CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

202543Orig1s000

Trade Name:	Levetiracetam in Sodium Chloride Injection, 500 mg/100 mL, 1000 mg/ 100 mL, and 1500 mg/100 mL.
Generic Name:	Levetiracetam in Sodium Chloride
Sponsor:	H Q Specialty Pharma Corporation
Approval Date:	November 9, 2011
Indications:	Provides for three pre-mixed solutions of 500 mg, 1000 mg, and 1500 mg of levetiracetam pre-diluted in 100 mL of sodium chloride injection.

CENTER FOR DRUG EVALUATION AND RESEARCH

202543Orig1s000

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Other Action Letters	
Labeling	**X**
REMS	
Summary Review	**X**
Officer/Employee List	**X**
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	**X**
Chemistry Review(s)	**X**
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	**X**
Clinical Pharmacology/Biopharmaceutics Review(s)	**X**
Other Reviews	**X**
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202543Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202543

NDA APPROVAL

H Q Specialty Pharma Corporation
Attention: Joseph M. Pizza
President
120 Route 17 North, Suite 130
Paramus, NJ 07653

Dear Mr. Pizza:

Please refer to your New Drug Application (NDA) dated January 13, 2011, received January 13, 2011, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Levetiracetam in Sodium Chloride Injection, 500 mg/100 mL, 1000 mg/ 100 mL, and 1500 mg/100 mL.

We acknowledge receipt of your amendments dated March 20, 2011, April 26, 2011, July 14, 2011, August 3, 2011, August 18, 2011, September 28, 2011, September 30, 2011 and October 27, 2011.

This new drug application provides for three pre-mixed solutions of 500 mg, 1000 mg, and 1500 mg of levetiracetam pre-diluted in 100 mL of sodium chloride injection.

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). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" 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

Submit final printed carton and container labels for product launch (approximately (b) (4) labels) that are identical to the carton and immediate container labels (i.e., container label, overwrap, and carton) submitted on August 18, 2011, as soon as they are available.

In addition, as discussed with you during the October 25, 2011 teleconference, we note your commitment to remove the terms (b) (4) from the container label, overwrap, and carton at the next print. Therefore, submit these final printed carton and container labeling for the next print that are identical to the carton and immediate container labels (i.e., container label, overwrap, and carton) that you submitted on October 27, 2011, as soon as they are available, but no more than 30 days after they are printed.

Please submit both versions of 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 (June 2008)." 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 202543**." 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.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry titled, "Contents of a Complete Submission for the Evaluation of Proprietary Names", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

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 none of these criteria apply to your application, 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.

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 questions, call or email Jacqueline H. Ware, PharmD, Senior Regulatory Project Manager, at (301) 796-1160 or Jacqueline.Ware@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
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/

RUSSELL G KATZ
11/09/2011