

with 21 CFR 1301.34(a) on or before September 23, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 23, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette 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 1301.34(a), this is notice that on June 3, 2016, Akorn, Inc., 1222 W. Grand Avenue, Decatur, Illinois 62522 applied to be registered as an importer of remifentanyl (9739), a basic class of controlled substances listed in schedule II.

The company plans to import remifentanyl in dosage form for distribution.

Louis J. Milione,

Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Noramco, Inc.

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 October 24, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette 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 July 20, 2016, Noramco, Inc., 1440 Olympic Drive, Athens, Georgia 30601 applied to be registered as a bulk manufacturer the following basic classes of controlled substances:

Controlled substance	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Hydromorphenol (9301)	I
Nabilone (7379)	II

The company plans to manufacture bulk active pharmaceutical ingredients (APIs) and reference standards for distribution to their customers.

In reference to drug codes 7360 (marihuana) and 7370 (tetrahydrocannabinols), the company plans to bulk manufacturer these drugs as synthetic. No other activities for these

drug codes are authorized for this registration.

Louis J. Milione,

Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On August 18, 2016, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Columbia in the lawsuit entitled *United States v. Harley-Davidson, Inc., et al.*, Civil Action No. 1:16–cv–01687.

The United States’ Complaint alleges that Harley-Davidson, Inc. (and three related companies) manufactured and sold over 339,392 after-market devices (known as “Super Tuners” and used with Harley-Davidson motorcycles) in violation of the Clean Air Act prohibition on the manufacture or sale of devices that defeat the functioning of the motorcycle’s certified emissions control system. The Complaint also alleges, relatedly, that Defendants violated the provision of the Act that prohibits any person from removing or rendering inoperative a motor vehicle’s certified emissions control system and from causing such “tampering.” Finally, the Complaint alleges that Defendants manufactured and sold more than 12,000 motorcycles from model years 2006, 2007 and 2008 that were not certified by EPA as required by the Clean Air Act.

The Consent Decree requires Defendants to stop selling the illegal tuners in the United States by August 23, 2016. Defendants will also offer to buy back all such tuners in stock at Harley-Davidson dealerships across the country and destroy them. The Decree requires Defendants to obtain an Executive order from the California Air Resources Board (CARB) for any tuners it sells in the United States in the future. These Executive orders (E.O.s) will demonstrate that the CARB-certified tuners do not cause Defendants’ motorcycles to exceed the EPA-certified emissions limits. Defendants must also conduct tests on motorcycles that have been tuned with the E.O.-certified tuners and provide the results to EPA to ensure that their motorcycles remain in compliance with EPA emissions requirements. In addition, for any uncertified Super Tuners that Defendants sell outside the United