U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA UNITED PARCEL SERVICE AND EMAIL

October 7, 2026

Addex Pharma S.A.
Attention: Hilde Williams, Regulatory Consultant
12 Chemin Des Aulx
1228 Plan-Les-Ouates, Geneva
SWITZERLAND

Re: Noncompliance with the Requirements for Submission of Clinical Trial Results Information for "Phase 2b/3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of Dipraglurant (ADX48621) for the Treatment of Dyskinesia in Patients With Parkinson's Disease Receiving Levodopa-based Therapy"
FDA Reference Number: CDER-2025-136
NCT04857359

Dear Ms. Williams:

The U.S. Food and Drug Administration (FDA) sent you a letter dated July 3, 2025, alerting you to potential noncompliance with the requirement to submit clinical trial results information to the ClinicalTrials.gov data bank, operated by the National Library of Medicine (NLM) (a part of the National Institutes of Health), for the above-referenced clinical trial. Addex Pharma S.A. is the "responsible party"[1] for the above-referenced clinical trial, which is an "applicable clinical trial"[2] that is subject to the requirements in section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), 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

[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."

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, a request for an extension for good cause, or a request for a waiver of the requirements for submission of results information.[4]

In our July 3, 2025, letter, we asked your company to review its records for this clinical trial and submit all required results information promptly. We also stated that we intended to further review and assess this clinical trial beginning 30 calendar days after you received our July 3, 2025, letter, and that we might take regulatory action if we determined that your company was not in compliance at that time. Despite multiple emails exchanged between your company and the FDA, after Addex Pharma S.A. received the July 3, 2025, letter, results information has not been submitted.

FDA has determined that your company failed to submit results information for the applicable clinical trial referenced above, as required under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)) and 42 CFR 11.48.[5] Pursuant to section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)), FDA is notifying you that your company is not in compliance with FDAAA's results information submission requirements, which include the requirements in 42 CFR part 11, and is providing your company with the opportunity to remedy its noncompliance by submitting the required clinical trial results information within 30 calendar days after you receive this Notice of Noncompliance (Notice). Your company must submit this information as specified at https://clinicaltrials.gov. For more information, see https://clinicaltrials.gov/ct2/manage-recs/how-report.

Because failure to submit 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, 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)), FDA may initiate an enforcement action against you.

If you have any questions about this Notice, you may call Laurie Muldowney, M.D., at (301) 796-1571. Please have the FDA reference number provided at the top of this Notice available when you call. Alternatively, you may email Dr. Muldowney at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any email communications.

[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 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 submission requirements.

[5] We acknowledge that, as recently as June 21, 2026, your company entered results information for NCT04857359 into the NLM Protocol Registration and Results System (PRS); however, your company did not complete the process for submitting results information, and the preliminary steps taken by your company do not constitute submission of results information under 42 CFR 11.44(a).

We ask that your company submit a written response to FDA within 30 calendar days after you receive this Notice, stating the actions your company has taken in response to this Notice. Please direct your response to the address below and include the FDA reference number in all correspondence relating to this matter.

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
Building 51, Room 5342
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

Elizabeth P. Miller -S

Digitally signed by Elizabeth P. Miller -S
Date: 2026.10.07 09:27:28 -04'00'

Elizabeth Miller, Pharm.D.
Associate Commissioner for Inspections and Investigations
Office of Inspections and Investigations
U.S. Food and Drug Administration

cc: (b) (6) Regulatory Affairs Consultant
Addex Pharma S.A.
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(b) (6)
Addex Pharma S.A.