DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-157/S-028

Graceway Pharmaceuticals, LLC
340 Edgemont Avenue
Suite 500
Bristol, TN 37620

Attention: Jefferson J. Gregory
Chairman and Chief Executive Officer

Dear Mr. Gregory:

Please refer to your supplemental new drug application dated October 26, 2006, received October 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norflex™ (Orphenadrine Citrate) Extended-Release Tablets and Injection.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY** section and addition of **DRUG ABUSE AND DEPENDENCE** and **OVERDOSAGE** sections.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text for the package insert and patient package insert. For administrative purposes, designate this submission "**Content of labeling for approved supplement NDA 12-157/S-028**." Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit this version to the National Library of Medicine for public dissemination.

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

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

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

/s/

Bob Rappaport

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