



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 18-766/S-014

Pharmacia & Upjohn Company  
C/O Pfizer, Inc.  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Attention: Robert B. Clark  
Vice President, US Regulatory Strategy

Dear Mr. Clark :

Please refer to your supplemental new drug application dated February 26, 2007, received February 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ansaid<sup>®</sup> (flurbiprofen) tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to the NSAID Medication Guide as requested in our January 18, 2007 letter.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling (text for package insert and Medication Guide) submitted on February 26, 2007. We note that you have submitted content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format that is identical to the enclosed labeling.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Kathleen Davies, Regulatory Project Manager, at (301) 796-2205.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, MD  
Director  
Division of Anesthesia, Analgesia  
And Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Sharon Hertz  
6/21/2007 12:29:06 PM  
Signing for Bob Rappaport, M.D.