DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-651/S-025 and S-026

Solvay Pharmaceuticals, Inc.
Authorized representative for Unimed Pharmaceuticals, Inc.
901 Sawyer Road
Marietta, GA 30062

Dear Mr. Hare:

Please refer to your supplemental new drug applications dated December 20, 2005 (supplement 025 and supplement 026), received December 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Marinol® (dronabinol) Capsules.

We acknowledge receipt of your submissions dated February 15, 2006 and June 12, 2006 (supplement 025) and May 18, 2006 (supplement 026).

Supplemental new drug application 025, "Changes Being Effected in 30 days" provides for revision of the product DESCRIPTION to reflect the change in gelatin formulation per Supplement 022, add new safety statements to INDIVIDUALIZATION OF DOSAGES, PRECAUTIONS AND ADVERSE REACTIONS based on data from the Periodic Safety Update (submitted July 2004).

Supplemental new drug application 026 provides for revisions to the Clinical Trials section.

We completed our review of these applications, as amended. These applications are 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).

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 these submissions "**FPL for approved supplement NDA 18-651/S-025, S-026**". Approval of these submissions by FDA is not required before the labeling is used.

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 Giuseppe Randazzo, Regulatory Project Manager, at (301) 796-0980.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Brian Harvey
6/21/2006 04:19:31 PM