PURDUE

The Purdue Frederick Company

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March 28, 2003

Via Federal Express
SUBMITTED IN TRIPLICATE

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

RE: Docket No. 78N-036L
Comments No. RPT13 and ANS6

Dear Sir/Madam:

Reference is made to our submissions to the subject Docket dated June 30, 1999, March 27, 2001 and April 16, 2001 in support of the safety of senna as a Category I OTC laxative drug ingredient and your letters of February 29, 2000 and March 27, 2001.

This study was conducted in response to the Food and Drug Administration's request (FR 33592) for further testing to support Category I status of senna-containing OTC laxative drug products. The purpose of this study (Purdue Pharma LP; study no. DSE-312-GLP) was to investigate the potential carcinogenic response to Senna after oral administration to Sprague-Dawley rats (60/sex/group in the main study and 18/sex/group in the toxicokinetic groups) at dose levels of 0, 0, 25, 100 and 300 mg/kg/day for up to 104 consecutive weeks. The study was conducted at ClinTrials BioResearch(CTBR) (Montreal, Canada). Four companies sponsored the study: Purdue Pharma LP (Stamford, CT), Madaus AG (Koln, Germany), Novartis Consumer Health (Parsippany, NJ) and Reckitt and Benckiser (Hull, UK).

The results of this study show that lifetime daily administration of Senna-MIS to Sprague-Dawley rats, at dosage levels of up to 300 mg/kg/day, did not reveal any evidence that Senna-MIS is a carcinogen.

Therefore, based upon the data presented in this submission, The Purdue Frederick Company respectfully requests that senna-containing laxatives be reclassified from Category III to Category I in the Final Monograph for OTC Laxative Drug Products.

78N-036L

RPT16

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

Sincerely,
For The Purdue Frederick Company
By:

David Grob

David W. Grob, MS, RAC
Director
Regulatory Affairs OTC & Labeling
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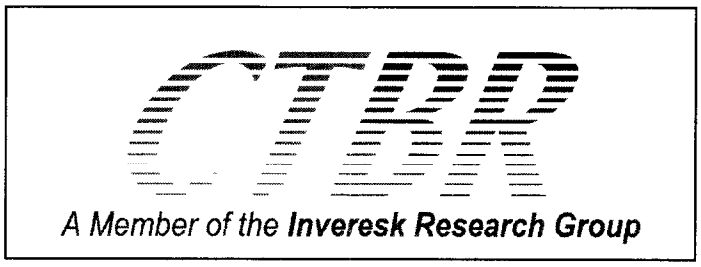
Enclosure



STUDY TITLE: AN ORAL CARCINOGENICITY STUDY OF SENNA-MIS IN THE ALBINO RAT

TESTING FACILITY:
ClinTrials BioResearch Ltd
87 Senneville Road
Senneville Quebec, Canada H9X 3R3

TESTING FACILITY PROTOCOL NUMBER: 88633

PPLP, MADAUS PROJECT NUMBER: DSE-312-GLP, TX220

TESTING FACILITY STUDY DIRECTOR:
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Novartis Consumer Health
200 Kimball Drive, Parsippany NJ, 07054-0622

Reckitt & Benckiser Dansom Lane
Hull, HU8 7DS

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Purdue Study Number. DSE-312-GLP
Madaus AG Study Number: TX220

CTBR No. 88633

APPROVAL OF STUDY REPORT

Reviewed By: _____

P. Batham
Scientific Director
General Toxicology

4 March 2003
Date