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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

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MAR 27 2001

Anthony C. Santopolo, M.D.
Vice President
U.S. Regulatory Affairs
Purdue Pharma, L.P.
One Stamford Forum
Stamford, Connecticut 06901

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

Dear Dr. Santopolo:

Reference is made to our letter to Dr. James Conover, dated February 29, 2000, identified as Comment No. ANS6, under Docket No. 78N-036L. That letter was in response to Purdue Pharma L.P.'s June 30, 1999, submission (Comment No. RPT13; Docket No. 78N-036L) concerning results of analytical and toxicity testing on senna and a protocol for a proposed industry-wide 2-year rat carcinogenicity study of senna. Purdue Pharma L.P. submitted this information to support the safety of senna as a Category I (safe and effective) over-the-counter (OTC) laxative drug ingredient. Dr. Conover's cover letter stated that Purdue Pharma L.P. planned to begin the carcinogenicity study soon. The letter also requested a delay in the reclassification of senna until the carcinogencity study report is issued.

In our letter to Dr. Conover, we provided comments on the protocol for the proposed 2-year rat carcinogenicity study. At this time, we are requesting an update on the progress of the carcinogenicity study and the targeted completion date for analysis of the data and submission of the study results to FDA. As you are aware, the Agency reclassified senna (including sennosides A and B) from Category I to Category III in the FEDERAL REGISTER of June 19, 1998 (63 FR 33592). In order to establish a timetable for completion of the Agency's rulemaking for OTC laxative drug products, we would appreciate your response within 4 weeks from the date of this letter.

Sincerely yours,

Charles J. Ganley, M.D.

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

78N-036L

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