DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-651/S-018

Solvay Pharmaceuticals, Inc.
Attention: Beth Zaborny
Manager, Regulatory Affairs
901 Sawyer Road
Marietta, GA 30062

Dear Ms. Zaborny:

Please refer to your supplemental new drug application dated October 25, 2002, received October 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MARINOL® (dronabinol) Capsules, 2.5mg, 5mg, and 10mg.

We also refer to your amendments dated April 24 and 28, 2003.

This supplemental new drug application provides for changes to the Carcinogenesis, Mutagenesis, and Impairment of Fertility section of the package insert.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). In addition, at the next printing please add the following text to the immediate container labels for all strengths:

> MARINOL ®(dronabinol) should be packaged in a well-closed container and stored in a cool environment between 8◦ and 15◦C (46◦ and 59◦F) and alternatively could be stored in a refrigerator. Protect from freezing.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format-NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-651/S-018". Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Brian Strongin, R.Ph., M.B.A., Regulatory Project Manager, at (301) 827-7473.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D., M.S.
Director
Division of Gastrointestinal and
Coagulation Drug Products, HFD-180
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
4/28/03 04:53:31 PM
for Dr. Robert Justice