



**ADVANCED MANUFACTURING
TECHNOLOGIES DESIGNATION
PROGRAM – GRANTED**

September 10, 2026

AustinPx, Pharmaceuticals and Manufacturing
Attention: Chris Brough, PhD
Chief Technology Officer

Dear Dr. Brough,

Thank you for your Advanced Manufacturing Technologies (AMT) Designation Program submission dated March 13, 2026, submitted pursuant to section 506L of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) has reviewed your request and has determined that the KinetiSol Amorphous Solid Dispersions (ASDs) Technology, which is intended for the manufacture of amorphous solid dispersions of poorly water-soluble APIs for incorporation into solid oral dosage forms, meets the criteria for AMT designation. Therefore, we are granting your request for AMT designation within the abovementioned context of use.

Please note that as the holder of the AMT designation, you or another party that you authorize may reference or rely upon data or information (e.g., from a Drug Master File) about the designated AMT in an application in the same context of use for which the designation was granted.

You, as the holder of the AMT designation, must inform the AMT Designation Program mailbox (AMT_designation_requests@fda.hhs.gov) of the submission of any meeting requests or regulatory filings (including Drug Master Files) in order to experience the benefits of the AMT Designation as outlined in FDA guidance. We encourage early interactions to discuss the implementation of your designated AMT in drug manufacturing. The AMT designation provides the option to request:

- A Type C or Type D meeting for PDUFA-focused applications, or
- A Product Development (PDEV) or Pre-submission (PSUB) meeting for GDUFA-focused applications.

The meeting request should be made in accordance with the appropriate guidance: [Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products](#) or [Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA](#).

Please note that any applicant can cross-reference data or information (e.g., from a Drug Master File) about the designated AMT, regardless of the granted AMT context of use. However, the AMT Designation Program will only be extended to the applications under the granted context of use.

As an AMT designee, please direct all future engagements *for this designated technology and context of use* through the AMT Designation Program. Pursuant to FDA guidance, if you, as the designated AMT holder, have updates or proposed changes that could affect the context of use or eligibility of your designated AMT, such as when additional supportive data become available (e.g., additional batch analysis data), please email this information to AMT_designation_requests@fda.hhs.gov. The subject line should be: **PROPOSED CHANGE FOR DESIGNATED AMT** in uppercase letters.

Please refer to FDA's guidance for industry [Advanced Manufacturing Technologies Designation Program](#).

Sincerely,

RUTH AUGUSTE
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Ruth Auguste
Project Manager
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
Food and Drug Administration