



David W. Grob, MS, RAC
Senior Director, Regulatory Affairs OTC
Purdue Pharma L.P.
The Purdue Frederick Company
One Stamford Forum
Stamford, Connecticut 06901-3431

NOV 10 2004

Re: Docket No. 1978N-036L
Comment No. CP29

Dear Mr. Grob:

This letter is in response to your citizen petition (CP29), dated April 12, 2004, and filed under Docket No. 1978N-036L in the Division of Dockets Management on April 13, 2004. The petition requested that FDA reopen the administrative record for the tentative final monograph on OTC laxative drug products to allow for additional comments on senna active ingredients. Alternatively, if the petition is not granted, you asked FDA to include your submission as a comment into the final administrative record. You further requested that FDA reject a comment (Comment No. C211) submitted by Hyman, Phelps & McNamara on January 20, 2004, on behalf of Madaus AG (Cologne, Germany) based on the information submitted in your petition.

On October 22, 2003, FDA reopened the administrative record for the rulemaking for OTC laxative drug products (68 FR 60302) to accept comments and data on these drug products because the administrative record officially closed at various times during the course of this rulemaking. FDA determined that there was good cause to consider these new data in developing the final monograph (FM) for OTC laxative drug products. The comment period closed on January 20, 2004.

Hyman, Phelps & McNamara, on behalf of Madaus AG (Cologne, Germany), submitted a comment on senna (Comment No. C211), on January 20, 2004, the last day that the administrative record was open. The comment requested that FDA change the definition of sennosides to reflect the European Pharmacopeia Monograph, specify the spectrophotometric method as the standard analytical method to calculate the amount of sennosides, and include combinations containing senna, plantago seed, and plantago ovata husks in the laxative FM. Your citizen petition refutes the data and requests made by Madaus AG.

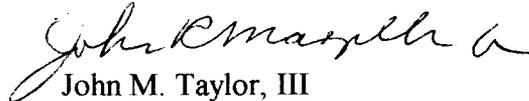
We are currently developing the FM for OTC laxative drug products; however, senna will not be included in that FM. Senna will be addressed in a future Federal Register notice. For further information, see the Federal Register of June 19, 1998 (63 FR 33592) which reclassified senna from Category I (generally recognized as safe and effective) to Category III (further testing is required).

Because your comments are relevant to the final classification of senna, FDA intends to consider your comments in developing the FM for these products based on the OTC drug review procedures in 21 CFR 330.10(a)(7)(v) and (a)(10)(iii). FDA considers resolution of the requests made by Hyman, Phelps & McNamera, on behalf of Madaus AG and your rebuttal of those requests essential and relevant to the standards applicable to senna laxative drug products in the FM. The agency finds good cause has been shown that warrants consideration of your comments before issuing a FM.

Therefore, we are granting your request to include your submission into the final administrative record. Your request that we reject the comment submitted on behalf of Madaus AG will be addressed in the final monograph on senna laxative drug products.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries (3 copies) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,



John M. Taylor, III
Associate Commissioner
for Regulatory Affairs