



JUN 20 2006

Bruce S. Manheim, Jr.
Ropes & Gray LLP
One Metro Center
Suite 900; 700 12th Street NW
Washington, DC 20005-3948

Dear Mr. Manheim:

We are writing in response to the time and extent application (TEA) that you submitted on June 24, 2005, for the laxative ingredient sodium picosulfate. Following telephone conversations with Dr. Michael Koenig of this division on May 16 and 22, 2006, you submitted a revised TEA with confidential commercial information redacted. We received the revised TEA on May 23, 2006.

We agree that the following redacted information represents confidential commercial information as defined in 5 U.S.C. 552(b)(4) and 21 CFR 20.61(b) and (c):

- Table in Section III.B. entitled "Annual Total Units Worldwide per Formulation": All data other than the data contained in the three rows entitled "Total Units (1987-2003)," "Largest Package Size," and "Minimum Consumer Exposure." All column and row titles will remain so that readers know the nature of the information presented (and redacted).
- Tables in Section III.C.: All numeric data and footnote material specifically citing cumulative total numbers of dosage units sold and consumer exposures in each of the five countries. Dosage forms will not be redacted.
- Table in Section III.D. entitled "Summary of Marketing Experience Among the Five Countries": All numeric data specifically citing cumulative total numbers of dosage units sold (consumer exposures) in columns A through E. Dosage forms will not be redacted.
- Exhibit A (Method of Synthesis/Manufacturing Process of Sodium Picosulfate)

We are placing the May 23, 2006, revision of your TEA on public display at the Division of Dockets Management in Docket No. 2006O-0232. If you have any questions or comments regarding this matter, please contact Dr. Michael Koenig at 301-796-2090.

Sincerely,

Susan Johnson, Ph.D.
Acting Director,
Division of Nonprescription Regulation Development
Office of Nonprescription Products
Center for Drug Evaluation and Research

2006 O -0232

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