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

Re: **Comments to Docket No. 78N-036L -- Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph**

Dear Sir or Madam:

On behalf of MADAUS GmbH, (Madaus), a marketer of over-the-counter (OTC) laxative products, we respectfully offer these comments regarding permissible active ingredients provided for in the Tentative Final Monograph for Over-the-Counter Laxative Products (TFM).

The 1985 TFM would permit both a psyllium-only powder laxative product and a psyllium-senna (sennosides A and B) combination product under specified conditions. 50 Fed. Reg. 2124 (Jan. 15, 1985). Based on the October 3, 2006 letter from Charles Ganley, M.D. to David Grob at Purdue Pharma, LLP, it is Madaus' understanding that the Final Monograph will include senna (including sennosides A and B) as a Category I ingredient, and will permit its combination with psyllium, at least in powdered form.

As FDA is aware, both psyllium and senna have been used in laxative drug products in different forms. While the TFM recognized a variety of forms of psyllium (proposed 21 C.F.R. 334.10), the list of different forms of senna was more limited (proposed 21 C.F.R. 334.30(c)(1)). Madaus urges FDA to be expansive in its ultimate recognition of the acceptability of different forms of psyllium (Plantago psyllium, Plantago ovata seeds and husks) and psyllium-senna laxative drug combination products for OTC use. By way of example, Madaus requests FDA to specifically permit a psyllium-senna combination consisting of plantago ovata husks and seeds and Tinnevelly senna pods (or senna fruits).

In order to permit industry to plan for the monograph's eventual finalization, Madaus respectfully suggests that FDA clarify the situation with regard to its current thinking regarding the acceptability of powder-form psyllium-only and psyllium-senna laxative drug combination products as described above.

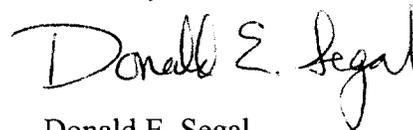
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Madaus would be pleased to discuss with FDA its current thinking in this regard and whatever additional clarification FDA is able to provide at this time, including expected time frames for finalization of the monograph.

Thank you for your time and consideration.

Sincerely,



Donald E. Segal  
Sharon D. Brooks  
Counsel to MADAUS GmbH

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