



Billing Code 4410-09-M

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
IMPORTER OF CONTROLLED SUBSTANCES
NOTICE OF APPLICATION
MERIDIAN MEDICAL TECHNOLOGIES

Pursuant to 21 USC § 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 21 USC § 952(a)(2) 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 21 CFR § 1301.34(a), this is notice that on January 4, 2012, Meridian Medical Technologies, 2555 Hermelin Drive, St. Louis, Missouri 63144, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Morphine (9300), a basic class of controlled substance listed in schedule II.

The company manufactures a product containing morphine in the United States. The company exports this product to customers around the world, including in Europe. The company has been asked to ensure that its product sold to European customers meets standards established by the European Pharmacopeia, which is administered by the Directorate for the Quality of Medicines (EDQM). In order to ensure that its product will meet European specifications, the company seeks to import morphine supplied by EDQM to use as reference standards. This is the sole purpose for which the company will be authorized by DEA to import morphine.

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 § 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 Morrisette Drive,

Springfield, Virginia 22152; and must be filed no later than [insert date 30 days from date of publication].

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 43745-46, 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 USC § 958(a); 21 USC § 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

DATED: March 23, 2012

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