



NDA 15193/S-020

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

Dear Mr. Hiteshi:

Please refer to your supplemental new drug application dated February 8, 2002, received February 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mestinon (pyridostigmine) Syrup.

This supplemental new drug application provides for a new site of manufacture, packaging, and testing, a change in the active pharmaceutical ingredient specifications and test procedures, a change in the finished product specifications and test procedures, a change in equipment, a bioavailability waiver request, and a change in labeling.

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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The bioavailability waiver request is granted.

Additionally, the final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted February 8, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 15193/S-020." 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

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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 Teresa Wheelous, R.Ph., Regulatory Management Officer, at (301) 594-2850.

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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