DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 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 registration under 21 U.S.C. 952(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 Title 21 Code of Federal Regulations (CFR), 1301.34(a), this is notice that on January 31, 2010, Meda Pharmaceuticals Inc., 705 Eldorado Street, Decatur, Illinois 62523, made application by letter to the Drug Enforcement Administration (DEA) to be registered as an importer of Nabilone (7379), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance as a finished drug product in dosage form only for distribution to its customers. The company does not import the listed controlled substance in bulk active pharmaceutical ingredient (API) form.

There are no domestic sources of Nabilone in finished drug product form available in the United States. The U.S. Food and Drug Administration has approved this product for medical use in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1316.47.

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than July 8, 2010.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1316.47. As noted in a previous notice published in the Federal Register on September 23, 1975 (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance listed 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 1301.34(b), (c), (d), (e), and (f) are satisfied.


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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated October 21, 2009, and published in the Federal Register on October 29, 2009 (74 FR 55858), Johnson Matthey, Inc., Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, New Jersey 08066–1742, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II.

The company plans to import the listed controlled substances as raw materials for use in the manufacture of bulk controlled substances for distribution to its customers.

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 Johnson Matthey, Inc. to import the basic classes of controlled substances 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 Johnson Matthey, 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. 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 classes of controlled substances listed.


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

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