

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,