DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18-538/S-028 **APPROVAL LETTER**

Sanofi Aventis U.S. LLC
Attention: Mr. John Cook
U.S. Regulatory Affairs Marketed Products
55 Corporate Drive
Bridgewater NJ 08807

Dear Mr. Cook:

Please refer to your supplemental new drug application dated November 24, 2003, received November 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lozol® (indapamide) 1.25 and 2.5mg Tablets.

We also acknowledge receipt of your submission dated February 17, 2006, in response to our approvable letter dated April 28, 2004.

This supplemental new drug application provides for revision to the labeling by adding a **Geriatric Use** subsection under **PRECAUTIONS** as follows:

> **Geriatric Use**
>
> Clinical studies of indapamide 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 the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, 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.
> Severe cases of hyponatremia, accompanied by hypokalemia have been reported with recommended doses of indapamide in elderly females (see **WARNINGS**).

Under **HOW SUPPLIED**, we note that the 2.5mg strength has been removed from the label.

We completed our review of this supplemental new drug application, as amended, it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 17, 2006.

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, please call Michael Monteleone, Regulatory Project Manager, at (301) 796-1952.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Enclosed Labeling Text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18538	SUPPL-28	SANOFI AVENTIS US LLC	LOZOL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
09/03/2009