DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020516/S-030

SUPPLEMENT APPROVAL

McNeil Consumer Healthcare
Attention: Victoria Wagner-Weber
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Wagner-Weber:

Please refer to your Supplemental New Drug Application (sNDA) dated October 15, 2014, received October 15, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Motrin (ibuprofen) oral suspension, 100 mg per 5 mL.

We acknowledge receipt of your amendments dated December 18, 2014 and March 27, 2015.

This "Prior Approval" sNDA proposes to make changes per the FDA Guidance for Industry "Dosage Devices for Orally Ingested OTC Liquid Drug Products" and per the CHPA Voluntary Guidelines "CDC Stakeholder Initiative: Preventing Unsupervised Medication Ingestions and Overdoses in Children" in addition to editorial changes.

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

LABELING

Submit final printed labeling (FPL) as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the following labels submitted on March 27, 2015 and be in the "Drug Facts" format (21 CFR 201.66), where applicable:

- 4 fl. oz. (grape, bubblegum, berry and berry dye-free flavored) carton and bottle labels
- 4 fl. oz. berry flavored (Hospital/Government) carton and bottle labels
- 4 fl. oz. berry flavored (Twin-Pack) panel card
- 1 fl. oz. berry flavored carton and bottle labels

The FPL should be submitted 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 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission **"Final Printed Labeling for approved NDA 020516/S-030."** Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 Jade Pham, Regulatory Project Manager, at (301) 796-7031.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
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/

THERESA M MICHELE
04/16/2015