

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DRG No. 25-0094]

Bulk Manufacturer of Controlled Substances Registration

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and been granted a registration by the Drug Enforcement Administration (DEA) as a bulk manufacturer of schedule II controlled substance(s).

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as a bulk manufacturer of schedule II controlled substance(s). Information on a previously published notice is listed below. No comments or objections were submitted for this notice.

Company	FR Docket	Published
ANI Pharmaceuticals Inc.	90 FR 23954-23955	June 5, 2025

DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable controlled substance(s) is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. 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, DEA has granted a registration as a bulk manufacturer to the above listed company.

Dated: 12/18/2025

Thomas Prevoznik,
Deputy Assistant Administrator.