Procter & Gamble

The Procter & Gamble Company
Health Care Research Center
8700 Mason-Montgomery Road, Mason, Ohio 45040-9462

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July 16, 2003

Dockets Management Branch (HFA - 305)
U.S. Food and Drug Administration
Room 1061
5360 Fishers Lane
Rockville, MD 20852

Re: Docket No. 78N-036T
Antidiarrheal Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Final Monograph; Proposed Rule [21CFR 335], Federal Register Vol. 68, No. 74

Dear Sir or Madam:

The Procter & Gamble Company (Procter & Gamble) herewith submits, in triplicate, comments in response to the proposed rule: antidiarrheal drug products for over-the-counter (OTC) human use; proposed amendment of the final monograph, published on April 17, 2003 in the Federal Register (Vol. 68, No. 74, pages 18915-18917). Procter & Gamble, as a manufacturer and distributor of antidiarrheal drug products for OTC human use, is directly affected by this proposed rule.

We (Procter & Gamble) support the Food and Drug Administration's (FDA) proposal to amend the final monograph for OTC antidiarrheal drug products to include "controls" or "relieves" travelers' diarrhea as an indication for products containing bismuth subsalicylate. This amendment will provide and effective therapy for the treatment of travelers' diarrhea.

Procter & Gamble encourages the FDA to expeditiously amend the antidiarrheal monograph so this statement can be used on appropriate OTC products or agree to provide a stay of enforcement letter to companies which so request.

As separately submitted to docket no. 78N-036D on July 16, 2003:

> "We (Procter & Gamble) support the Food and Drug Administration's (FDA) statement that there is no definitive evidence that drugs containing nonaspirin salicylates, which include bismuth subsalicylate, significantly increase the risk of Reye's syndrome (FR Vol.68, No. 74, pg. 18863, col. 3)."

Sincerely,
The Procter & Gamble Company
Product Safety and Regulatory Affairs Department

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