Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bulk Manufacturer of Controlled Substances Application: Pharmacore, Inc.

[Docket No. DEA-392]

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on December 3, 2015, Pharmacore, Inc., 4180 Mendenhall Oaks Parkway, High Point, North Carolina 27265 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled Substance	Schedule
Oxymorphone (9652)	II
Noroxymorphone (9668)	II

The company plans to manufacture the listed controlled substances as active pharmaceutical ingredients (APIs) for clinical trials.

Dated: January 27, 2016

Louis J. Milione,
Deputy Assistant Administrator.

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