



NDA 19-507S-006

Sanofi-Aventis U.S. LLC
Attention: Mr. John Cook
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Cook:

Please refer to your supplemental new drug application dated February 12, 2008, received February 13, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kerlone (betaxolol hydrochloride) 10 and 20 mg Tablets.

This supplemental new drug application provides for changes to the **PRECAUTIONS**, section of the package insert as follows:

“Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.”

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the structured product labeling (SPL) submitted on February 12, 2008.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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:

Dan Brum, Pharm.D.
Regulatory Health Project Manager
301-796-0578

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Attached:
label

**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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