



NDA 16-949/S-033

ICN Pharmaceuticals, Inc.  
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, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Limbitrol (chlordiazepoxide and amitriptyline hydrochloride) Tablets.

We additionally refer to an Agency approvable letter dated September 27, 2000 for the above supplemental application.

We acknowledge receipt of your submission dated April 24, 2001, providing for a response to our September 27, 2000, Agency letter.

This supplemental new drug application provides a new subsection in labeling under the **PRECAUTIONS** section entitled **Geriatric Use**.

We have completed the review of this supplemental 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 submitted final printed labeling (package insert submitted April 24, 2001/Label Code 26334520-0898), which incorporates all of the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

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

NDA 16-949/S-033

Page 2

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 Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

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  
6/5/01 08:46:16 AM