DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-922/S-016

Graceway Pharmaceuticals, LLC
Attention: Sean Brennan, Ph.D.
340 Martin Luther King Jr. Blvd., Suite 500
Bristol, TN 37620

Dear Dr. Brennan:

Please refer to your supplemental new drug application dated January 27, 2009, received January 29, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Calcium Disodium Versenate (edetate calcium disodium) Injection.

We acknowledge receipt of your submissions dated April 28, May 15 and May 19, 2009.

This supplemental new drug application provides for revisions to the ampul and carton labels, and the package insert. The proposed labeling reflects Graceway as the distributor and Luitpold as the manufacturer in addition to the new ampul size, new carton and new NDC number.

We completed our review of this application, as amended. This application 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, immediate container and carton labels) and/or submitted labeling (package insert submitted May 19, 2009, immediate container submitted April 28, 2009 and carton labels submitted May 15, 2009).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 8-922/S-016**." Approval of this submission by FDA is not required before the labeling is used.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Hyon-Zu Lee, Regulatory Health Project Manager, at (301) 796-2192.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Rafel Rieves

5/19/2009 02:48:06 PM