(6).

Sincerely,


Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control



U. S. Department of Justice
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

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FEB 12 2014

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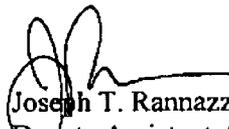
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