PURDUE

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October 31, 2003

Via Federal Express
SUBMITTED IN TRIPLICATE

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 78N-036L
Comment No. RPT 16

Dear Sir/Madam:

Reference is made to your letter dated October 21, 2003, regarding the 2-year oral carcinogenicity study in rats to support the safety of senna-containing over-the-counter (OTC) laxative drug products.

Your letter requests the completion of histopathological examinations of the brain tissues from the remaining animals of the low and mid dose groups and we agree to provide the additional information. It must be noted that the protocol for this study was reviewed and accepted by the Carcinogenicity Assessment Committee, and that the study was conducted with strict adherence to the protocol. This additional analysis was not required according to the protocol.

Nevertheless, we agree to conduct a histological evaluation of the brains of 18 animals in the low-dose group (25 mg/kg/day) and the brains of 15 animals in the mid-dose group (100 mg/kg/day).

It is anticipated that the study protocol will be amended, the tissues evaluated and the final report amended and submitted to the agency by March 30, 2004.

We hope this additional information will answer your questions and allow the completion of the monograph process. We believe this study shows that Senna is not a carcinogen and the monograph should be finalized as a Category I.

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Please do not hesitate to contact me for further information at (203) 588-8107.

Sincerely,
The Purdue Frederick Company
By:

David Grob

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CC: Dr. Charles J. Ganley