NDA 9-193/S-037
NDA 12-015/S-023

Merck Research Laboratories
Attention: Dennis Erb, Ph.D.
Senior Director, Regulatory Affairs
P.O. Box 4, Sumneytown Pike
West Point, PA 19486-0004

Dear Dr. Erb:

Please refer to your supplemental new drug applications dated April 7, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cogentin (benztropine mesylate) Tablets (NDA 9-193) and Injection (NDA 12-015).

These supplements provide for the following revisions to product labeling:

1. Changed the terminology from “children” to pediatric patients” under the **CONTRAINDICATIONS** section.
2. Added a new subsection under **PRECAUTIONS** entitled **Pediatric Use** which references the practitioner to the **CONTRAINDICATIONS** section.
3. Deleted the 1 mg unit doses packages of 100 under the **HOW SUPPLIED** section.

We have completed the review of these supplemental 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 submitted final printed labeling (package insert submitted April 7, 1997 /Label Code 7924121), which incorporates the revisions listed. Accordingly, these supplemental applications are approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental applications 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 supplements, 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,

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