DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-273/S-057

Aventis Pharmaceuticals, Inc
Attention: Ms. Liza Karpiak, R.Ph.
300 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Ms. Karpiak:

Please refer to your electronic supplemental new drug application dated January 6, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lasix® (furosemide) 20, 40 and 80 mg Tablets.

We acknowledge receipt of your submission dated September 23, 2005 that constituted a complete response to our July 2, 2004 action letter.

This electronic supplemental new drug application provides for final printed labeling in response to our approvable letter of July 2, 2004. The **CLINICAL PHARMACOLOGY, Geriatric Population**; **PRECAUTIONS, Geriatric Use**; and **HOW SUPPLIED** sections were revised as follows:

CLINICAL PHARMACOLOGY
Geriatric Population
Furosemide binding to albumin may be reduced in elderly patients. Furosemide is predominantly excreted unchanged in the urine. The renal clearance of furosemide after intravenous administration in older healthy male subjects (60-70 years of age) is statistically significantly smaller than in younger healthy male subjects (20-35 years of age). The initial diuretic effect of furosemide in older subjects is decreased relative to younger subjects. (See PRECAUTIONS: Geriatric Use.)

PRECAUTIONS
Geriatric Use
Controlled clinical studies of Lasix did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for the elderly patient should be cautions, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased, hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function. (See PRECAUTIONS: General and DOSAGE AND ADMINISTRATION.)

HOW SUPPLIED
Store at 25° C (77° F); excursions permitted to 15- 30° C (59- 86° F). [See USP Controlled Room Temperature.]

In addition, following changes were noted:

1. Under the DESCRIPTION section, second sentence, “lactose USP” was changed to “lactose monohydrate NF” in the list of inactive ingredients.

2. The revision date was updated.

3. The zip code was revised.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 23, 2005.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions, please call Mr. Daryl Allis, Regulatory Project Manager, at (301) 796-1034.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardiovascular and Renal 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/

Norman Stockbridge

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