DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-651/S-021

Unimed Pharmaceuticals, Inc.
Attention: Jennifer Stafford
Regulatory, Labeling Liaison
901 Sawyer Rd.
Marrieta, GA 30062

Dear Ms. Stafford:

Please refer to your supplemental new drug application dated October 25, 2004, received October 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Marinol® (dronabinol) Capsules, 2.5 mg, 5 mg, and 10 mg.

This supplemental new drug application provides for submission of final pharmacokinetic (PK) study reports to fulfill postmarketing commitments and update the label with PK information.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the physician 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 this submission "**FPL for approved supplement NDA 18-651/S-021**." Approval of this submission 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, Consumer Safety Officer, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug 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/

Joyce Korvick

4/26/05 09:00:55 PM