DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202278/S-001 & S-002

SUPPLEMENT APPROVAL

NuPathe Inc.
Attention: Nita U. Patel, Ph.D.
Regulatory Consultant to NuPathe
7 Great Valley Parkway, Suite 300
Malvern, PA 19355

Dear Dr. Patel:

Please refer to your Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zecuity Patch (sumatriptan iontophoretic transdermal system).

Application	Product Name	Submitted on:	Received on:
NDA 202278/S-001	Zecuity (sumatriptan) Patch	June 3, 2013	June 4, 2013
This supplement proposes:			
1. Replacement of the trademark symbol on the Zecuity product name by the registered mark symbol. 2. Changing the number of Zecuity systems per carton from 6 to 4 in Section 16 (*How Supplied/Storage And Handling*).			

We acknowledge receipt of your amendments dated July 9, 2013, July 15, 2013, and August 23, 2013.

Application	Product Name	Submitted on:	Received on:
NDA 202278/S-002	Zecuity (sumatriptan) Patch	August 23, 2013	August 23, 2013
This supplement proposes:			
1. Updated information in the *Instructions for Use* clarifying how to open the clear pouch. 2. Revision of the container package carton to includes a cut-out window on the carton labeling as a quality control measure.			

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your July 9, 2013, submission to sNDA 202278/S-001 includes final printed labeling (FPL) for your package insert, patient package insert, and Instructions for Use. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

We acknowledge your July 9, 2013, submission to sNDA 202278/S-001 containing final printed carton and container labels.

We acknowledge your July 15, 2013, submission to sNDA 202278/S-001 containing the content of labeling in structured product labeling (SPL) format.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, contact Laurie Kelley, PA-C, Regulatory Project Manager, via telephone at (301) 796-5068 or via email at Laurie.Kelley@fda.hhs.gov.

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

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

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

/s/

LAURIE A KELLEY
03/14/2014

ERIC P BASTINGS
03/21/2014