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May 30, 2000

Patricia L. DeSantis  
Dockets Management Branch (HFA - 305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 00N-1256: "FDA Regulation of OTC Drug Products Hearing"  
Notice of Participation

Dear Ms. DeSantis:

I would like to participate in the above-referenced hearing announced by the Food and Drug Administration ("FDA") in the Federal Register on April 27, 2000.

My remarks will address the first question posed by the agency in its notice—"what criteria should FDA consider in rendering decisions on the OTC availability of drug products?". More specifically, I will discuss the meaning of "collateral measures" as added to the Federal Food, Drug, and Cosmetic Act by the Humphrey-Durham Act of 1951 (21 U.S.C. § 503 (b)(1)(A)) and the implementing prescription-exemption regulations (21 C.F.R. § 310.200 (b)). I anticipate that I will need ten minutes to deliver my oral presentation. I will be prepared to respond to questions posed at the hearing. I will be speaking on behalf of my client, the Bristol-Myers Squibb Company.

If you have any questions or need any further information, please do not hesitate to contact me. I look forward to hearing from you when you establish a specific schedule for speakers at the hearing.

Thank you for attention to this matter.

Sincerely,

  
Alan R. Bennett

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