DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-600/S-006 & S-009

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 applications for S-006, dated August 12, 1998, received August 14, 1998, and for S-009, dated June 6, 2001, received June 12, 2001, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Oxsoralen-Ultra® (methosalen), USP, Capsules, 10 mg.

These supplemental new drug applications provide updated information about the risk of melanoma for patients receiving PUVA therapy (S-006), and (S-009) adds geriatric wording in the label as required by 21 CFR 201.57(f)(10).

We have completed the review of these applications 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, these applications are 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 package 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 19-600/S-006 and S-009." 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 04:39:27 PM
for Dr. Wilkin