

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-395**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 022395

**NDA APPROVAL**

Neurogesx, Inc.  
2215 Bridgepointe Parkway  
Suite 200  
San Mateo, CA 94404

Attention: Susan Rinne, M.S.  
Vice President, Regulatory Affairs

Dear Ms. Rinne:

Please refer to your new drug application (NDA) dated October 13, 2008, received October 16, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for QUTENZA™ (capsaicin) 8% patch.

We acknowledge receipt of your submissions dated December 11, 2008 and January 29, February 4, 11, and 12, March 4, 6, 10, 11, 16, 26, 27 and 30, April 7 and 13, May 19, June 24, July 30, and August 18, 2009.

This new drug application provides for the use of QUTENZA™ (capsaicin) 8% patch for the management of neuropathic pain associated with postherpetic neuralgia.

We have completed our review of this application. 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, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). For administrative purposes, please designate this submission, “**SPL for approved NDA 022395.**”

**CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*.

Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission **“Final Printed Carton and Container Labels for approved NDA 022395.”** Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

### **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.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

### **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 to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **EXPIRATION DATING PERIOD**

An expiry of 36 months is granted for the finished product, including both the patch and cleansing gel components under the recommended storage conditions: Store carton between 20° to 25°C (68° to 77°F); excursions between 15° and 30°C (59° and 86°F) are permitted.

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B-05  
5600 Fishers Lane  
Rockville, MD 20857

## **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 Tanya Clayton, Regulatory Project Manager, at (301) 796-0871.

Sincerely,

*{See appended electronic signature page}*

Curtis J. Rosebraugh, M.D., M.P.H.  
Director  
Office of Drug Evaluation II  
Office of New Drugs  
Center for Drug Evaluation and Research

Enclosures: Package Insert  
Carton and Container Labels

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
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NDA-22395	ORIG-1	NEUROGESX INC	Qutenza

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

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/s/

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CURTIS J ROSEBRAUGH  
11/16/2009