



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-716/S-010

Abbott Laboratories  
200 Abbott Park Road  
D-RA76, Bldg. AP30-1NE  
Abbott Park, IL 60064-6157

Attention: Jeremy McCumber  
Senior Regulatory Affairs Specialist

Dear Mr. McCumber:

Please refer to your supplemental new drug application dated May 9, 2008, received May 12, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vicoprofen<sup>®</sup> (hydrocodone bitartrate/ibuprofen) Tablets.

This supplemental new drug application provides for the addition of the toll-free number for reporting adverse events to the Medication Guide.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the Package Insert and Medication Guide.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "SPL for approved supplement NDA 20-716/S-010." Approval of these submissions by FDA is not required before the labeling is used.

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  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sharon Turner-Rinehardt, Regulatory Health Project Manager, at (301) 796-2254.

Sincerely,

*{See appended electronic signature page}*

Sharon Hertz, M.D.  
Deputy Director  
Division of Anesthesia, Analgesia and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: Package Insert  
Medication Guide

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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

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