DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-721/S-074

ICN Pharmaceuticals
Attention: Anil K. Hiteshi, R.A.C
Senior Manager, Corporate Regulatory Affairs
3300 Hyland Avenue
Costa Mesa, CA 92626

Dear Ms. Hiteshi:

Please refer to your supplemental new drug application dated August 19, 1998, received August 20, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dalmane® (flurazepam hydrochloride) Capsules, 15mg and 30 mg.

We acknowledge receipt of your submission dated April 10, 2001. Your submission of April 10, 2001 constituted a complete response to our October 31, 2000 action letter.

This supplemental new drug application provides for the following:

- A Geriatric Use subsection was added under Precaution section in the labeling to strengthen the precautions information for the safe use of the drug.
- A Geriatric Pharmacokinetics subsection was added under Clinical Pharmacology section together with a new Reference section.

We have completed the review of this supplemental application, as amended, 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 submitted final printed labeling.

Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

Please submit one market package of the drug product when it is available.

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 Melaine Shin, R.Ph., Regulatory Management Officer, at (301) 594-5793.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Russell Katz
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