DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 8-370/S-030

Aventis Pharmaceuticals
Attention: Kimberly A. Davis
Senior Regulatory Analyst, US Liaison
300 Somerset Corporate Boulevard
Bridgewatewr, NJ 08807-0854

Dear Ms. Davis:

Please refer to your supplemental new drug application dated February 14, 2002, received February 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bentyl® (dicyclomine hydrocholride) Injection.

This supplemental new drug application provides for revised bottle labels to include the total quantity of contents (20 mg/2 mL).

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 bottle label and carton label, submitted February 14, 2002, with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

On the bottle label and carton label revise the phrase 20mg/2mL to read “20 mg/2 mL), placing a space between the number and the unit.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (immediate container and carton labels submitted February 14, 2002). These revisions are terms of the approval of this application.

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 8-370/S-030." 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

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 Alice Kacuba, R.N., MSN, RAC, Regulatory Health Project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
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/

Victor Raczkowski

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