DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Registration: Apertus Pharmaceuticals

[Docket No. DEA-392]

ACTION: Notice of registration.

SUMMARY: Apertus Pharmaceuticals applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Apertus Pharmaceuticals registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION:

By notice dated March 20, 2015, and published in the **Federal Register** on March 27, 2015, 80 FR 16440, Apertus Pharmaceuticals, 331 Consort Drive, St. Louis, Missouri 63011 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted to this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Apertus Pharmaceuticals to manufacture 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. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's

compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled Substance	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to divide the synthesized cannabidiol, with a portion going for sale as an API in nabiximol. The raw material will be used to synthesize dronabinol. Therefore, they anticipate consuming and purchasing small quantities of CS for generating data to support the Drug Master File with the FDA including validation batches, standards and stability studies.

No other activity for this drug code is authorized for this registration.

Dated: July 23, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

[FR Doc. 2015-18695 Filed: 7/29/2015 08:45 am; Publication Date: 7/30/2015]