

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****Manufacturer of Controlled Substances; Notice of Application**

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on October 13, 1998, Cauldron Inc., DBA Cauldron Process Chemistry, 383 Phoenixville Pike, Malvern, Pennsylvania 19355, made application by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of amphetamine (1100), a basic class of controlled substance listed in Schedule II.

The firm plans to bulk manufacture amphetamine for the purpose of performing bioequivalency studies.

Any other such applicant and any person who is presently registered with DEA to manufacture such substance may file comments or objections to the issuances of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than February 9, 1999.

Dated: December 2, 1998.

John H. King,

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

[FR Doc. 98-32979 Filed 12-10-98; 8:45 am]

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****Importation of Controlled Substances; Notice of Application**

Pursuant to Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Section 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on July 20, 1998, Celgene

Corporation, 7 Powder Horn Drive, Warren, New Jersey 07059, made application by renewal to the Drug Enforcement Administration to be registered as an importer of phenylacetone (8501), a basic class of controlled substance listed in Schedule II.

The firm plans to import the phenylacetone for the manufacture of amphetamine.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than January 11, 1999.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34 (b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), 21 CFR 1301.34 (a), (b), (c), (d), (e), and (f) are satisfied.

Dated: December 2, 1998.

John H. King,

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

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****Importation of Controlled Substances; Notice of Application**

Pursuant to Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing

a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Section 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on August 18, 1998, Glaxo Welcome Inc., Attn: Jeffrey A. Weiss, 1011 North Arendell Avenue, P.O. Box 1217, Zebulon, North Carolina 27597-2309, made application by renewal to the Drug Enforcement Administration to be registered as an importer of remifentanyl (9739), a basic class of controlled substance listed in Schedule II.

The remifentanyl is being imported for the production of Ultiva dosage forms and for research and new product development.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.43 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than January 11, 1999.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import basic class of any controlled substance in schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e), and (f) are satisfied.