CENTER FOR DRUG EVALUATION AND RESEARCH
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MEMORANDUM

Date: **April 18, 2008**

From: **Joel Schiffenbauer, M.D.**
Deputy Director, DNCE

Subject: **NDA 20-606 and 21-140; Imodium Multi-Symptom Relief**

Sponsor: **McNeil Consumer Healthcare**

McNeil Consumer Healthcare requested a new name, [redacted] for their Imodium Advanced product that contains loperamide and simethicone. [redacted] Subsequently the applicant requested an alternate name, Imodium Multi-Symptom Relief for this product and referred back to the original studies used to approve the product for supporting data for the use of the language "multi-symptom relief of diarrhea." Please see reviews by Dr. Osborne and Tan for details regarding the justification for the name change and specific labeling comments.

This memorandum will document 2 issues relating to this submission. First, the Division agrees with changing the wording for the indication on the Drug Facts label from "controls symptoms of diarrhea…" to "relieves symptoms of diarrhea…" for the following reasons: a) the monograph describing antidiarrheal drugs (21 CFR 355) states under the indication section for bismuth subsalicylate that labeling states [select one of the following: "controls" or relieves"] and therefore allows the use of either term; b) The Division agreed that the 2 words could be interchanged based on consumer understanding; c) the language on the PDP will reflect the language under the Uses section of the Drug Facts and should therefore reduce any potential for confusion by the consumer.

The second issue relates to the DMETS recommendation (see DMETS review dated March 26, 2008) regarding increasing the size and prominence of the flag "Formerly Imodium Advanced." The applicant agreed to do this after the initial printing which has already occurred, and will occur at approximately 6-8 weeks after the initial printing. The flag will be removed after 6 months as discussed in Dr. Tan's review. In addition DMETS recommends that the active ingredients and statement of identity be made more prominent. The applicant has agreed to move the active ingredients and statement of identity to under the trade name to make the information more prominent, and also agreed to increase the size of the active ingredients and statement of identity, at the next printing (6-8 weeks after the initial printing). Finally, DMETS had no objection to the use of proprietary name for this product.

Conclusions and Recommendations:

It is recommended that this NDA be approved with the agreed upon labeling changes.

APPEARS THIS WAY ON ORIGINAL

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/s/

Joel Schiffenbauer
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MEDICAL OFFICER