



Billing Code 4410-09-M

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
Importer of Controlled Substances
Notice of Registration
Alkermes Gainesville, LLC

By Notice dated January 16, 2013, and published in the Federal Register on January 29, 2013, 78 FR 6132, Alkermes Gainesville, LLC, 1300 Gould Drive, Gainesville, Georgia 30504, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Noroxymorphone (9668), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance for analytical research and testing.

The import of the above listed basic class of controlled substance would be 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 for commercial distribution in the United States.

No comments or objections have been received. DEA has considered the factors in 21 USC § 823(a) and § 952(a) and determined that the registration of Alkermes Gainesville,

LLC, to import the basic class of controlled substance 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 Alkermes Gainesville, LLC, 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 USC § 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 class of controlled substance listed.

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

DATED: June 18, 2013

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