DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-603/S-005

McNeil Consumer & Specialty Pharmaceuticals
Attention: Lynn A. Pawelski
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Pawelski:

Please refer to your supplemental new drug application dated July 20, 2001, received July 23, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infant's Motrin (50 mg/1.25 mL ibuprofen oral suspension).

We acknowledge receipt of your submissions dated August 2 and December 12, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an additional package size of 1 fl. oz. (Currently approved package sizes for Infants' Motrin are 0.25 and 0.5 fl. oz.)

We have completed the review of this supplemental application and it is approved effective on the date of this letter. However, we have the following recommendations. These recommendations should be incorporated at the time of next printing or within 180 days, whichever comes first, and noted in your next Annual Report.

Labeling

1. Under ***Purposes***, align the statement "Fever reducer/pain reliever" with the statement "Ibuprofen 50 mg. . .".
2. Under ***Warnings***, **Do not use**, the bolding is not prominent compared to the subheading "**Allergy alert."** Modify the label accordingly.
3. The statement that reads "dispense liquid slowly into the childs mouth toward the inner cheek" included in the previously approved labeling, should be retained under ***Directions.*** Place this statement after the statement that reads "Measure with the dosing device provided. Do not use with any other device."

Note that, the final printed labeling was not submitted for the ¼ ounce products. You are reminded that you will need to revise the labeling to comply with specifications stated in the OTC Labeling Requirements final rule under 21 CFR 201.66 within the time frames stated in that rule 65 FR 38193if you intend to market the ¼ ounce product.

The final printed labeling (FPL) must be identical to the draft labeling (immediate carton and container

labels) submitted on August 2, 2001, with the exception of the changes recommended above, and should be formatted in accordance with the requirements of 21 CFR 201.66 as of May 16, 2002.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-603/S-005." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Walter Ellenberg, Ph.D., Regulatory Project Manager, at 301-827-2247.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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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