



NDA 16-419/S-029

Baxter Healthcare Corporation  
Attention: Ms. Valerie Shinault, Regulatory Affairs  
2 Easterbrook Lane  
Cherry Hill, NJ 08003-4099

Dear Ms. Shinault:

Please refer to your supplemental new drug application dated December 12, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inderal (propranolol hydrochloride) Injection, 1 mg/ml.

This "Changes Being Effected" supplemental new drug application provides for labeling revised as follows:

1. Under PRECAUTIONS/General, the word "elevated" has been added to the third sentence of the second paragraph. The new sentence reads as follows:

Withdrawal may lead to a return of elevated intraocular pressure.

2. The item number has been updated.

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 final printed labeling (FPL) submitted on December 12, 2007.

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 Project Manager, at (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

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/s/

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Norman Stockbridge  
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