**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-055/S-021

Graceway Pharmaceuticals, LLC
340 Martin Luther Kind Jr Blvd
Bristol, TN 37620

Attention: Alicia M. Cabrelli
Senior Manager, Regulatory Affairs

Dear Ms. Cabrelli:

Please refer to your supplemental new drug application dated September 26, 2007, received September 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norflex™ (Orphenadrine Citrate) Injection.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY** section and addition of **DRUG ABUSE AND DEPENDENCE** and **OVERDOSAGE** sections. This supplement is intended to update the Norflex Injection NDA with the information approved on April 2, 2007 for Norflex Tablets (NDA 12-157/S-28). The Norflex Tablets package insert contains both dosage forms, however, due to an administrative oversight, a supplement was not submitted to the Norflex Injection NDA.

## CONTENT OF LABELING

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on September 26, 2007. We will transmit this version to the National Library of Medicine for public dissemination.

## LETTERS TO HEALTHCARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

**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 Kathleen Davies, Regulatory Health Project Manager, at (301) 796-2205.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia
And Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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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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Rigoberto Roca
2/11/2008 06:04:31 PM
for Bob Rappaport, M.D.