



NDA 9-048/S-037

ICN Pharmaceuticals, Inc.
Attention: Anil K. Hiteshi, R.A.C.
Senior Manager
International Headquarters
3300 Hyland Avenue
Costa Mesa, California 92626

Dear Mr. Hiteshi:

Please refer to your new supplemental drug application, dated August 12, 1998, received August 14, 1998, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for 8-MOP[®] (methoxsalen) Capsules, USP, 10 mg.

We acknowledge receipt of your submission dated September 24, 1998.

This supplemental new drug application provides updated information about the risk of melanoma for patients receiving PUVA therapy.

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 enclosed labeling text. Accordingly, the 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 and patient information insert).

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 individually mount 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 NDA 9-048/S-037." 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 Professional” 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 21CFR 314.80 and 314.81.

If you have any questions, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.

Director

Division of Dermatologic & Dental Drug Products

Office of Drug Evaluation ODE V

Center for Drug Evaluation and Research

Attachment (2)

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

/s/

John Kelsey
3/26/03 04:53:05 PM
for Dr. Wilkin