NDA 217901

NDA APPROVAL

Satsuma Pharmaceuticals, Inc.
Attention: Shannon Strom, Ph.D., R.A.C.
Vice President of Regulatory Affairs and Quality
4819 Emperor Blvd., Suite 340
Durham, NC 27703

Dear Dr. Strom:

Please refer to your new drug application (NDA) received on March 17, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Atzumi (dihydroergotamine) nasal powder.

We acknowledge receipt of your amendment dated October 30, 2024, which constituted a complete response to our January 17, 2024, action letter.

This NDA provides for the use of Atzumi (dihydroergotamine) nasal powder for the acute treatment of migraine with or without aura 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.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, 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 the 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 container (trade and sample) and protective pouch (trade, front) labeling submitted on October 30, 2024, and the protective pouch (sample, front) and carton (trade and sample) labeling with the revised portions submitted on March 27, 2025, with the quick reference guide portion of the protective pouch (trade and sample, back) as in the attached labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the 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 217901**." 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 Atzumi (dihydroergotamine) nasal powder shall be 30 months from the date of manufacture when stored at 20°C to 25°C.

ADVISORY COMMITTEE

Your application for Atzumi was not referred to an FDA advisory committee because this drug is not the first in its class.

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 requirement for pediatric studies in subjects less than 6 years of age because necessary studies are impossible or highly impracticable because migraine in this population is rare.

We are deferring submission of your pediatric studies for children and adolescents 6 through 17 years of age for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported

annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. These required studies are listed below.

4834-1 An open-label, single-dose study to evaluate the safety, tolerability, and single-dose pharmacokinetics (PK) of dihydroergotamine in patients with migraine 6 through 11 years of age.

Draft Protocol Submission:	04/2026
Final Protocol Submission:	10/2026
Study Completion:	04/2028
Final Report Submission:	10/2028

4834-2 A juvenile animal toxicology study of dihydroergotamine in one species.

Draft Protocol Submission:	04/2026
Final Protocol Submission:	10/2026
Study Completion:	10/2027
Final Report Submission:	04/2028

4834-3 A randomized, double-blind, placebo-controlled efficacy and safety study for the treatment of acute migraine with or without aura in patients 6 through 17 years of age. Part A should be for patients 12 through 17 years of age and Part B for patients 6 through 11 years of age. This study includes an initial single-blind placebo lead-in to identify patients who are non-responders to placebo for enrollment into the efficacy portion of the trial. The efficacy study must be designed to show superiority of dihydroergotamine over placebo.

Draft Protocol Submission:	01/2026
Final Protocol Submission:	07/2026
Study Completion (Part A):	07/2028
Study Completion (Part B):	04/2031
Final Report Submission:	10/2031

4834-4 A pediatric open-label safety study to evaluate the long-term safety of intermittent treatment with dihydroergotamine in patients 6 through 17 years of age, for up to one year. Part A should be for patients 12 through 17 years of age and Part B for patients 6 through 11 years of age.

Draft Protocol Submission:	01/2026
Final Protocol Submission:	07/2026

Study Completion (Part A):	07/2029
Study Completion (Part B):	04/2032
Final Report Submission (Part A):	01/2030
Final Report Submission (Part B):	01/2033

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocols to your IND 136585, with a cross-reference letter to this NDA. Reports of these required pediatric postmarketing studies must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[4]

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.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

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

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf

[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[7]

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[8].

If you have any questions, contact Daniel Ngembus, Regulatory Project Manager, at (301) 837-7345 or Daniel.Ngembus@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laura Jawidzik, MD
Director (Acting)
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Quick Reference Guide (protective pouch labeling back)

[7] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products

[8] 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/

LAURA A JAWIDZIK
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