



NDA 19-012/S-034

NDA 20-516/S-011

McNeil Consumer and Specialty Pharmaceuticals

Attention: Paula Oliver

Senior Director, Medical and Regulatory Affairs

7050 Camp Road

Fort Washington, Pennsylvania 19034-2299

Dear Ms. Oliver:

Please refer to your supplemental drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Motrin IB (200 mg ibuprofen) caplets

NDA Number: 19-012 / S-034

Name of Drug Product: Children's Motrin (100 mg ibuprofen /5 ml) oral suspension

NDA Number: 20-516 / S-011

Date of Applications: January 29, 2003

Date of Receipt: January 30, 2003

These supplemental new drug applications propose new labeling for the co-packaging of Motrin IB (200 mg ibuprofen) caplets with Children's Motrin (100 mg ibuprofen /5 ml) oral suspension.

We acknowledge receipt of your submissions dated July 10, 2003, and August 7, 2003.

Your submission of August 7, 2003 constituted a complete response to our July 28, 2003 action letter.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (carton label submitted August 7, 2003), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submission(s) should be designated "FPL for approved supplement NDA 19-012/S-034", and "NDA 20-516/S-011". Approval of these submissions by FDA is not required before the labeling is used.

We have the following additional recommendations for your consideration to be incorporated at the next printing:

1. Although the statement of identity on the outer carton for the combination product was increased in size, both the established names and the pharmacologic category appear to be smaller than in the January 29, 2003 submission. We note that the size of the trade name has been decreased, which thereby increases the relative size of the established name compared to that of the trade name. Nonetheless, the overall appearance of the established name is still too small. Increase the font size of the statement of identity for both the adult and children's product.
2. The font size of the product names that appear over the Drug Facts labeling on the outer combination carton should be increased for further distinction between the products.
3. The graphic symbols (arrows) for continuation of Drug Facts for the children's product on the outer combination carton should be more prominent. (The arrow for the adult product appears bolder than that for the children's product.)
4. The font size of the established name, "Ibuprofen Tablets USP, 200 mg" on the inner carton for the adult product is considerably smaller than in the January 29, 2003 submission. The font size should be increased to a size larger than that in the January 29, 2003 submission, as requested in our July 28, 2003, letter.
5. The inner carton for the children's product was not included in your August 7, 2003 submission. You are reminded of our July 28, 2003 request to increase the font size of the statement of identity on the inner carton of the children's product.
6. Change the color of the lines that enclose the Drug Facts labeling on the inside carton for the adult product from orange to blue to correspond to the color of that (for the adult) on the outer combination carton, and to be in contrast from that on the children's product, to avoid confusion.

The Agency is concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. We will provide guidance on wording and placement of organ-specific warnings in the labeling of drug products containing acetaminophen and/or NSAID's in the future.

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, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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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 Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.

Director

Division of Over-the-Counter Drug Products

Center for Drug Evaluation V

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Charles Ganley  
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