

Dated: May 13, 2011.

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**

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 regulation under 21 U.S.C. 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 March 8, 2010, Akorn, Inc., 1222 W. Grand Avenue, Decatur, Illinois 62522, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Remifentanyl (9739), a basic class of controlled substance listed in schedule II.

The company plans to import Remifentanyl in bulk for use in dosage-form manufacturing.

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 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 June 27, 2011.

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: May 13, 2011.

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 March 8, 2011, and published in the **Federal Register** on March 17, 2011, 76 FR 14688, Aptuit, 10245 Hickman Mills Drive, Kansas City, Missouri 64137, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

| Drug | Schedule |
|--------------------------------------|----------|
| Marihuana (7360) | I |
| Poppy Straw Concentrate (9670) | II |

The company plans to import a finished pharmaceutical product containing cannabis extracts in dosage form for packaging for a clinical trial study. In addition, the company also plans to import an ointment for the treatment of wounds which contain trace amounts of the controlled substances normally found in poppy straw concentrate for packaging and labeling for clinical trials.

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 Aptuit 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. DEA has investigated Aptuit 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.

Dated: May 12, 2011.

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 January 18, 2011, and published in the **Federal Register** on February 2, 2011, 76 FR 5827, Mallinckrodt Inc., 3600 North Second Street, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

| Drug | Schedule |
|--------------------------------------|----------|
| Phenylacetone (8501) | II |
| Coca Leaves (9040) | II |
| Opium, raw (9600) | II |
| Poppy Straw Concentrate (9670) | II |

The company plans to import the listed controlled substances for the manufacture of controlled substances in bulk 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 Mallinckrodt 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. DEA has investigated Mallinckrodt 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.