

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cody Laboratories to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Cody Laboratories to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: December 17, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7-25041 Filed 12-26-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated September 24, 2007 and published in the **Federal Register** on October 2, 2007, (72 FR 56102), ISP Freetown Fine Chemicals, 238 South Main Street, Assonet, Massachusetts 02702, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in schedule II.

The company plans to import the Phenylacetone to manufacture Amphetamine.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of ISP Freetown Fine Chemicals to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated ISP Freetown Fine Chemicals to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical

security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated September 12, 2007, and published in the **Federal Register** on September 19, 2007 (72 FR 53606), Research Triangle Institute, Kenneth H. Davis Jr., Hermann Building, P.O. Box 12194, East Institute Drive, Research Triangle, North Carolina 27709, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedules I and II:

Drug	Schedule
Marihuana (7360)	I
Cocaine (9041)	II

The Institute will manufacture small quantities of cocaine and marihuana derivatives for use by their customers in analytical kits, reagents, and reference standards as directed by NIDA.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Research Triangle Institute to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Research Triangle Institute to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of

the basic classes of controlled substances listed.

Dated: December 17, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7-25047 Filed 12-26-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated September 21, 2007, and published in the **Federal Register** on September 27, 2007, (72 FR 54931), Varian, Inc., Lake Forest, 25200 Commercentre Drive, Lake Forest, California 92630-8810, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Phencyclidine (7471)	II
1-Piperidinocyclohexane-carbonitrile (8603).	II
Benzoyllecgonine (9180)	II

The company plans to manufacture small quantities of the listed controlled substances for use in diagnostic products.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Varian, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Varian, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: December 17, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7-25050 Filed 12-26-07; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-307E]

Controlled Substances: Established Initial Aggregate Production Quotas for 2008

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2008.

SUMMARY: This notice establishes initial 2008 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

EFFECTIVE DATE: December 27, 2007.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, 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 2008 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2008 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 August 24, 2007, a notice of the proposed initial 2008 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (72 FR 48683). All interested persons were invited to comment on or object to these

proposed aggregate production quotas on or before September 14, 2007.

Seven responses were received resulting in comments on a total of 17 schedule I and II controlled substances within the published comment period. The commenters stated that the proposed aggregate production quotas for 14-hydroxymorphinone, alfentanil, amphetamine (for conversion), codeine (for sale), fentanyl, gamma hydroxybutyric acid, hydromorphone, lisdexamfetamine, marihuana, methadone, methylphenidate, noroxymorphone (for conversion), oxycodone, oxymorphone, sufentanil, tetrahydrocannabinols and thebaine were insufficient 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. The DEA has determined that 14-hydroxymorphinone is considered a morphine derivative controlled under the morphine basic drug class code and therefore the comment received for 14-hydroxymorphinone was treated as a comment for morphine.

One commenter stated that, "one or more manufacturers are preparing to receive Food and Drug Administration (FDA) approvals for generic version of Marinol. Generic versions of the drug, however, will not be approved for all of the indications for which FDA has found Marinol safe and effective. As a consequence, those newly approved generic versions should not be prescribed and distributed for all of the same indications as Marinol." The commenter further stated that if one of the generic Marinol manufacturers seeks an "upwardly adjusted quota" beyond that which is necessary for the medical requirements of the United States, then this would be contrary to the DEA's obligations under the Controlled Substances Act. For these reasons, the commenter requested a hearing regarding the aggregate production quota for tetrahydrocannabinols. The commenter believes that the approval of generic versions of Marinol will lead to an inappropriate increase in the "medical use" estimate for tetrahydrocannabinols in the United States. This is only one of the factors that DEA must consider when establishing the aggregate production quota. DEA must also consider the industrial and research requirements of the United States, lawful export requirements, and reserve stock requirements.

DEA notes it first established a 312,500 gram aggregate production quota for tetrahydrocannabinols in 2005

(70 FR 120, January 3, 2005). At that time, the increase from the proposed value of 211,000 grams was primarily due to an increase in the research and development efforts of DEA registered manufacturers, which included generic drug development efforts, increased drug requirements necessary to develop new indications of currently marketed drug products, and the development of novel drug delivery systems containing tetrahydrocannabinols. These research efforts continue today. Additionally, the FDA, which provides DEA with estimates of medical use of controlled substances each year, advised DEA that the medical use of Marinol is expected to grow by approximately 8.8 percent from 2006 to 2009. Export and industrial requirements are minimal and thus inconsequential to DEA's final analysis.

Pursuant to 21 CFR 1303.11(c), the DEA has determined that a hearing is not required in this matter. DEA has fully considered the comments received in connection with the hearing request within the context of the applications for manufacturing and procurement quotas received from DEA registered manufacturers and information provided by the FDA, and concludes that the amount proposed is sufficient 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. Therefore, DEA is establishing the 2008 aggregate production quota for tetrahydrocannabinols at the proposed value of 312,500 grams.

DEA has taken into consideration the above comments along with the relevant 2007 manufacturing quotas, current 2007 sales and inventories, 2008 export requirements, additional applications received, and research and product development requirements. Based on this information, the DEA has adjusted the initial aggregate production quotas for alfentanil, levorphanol, noroxymorphone (for sale), oxycodone (for conversion), and oxymorphone to meet the legitimate needs of the United States. The DEA also adjusted the initial aggregate production quota for hydrocodone due to known sales of hydrocodone products to companies that sell hydrocodone illegally through the Internet.

Regarding amphetamine (for conversion), codeine (for sale), fentanyl, gamma hydroxybutyric acid, hydromorphone, lisdexamfetamine, marihuana, methadone, methylphenidate, morphine, noroxymorphone (for conversion), oxycodone, sufentanil,