I order that the application of John V. Scalera, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This order is effective March 25, 2013.


Michele M. Leonhart,
Administrator.

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Mallinckrodt, LLC.

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on December 4, 2012, Mallinckrodt, LLC., 3600 North Second Street, St. Louis, Missouri 63147, made application 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 for distribution to its customers.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), 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 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written 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 March 25, 2013.

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 published in the Federal Register on September 23, 1975, 40 FR 43745, 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); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: February 8, 2013.

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 Application; Caraco Pharmaceutical Laboratories, LTD.

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on November 22, 2012, Caraco Pharmaceutical Laboratories, Ltd., 270 Prospect Plains Road, Cranbury, New Jersey 08512, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Fentanyl (9801), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance in finished dosage form for clinical trials, and research.

The import of the above listed basic class of controlled substance is granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Meda Pharmaceuticals, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on December 4, 2012, Meda Pharmaceuticals, Inc., 705 Eldorado Street, Decatur, Illinois 62523, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of amphetamine products listed controlled substance as a finished dosage form for clinical trials, and manufacture of amphetamine products listed controlled substance in finished dosage form for distribution to its customers.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), 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 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written 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 March 25, 2013.

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 published in the Federal Register on September 23, 1975, 40 FR 43745, 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); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: February 8, 2013.

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

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