NDA 5-378/S-020

Abbott Laboratories
Attention: David C. Ross
Regulatory Affairs
100 Abbott Park Road
D-491/AP 6B-1
Abbott Park, IL 60064-6108

Dear Mr. Ross:

Please refer to your supplemental new drug application dated January 4, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Desoxyn (methamphetamine HCl) 5 mg Tablets and Desoxyn (methamphetamine HCl) 5 mg, 10 mg, and 15 mg Gradumet Tablets.

The supplement provides for revisions to the **OVERDOSAGE** section of labeling as requested in an Agency letter dated July 14, 1995, as well as some minor editorial revisions.

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 January 4, 1996/Label Codes 03-4653-R4 (Desoxyn Tablets) & 03-5654-R3 (Desoxyn Gradumet Tablets)), which incorporates the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental application are permitted by section 314.70(c) of the regulations to be instituted prior to approval of the supplement. It is understood that the changes, described in the above NDA supplement, have been made.

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

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

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