

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

206099Orig1s000

Trade Name: Onzetra Xsail nasal powder 11 mg

Generic or Proper Name: sumatriptan

Sponsor: Avanir Pharmaceuticals

Approval Date: January 27, 2016

Indication: For migraine with or without aura.

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APPLICATION NUMBER:

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APPROVAL LETTER



NDA 206-099

NDA APPROVAL

Avanir Pharmaceuticals
Attention: Arthur Rosenthal
20 Enterprise, Suite 400
Aliso Viejo, CA 92656

Dear Mr. Rosenthal:

Please refer to your New Drug Application (NDA) dated and received January 27, 2014, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Onzetra Xsail (sumatriptan) nasal powder 11 mg.

We also acknowledge receipt of your amendment dated May 6, 2015, which constituted a complete response to our November 26, 2014, action letter.

Further, we acknowledge receipt of your major amendment dated October 21, 2015, which extended the goal date by three months.

This new drug application provides for the use of Onzetra Xsail (sumatriptan) nasal powder for migraine with or without aura.

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 text.

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). 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*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 14, 2015, submission containing final printed carton and container labels.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 months up to 6 years because necessary studies are impossible or highly impracticable in that age group.

We are deferring submission of your pediatric studies for ages 6-17 years for this application because pediatric studies should be delayed until additional safety or effectiveness data have been collected.

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)(3)(B) of the FDCA. These required studies are listed below.

3025-1 Conduct a pediatric study under the Pediatric Research Equity Act (PREA) to evaluate the efficacy and safety, including sparse pharmacokinetic (PK) sampling, of Onzetra Xsail (sumatriptan) for the acute treatment of migraine in pediatric patients of ages 12 to 17 years.

Protocol Submission:	September 2016
Study Completion:	November 2019
Final Report Submission:	June 2020

3025-2 Conduct a pediatric study under the Pediatric Research Equity Act (PREA) for the efficacy and safety of Onzetra Xsail (sumatriptan), including sparse pharmacokinetic sampling, for the acute treatment of migraine in pediatric patients ages 6 to 11 years. Conduct this study after its practicality has been determined based on the review of additional safety and efficacy data from the study of older children of ages 12 to 17 years under PMR 3025-1.

Protocol Submission:	December 2020
Study Completion:	June 2024
Final Report Submission:	December 2024

Submit the protocol(s) to your IND 110,090, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (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. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

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

If you have any questions, call Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ERIC P BASTINGS
01/27/2016