



NDA 020716/S-011

SUPPLEMENT APPROVAL

Abbott Laboratories
Dept. PA71 / Bldg. AP30-1
200 Abbott Park Road
Abbott Park, IL 60064-6157

Attention: Tracy L. Verciglio
Associate Director, Regulatory Affairs PPG

Dear Ms. Verciglio:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 30, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vicoprofen (hydrocodone bitartrate and ibuprofen) tablets, 7.5 mg/ 200 mg.

We acknowledge receipt of your amendments dated March 16 and May 10, 2012.

This "Prior Approval" supplemental new drug application proposes revisions to the carton and immediate container labeling for Vicoprofen.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labels for the carton and immediate containers.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels submitted on May 10, 2012, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with six of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020716/S-011.**" Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 Dominic Chiapperino, Ph.D., Senior Regulatory Health Project Manager, at (301) 796-1183.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

BOB A RAPPAPORT
08/27/2012