

III. Sanction

Where, as here, the Government has established grounds to revoke Respondent's registration, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33738, 33746 (2021).

Here, although Respondent initially requested a hearing, he withdrew his hearing request and did not otherwise avail himself of the opportunity to refute the Government's case. As such, Respondent has made no representations as to his future compliance with the CSA nor made any demonstration that he can be entrusted with registration. In fact, despite having already been subject to state action and a Federal citation in 2017 and thus put on notice of the impropriety of his actions, Respondent failed to change his ways and continued to commit much of the same misconduct. Moreover, the evidence presented by the Government clearly shows that Respondent violated the CSA, further indicating that Respondent cannot be entrusted. Accordingly, the Agency will order the revocation of Respondent's registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. AK7830640 issued to Jagjit Kaleka, D.V.M. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Jagjit Kaleka, D.V.M., to renew or modify this registration, as well as any other pending application of Jagjit Kaleka, D.V.M., for additional registration in Wisconsin. This Order is effective December 7, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 31, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1285]

Importer of Controlled Substances Application: Mylan Technologies Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Mylan Technologies Inc. as applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before December 7, 2023. Such persons may also file a written request for a hearing on the application on or before December 7, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If

you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on October 5, 2023, Mylan Technologies Inc. 110 Lake Street, Saint Albans, Vermont 05478-2266 applied to be registered as an importer of the following basic class(es) of controlled substance(s)

Controlled substance	Drug code	Schedule
Fentanyl	9801	II
Methylphenidate	1724	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically manufactured FDF to foreign markets. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Claude Redd,

Acting Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Modification to Consent Decree Under the Clean Water Act

On October 25, 2023, the Department of Justice lodged a proposed a Material Modification to the Consent Decrees' Wet Weather Improvement Program ("Modification") with the United States District Court for the Southern District