DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-429/S-023

Watson Laboratories
577 Chipeta Way
Salt Lake City, UT 84108

Attention: Wendy DeSpain, MS, MBA, RAC
Manager, Proprietary Regulatory Affairs

Dear Ms. DeSpain:

Please refer to your supplemental new drug application dated September 11, 2007, received September 12, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fiorinal® with Codeine Capsules (butalbital, acetaminophen, caffeine, and codeine phosphate) 50 mg, 325 mg, 40 mg, 30 mg. We also refer to your alternate trade-dress (Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules).

We acknowledge receipt of your submissions dated September 12, 2007, January 21, and March 7, 2008.

This "Changes Being Effected" supplemental new drug application revises the package insert to include language regarding ultra-rapid metabolizers of codeine in the PRECAUTIONS section of your package insert as requested in our July 13, 2007 supplement request letter. In addition, this supplement also provides for minor edits to the DESCRIPTION, CLINICAL PHARMACOLOGY, ADVERSE REACTIONS, OVERDOSAGE, and HOW SUPPLIED sections of the package insert.

We have completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the attached content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on September 11, 2007. We will transmit this version to the National Library of Medicine for public dissemination.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Tanya Clayton, Regulatory Project Manager, at (301) 796-0871.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Bob Rappaport

4/8/2008 02:33:16 PM