investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, COBENFY (xanomeline tartrate and trospium chloride). COBENFY is indicated for the treatment of schizophrenia in adults. Subsequent to this approval, the USPTO received patent term restoration applications for COBENFY (U.S. Patent Nos. 10,238,643; 10,369,143; 10,369,144) from PureTech Health LLC and the USPTO requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated August 26, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of COBENFY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for COBENFY is 11,751 days. Of this time, 11,384 days occurred during the testing phase of the regulatory review period, while 367 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 27, 1992. PureTech Health LLC claims that August 19, 2016, is the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 27, 1992, which was 30 days after FDA receipt of an earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 26, 2023. FDA has verified the applicant's claim that the new drug application (NDA) for COBENFY (NDA 216158) was initially submitted on September 26, 2023.

3. *The date the application was approved:* September 26, 2024. PureTech Health LLC claims that the new drug application (NDA) for COBENFY (NDA 216158) was approved on September 27, 2024. However, FDA records indicate that NDA 216158 was approved on September 26, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,124 or 1,191 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see DATES), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2026–02388 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1956]

Matthew Teltser: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Matthew Teltser from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Matthew Teltser was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Dr. Teltser was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred within the timeframe prescribed by regulation. As of November 14, 2025 (more than 30 days after receipt of the notice), Dr. Teltser has not responded. Dr. Teltser's failure to respond and request a hearing constitutes a waiver of Dr. Teltser's right to a hearing concerning this matter.

DATES: This order is applicable February 6, 2026.

ADDRESSES: Any application by Dr. Teltser for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2025–N–1956. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On June 10, 2025, Dr. Teltser was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Southern District of Florida, Fort Lauderdale Division, when the court accepted his plea of guilty and entered judgment against him for the offense of making a false statement in violation of 18 U.S.C. 1001(a)(2). The underlying facts supporting the conviction are as follows:

As contained in the Information, Plea Agreement, and Factual Proffer in support of Dr. Teltser's guilty plea, Dr. Teltser was a licensed medical doctor who served as the clinical investigator at A&R Research Group LLC (A&R), a medical research clinic that conducted clinical trials on behalf of drug trial sponsors. Between at least in or around January 2019 and continuing through at least in or around January 2020, Dr. Teltser conducted two clinical research trials at A&R on behalf of a drug sponsor as the clinical investigator. The two clinical research trials concerned investigational drugs intended to treat human subjects with moderate to severe asthma and mild to moderate asthma (collectively, ''the asthma trials'').

As the clinical investigator, Dr. Teltser was responsible for, among other things, personally overseeing the conduct of the studies and study staff, performing physical examinations on study subjects, reviewing lab results and echocardiograms, and preparing and maintaining accurate medical records, also referred to as case histories.

Prior to beginning the clinical trials, Dr. Teltser and A&R entered into a Clinical Trial Agreement for each of the asthma trials with the contract research organization which was acting on behalf of the drug sponsor. By signing the Clinical Trial Agreements, Dr. Teltser knew he was required, among other things, to follow the study protocol and applicable Federal regulations. Dr. Teltser signed a Form FDA 1572, Statement of Investigator, for at least one of the asthma trials. By signing the Form FDA 1572, Statement of Investigator, Dr. Teltser agreed to (1) conduct the trial according to the study protocol and in compliance with all applicable Federal regulations; and (2) personally conduct and supervise the trial.

Dr. Teltser's responsibilities included monitoring the safety and well-being of subjects in the clinical trials, performing physical examinations on subjects, and reviewing and maintaining the case histories. The study protocols for the asthma trials required subjects to meet certain eligibility criteria to qualify for and be enrolled in the trials. Once enrolled in the asthma trials, the study protocols required the subjects to submit to routine clinical procedures and safety measurements, such as physical examinations and check of vital signs, as well as study specific assessments, such as electrocardiogram readings, pulmonary functions tests, and the drawing of blood samples for hematology and clinical chemistry.

Between approximately January 23, 2020, and January 31, 2020, FDA conducted a for-cause inspection at A&R. As part of the inspection, Dr. Teltser was required to make records related to the asthma trials available to the FDA investigator. The FDA investigator interviewed Dr. Teltser as part of the inspection on or about January 31, 2020. During the interview, Dr. Teltser knowingly and falsely stated to the FDA investigator that he had been present at every subject visit during the asthma trials. In fact, Dr. Teltser had not been present at every subject visit in the asthma trials.

As a result of this conviction, FDA sent Dr. Teltser, by certified mail, on September 2, 2025, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Dr. Teltser was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. The proposal informed Dr. Teltser of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of

receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and a waiver of any contentions concerning this action. Dr. Teltser received the proposal and notice of opportunity for a hearing on September 8, 2025. Dr. Teltser failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Dr. Matthew Teltser has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Teltser is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Dr. Teltser during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Teltser provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Dr. Teltser during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of the FD&C Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–02349 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–3535 and FDA–2024–E–3536]

Determination of Regulatory Review Period for Purposes of Patent Extension; AURORA EV–ICD

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AURORA EV–ICD and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 6, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2024–E–3535; and FDA–2024–E–3536 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AURORA EV–ICD.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you