



NDA 19-899/S-008/S-011/S-012

McNeil Consumer and Specialty Pharmaceuticals
Attention: Paula J. Oliver
Senior Director, Medical and Regulatory Science
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Oliver:

Please refer to your supplemental new drug application (NDA) submitted on April 5, 2000 (S-012), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Motrin Sinus/Headache (ibuprofen and pseudoephedrine HCl) Caplets.

We also refer your submissions dated May 1, 2000, and January 16 and 21, 2002.

This supplement provides for revised labeling (20 and 40 Caplet-count carton labels) to comply with the content and format requirements of 21 CFR 201.66.

We completed our review of this supplemental application and it is approved effective on the date of this letter.

We also refer to your supplemental NDAs 19-899/S-008 and S-011, submitted on February 29, 2000, and April 5, 2000, respectively, and the submissions dated August 17, 2000 (S-011 only), and January 16 and 21, 2002, amending these applications. Our approval of the labeling for supplemental NDA S-012 supercedes consideration of the proposed labeling for S-008 and S-011. Therefore, supplemental applications S-008 and S-011 will be administratively closed as of the date of this letter and retained in our files without further review.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

{See appended electronic signature page}

Charles Ganley, MD

Director

Division of Over the Counter Drug Products

Office of Drug Evaluation V

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/

Charles Ganley
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