

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DRG No. 23-0079]

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 various basic class(es) of schedule I and II controlled substance(s).

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

| <u>Company</u> | <u>FR Docket</u> | <u>Published</u> |
|---------------------|------------------|------------------|
| ANI Pharmaceuticals | 89 FR 47176 | May 31, 2024 |

DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable various basic class(es) of schedule I and II 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.

Marsha L. Ikner,
Acting Deputy Assistant Administrator.