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(sNDA) 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, aspirin, caffeine, and codeine phosphate) 50 mg, 325 mg, 40 mg, and 30 mg

We also refer to our Approval letter for this sNDA dated April 8, 2008, in which we noticed the product name in the first paragraph is incorrect. We listed "Fioricet" instead of "Fiorinal". In order to rectify the mistake, we will be issuing a replacement Approval Letter to include the correct product name. Please note the action date will be unchanged, but the signature time will be one minute later than the original Approval letter to permit differentiation between the two letters.

If you have any questions, call Tanya Clayton, Regulatory Health Project Manager, at (301) 796-0871.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
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

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