

NDA 219007

NDA APPROVAL

Teva Neuroscience, Inc.
Attention: Scott Martynuk
Manager, Regulatory Affairs, Neuroscience
145 Brandywine Parkway
West Chester, PA 19380

Dear Scott Martynuk:

Please refer to your new drug application (NDA) received December 8, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Weltruza (olanzapine) for extended-release injectable suspension.

This NDA provides for the use of Weltruza (olanzapine) for extended-release injectable suspension for the treatment of schizophrenia in adults.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at [FDA.gov](http://www.fda.gov).¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Quick Reference Guide, and Medication Guide) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible via publicly available labeling repositories.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 219007.**” Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Weltruza (olanzapine) for extended-release injectable suspension shall be 24 months from the date of manufacture when stored at 2°C – 8°C.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable and this product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients **and** is not likely to be used in a substantial number of pediatric patients.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*.

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication,

accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.³ Information and Instructions for completing the form can be found at FDA.gov.⁴

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.⁵

REQUESTED ENHANCED PHARMACOVIGILANCE (EPV)

We request that for Weltruza you submit all serious and non-serious domestic and/or foreign cases of post-injection delirium/sedation syndrome (PDSS) as though they were 15-day “Alert reports” (which are described under 21 CFR 314.80(c)(1)) during the first 5 years following initial U.S. approval date.

As described in 21 CFR 314.80(c)(1)(ii), we request that you promptly investigate all 15-day Alert reports of PDSS and submit follow-up reports within 15 calendar days of receipt of new information.

We also request that you provide a narrative summary including analysis of cases of PDSS as part of your required periodic safety reports [e.g., periodic adverse drug experience report (PADER) required under 21 CFR 314.80(c)(2)], quarterly during the first 3 years post-approval and annually thereafter, through the fifth year following initial U.S. approval date.

Your analysis should include interval and cumulative data relative to the date of approval of Weltruza. Your analysis should provide an assessment of causality, with documentation of indication, dose and frequency of therapy, duration of therapy, temporal association, associated signs and symptoms, confounders, underlying risk factors, treatment given for the event, outcome, and dechallenge/rechallenge.

We request that you search your global safety database, the medical literature, and other relevant data sources using, at minimum, the search terms in the table below.

³ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

⁵ <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>

Apply the following case definition to the reports retrieved with your search strategy to identify cases of PDSS:

Meets criteria listed in (a), (b), or both, that develop within 24 hours of a Weltruza injection:

- a. Symptom Clusters: A minimum of 1 sign or symptom from at least 3 of the following symptom clusters consistent with olanzapine overdose, with 1 or more signs or symptoms of at least moderate severity:
 - Sedation/somnolence
 - Delirium/confusion/disorientation/other cognitive impairment
 - Dysarthria/other speech impairment
 - Ataxia/paralysis/other motor impairment
 - Bradykinesia/muscle rigidity/tremor/other extrapyramidal symptoms
 - Agitation/irritability/anxiety/restlessness
 - Dizziness/weakness/general malaise
 - Seizure/convulsions
 - Other signs/symptoms consistent with olanzapine overdose
- b. Change in Level of Consciousness: Any change in level of consciousness (e.g., stuporous, unarousable, unconscious, comatose).

We also request that, when submitting any individual case safety reports (ICSRs) associated with Weltruza, you include, among other data:

- Proprietary name: The product should be identified using the proprietary name "Weltruza" in the relevant structured data field.
- Formulation/route of administration: The subcutaneous formulation should be specified in the relevant structured data field.

These measures will enable the Agency to accurately distinguish and attribute adverse event reports specific to Weltruza from those associated with other products containing the same active ingredient.

MedDRA Terms for Identifying Cases of PDSS			
Preferred Term	Preferred Term	Preferred Term	Lowest Level Term
<i>Acute respiratory distress syndrome</i>	<i>Dizziness</i>	<i>Psychomotor retardation</i>	<i>Post injection phenomenon</i>
<i>Acute respiratory failure</i>	<i>Dysarthria</i>	<i>Quadriparesis</i>	
<i>Aggression</i>	<i>Extrapyramidal disorder</i>	<i>Quadriplegia</i>	
<i>Agitation</i>	<i>Fatigue</i>	<i>Respiratory arrest</i>	

<i>Akathisia</i>	<i>Gait disturbance</i>	<i>Respiratory depression</i>	
<i>Altered state of consciousness</i>	<i>Generalized tonic-clonic seizure</i>	<i>Restlessness</i>	
<i>Anxiety</i>	<i>Heart rate increased</i>	<i>Sedation</i>	
<i>Arrhythmia</i>	<i>Hypersomnia</i>	<i>Seizure</i>	
<i>Aspiration</i>	<i>Hypertension</i>	<i>Seizure like phenomena</i>	
<i>Asthenia</i>	<i>Hypertensive crisis</i>	<i>Simple partial seizures</i>	
<i>Ataxia</i>	<i>Hypokinesia</i>	<i>Sluggishness</i>	
<i>Blood pressure decreased</i>	<i>Hypotension</i>	<i>Somnolence</i>	
<i>Blood pressure increased</i>	<i>Hypotensive crisis</i>	<i>Sopor</i>	
<i>Bradykinesia</i>	<i>Incoherent</i>	<i>Speech disorder</i>	
<i>Cardiac arrest</i>	<i>Irritability</i>	<i>Status epilepticus</i>	
<i>Cardiopulmonary failure</i>	<i>Lethargy</i>	<i>Stupor</i>	
<i>Cardio-respiratory arrest</i>	<i>Listless</i>	<i>Sudden cardiac death</i>	
<i>Cardio-respiratory distress</i>	<i>Loss of consciousness</i>	<i>Sudden death</i>	
<i>Cerebellar ataxia</i>	<i>Malaise</i>	<i>Syncope</i>	
<i>Clonic convulsion</i>	<i>Motor dysfunction</i>	<i>Tachycardia</i>	
<i>Cognitive disorder</i>	<i>Muscle rigidity</i>	<i>Tension</i>	
<i>Cogwheel rigidity</i>	<i>Muscular weakness</i>	<i>Tonic clonic movements</i>	
<i>Coma</i>	<i>Myocardial infarction</i>	<i>Tonic convulsion</i>	
<i>Confusional state</i>	<i>Neuroleptic malignant syndrome</i>	<i>Tremor</i>	
<i>Consciousness fluctuating</i>	<i>New onset refractory status epilepticus</i>	<i>Unresponsive to stimuli</i>	
<i>Convulsions local</i>	<i>Paralysis</i>	<i>Ventricular arrhythmia</i>	
<i>Coordination abnormal</i>	<i>Paresis</i>	<i>Ventricular fibrillation</i>	
<i>Delirium</i>	<i>Partial seizures</i>	<i>Ventricular flutter</i>	
<i>Depressed level of consciousness</i>	<i>Postictal state</i>	<i>Ventricular tachycardia</i>	
<i>Disorientation</i>	<i>Post-injection delirium sedation syndrome</i>		

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website.⁶

If you have any questions, contact Sujin Wolff, Regulatory Project Manager, at Sujin.Wolff@fda.hhs.gov or 301-796-1519.

Sincerely,

{See appended electronic signature page}

Tiffany R. Farchione, MD
Director
Division of Psychiatry
Office of Neuroscience
Office of New Drugs
Center for Drug Evaluation and
Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Medication Guide
 - Quick Reference Guide
- Carton and Container Labeling

⁶ <https://www.uspnf.com/>

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/

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