U.S. FOOD & DRUG ADMINISTRATION

VIA UNITED PARCEL SERVICE AND E-MAIL

Otsuka Pharmaceutical Development & Commercialization, Inc.
Attention: Sina Pusht-Mashhad, Senior Manager, Global Regulatory Affairs
2440 Research Boulevard
Rockville, Maryland 20850

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2026-128
NCT03896945

Dear Mr. Pusht-Mashhad:

Based on an initial review of Food and Drug Administration (FDA) records, information from the ClinicalTrials.gov data bank operated by the National Library of Medicine, a part of the National Institutes of Health, and any available public information, it appears that Otsuka Pharmaceutical & Commercialization, Inc., the "responsible party"[1] for the above-identified clinical trial, which appears to be an "applicable clinical trial"[2] subject to the requirements of section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date[3] of the applicable clinical trial, unless the responsible party has submitted a timely certification of delay, request for an extension for good cause, or request for a waiver of the requirements for submission of results information.[4]

[1] *See* sections 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of "responsible party."
[2] *See* sections 402(j)(1)(A)(i)-(iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)-(iii)) and 42 CFR 11.10 for the definition of "applicable clinical trial."
[3] *See* 42 CFR 11.10 for the definition of "primary completion date." *See also* section 402(j)(1)(A)(v) of the PHS Act (42 U.S.C. 282(j)(1)(A)(v)), which defines "completion date." As reflected in 42 CFR 11.10, the terms "primary completion date" and "completion date" are synonymous for the purposes of 42 CFR part 11.
[4] *See* sections 402(j)(3)(E) and (H) of the PHS Act (42 U.S.C. 282(j)(3)(E) and (H)) and 42 CFR part 11, subpart C for results information submission requirements.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We note that on May 21, 2024, your company submitted a timely certification for delayed submission of results information under 42 CFR 11.44(c)(1).[5] When a timely certification for delayed submission of results information is submitted under 42 CFR 11.44(c)(1), results information must be submitted no later than two years after the date on which the certification was submitted. See 42 CFR 11.44(c)(2).[6] Notwithstanding that deadline, results information must be submitted sooner if 1) FDA approves the drug product for any use that is studied in the applicable clinical trial or 2) the marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days; if either of these two scenarios occurs, results information must be submitted within 30 calendar days of such event. See 42 CFR 11.44(c)(1).

FDA has identified potential noncompliance related to the above-identified clinical trial, titled "A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-arm Study to Assess the Efficacy, Safety, and Tolerability of AVP-786 (Deudextromethorphan Hydrobromide [d6-DM]/Quinidine Sulfate [Q]) for the Treatment of Negative Symptoms of Schizophrenia." It appears that results information for the referenced trial has not been submitted to the ClinicalTrials.gov data bank. Moreover, it appears that your company failed to update the responsible party contact information for this clinical trial as required under 42 CFR 11.64(a)(1)(ii)(L).[7] Your company should review its records of this clinical trial and determine whether your company submitted all required information. If your company determines that information is required and due for this clinical trial, please submit the information promptly.

Failure to submit clinical trial information[8] required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including information required under the regulations found in 42 CFR part 11, is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(jj)(2)). Beginning 30 calendar days after you receive this letter,

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[5] Under 42 CFR 11.44(c)(1), delayed submission of results information is available if the responsible party for an applicable clinical trial of an FDA-regulated drug product that was not approved for any use before the primary completion date of the trial submits a certification that the sponsor intends to continue with product development and is seeking, or may at a future date seek, FDA approval of the drug product under study. We note that Otsuka Pharmaceutical & Commercialization, Inc., issued a press release on May 22, 2024, publicly announcing the termination of development of the novel compound AVP-786. https://www.otsuka-us.com/news/otsuka-terminate-development-avp-786.

[6] The regulation contains an exception, not applicable here, regarding the submission of partial results information. 42 CFR 11.44(c)(2) and (d).

[7] For applicable clinical trials initiated on or after January 18, 2017, such as the referenced clinical trial, 42 CFR 11.64(a)(1)(ii)(L) requires that responsible party contact information be "updated not later than 30 calendar days after a change in the responsible party or the contact information for the responsible party." If your company is no longer the responsible party for this clinical trial, your company should notify FDA and must update this information in the ClinicalTrials.gov data bank.

[8] *See* section 402(j)(1)(A)(iv) of the PHS Act (42 U.S.C. 282(j)(1)(A)(iv)) and 42 CFR 11.10 for the definition of "clinical trial information."

FDA intends to further review and assess the above-identified clinical trial. If FDA determines that your company has failed to submit any clinical trial information required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, your company may receive from FDA a Notice of Noncompliance,[9] and FDA may thereafter initiate an administrative action seeking a civil money penalty.[10] In addition to civil money penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could result in other regulatory action, such as injunction and/or criminal prosecution, without further notice.

As requested, please review your company's clinical trial records and submit any required results information to the ClinicalTrials.gov data bank. We also request that you review all applicable clinical trials for which your company is the responsible party to ensure compliance with all ClinicalTrials.gov registration and results information submission requirements. You can access the ClinicalTrials.gov website at https://register.clinicaltrials.gov.

We request that you submit a written response to FDA within 30 calendar days after you receive this letter, stating the actions you have taken in response to this letter. If you believe that your company has complied with applicable requirements, please provide us with your reasoning and include any supporting information for our consideration.

Your written response, and any questions or concerns regarding this letter, should be sent via email to the FDA at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

[9] *See* section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

[10] Pursuant to section 303(f)(3)(A) of the FD&C Act (21 U.S.C. 333(f)(3)(A)), "[a]ny person who violates section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding." Moreover, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. 333(f)(3)(B)) provides that "[i]f a violation of section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected." These civil money penalty amounts reflect the amounts found in the statute. These amounts are updated annually to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461, note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR 102.3.

Sincerely yours,

{See appended electronic signature page}

Laurie Muldowney, M.D.
Deputy Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

cc: (b) (6), Senior Manager
Otsuka Pharmaceutical & Commercialization, Inc.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LAURIE B MULDOWNEY
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