



Schering-Plough  
HealthCare Products

Schering-Plough Corporation  
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August 24, 2001

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

**Re: Docket No. 96P-0460:  
Topical Antifungal Drug Products for Over-the-Counter Human Use;  
Proposed Amendment to the Final Monograph**

Dear Sir or Madam:

We refer to the Federal Register of May 29, 2001, which contained a proposed rule (pp. 29059-29064) that would amend the final monograph for over-the-counter (OTC) topical antifungal drug products to add the ingredient clotrimazole, 1%, as generally recognized as safe and effective for the treatment of athlete's foot, jock itch, and ringworm.

Schering-Plough HealthCare Products supports the agency's determination that clotrimazole has been marketed to a material extent and for a material time as a topical antifungal drug and, based on the available data, can be generally recognized as safe and effective for these uses and included in the OTC drug monograph for this class of products.

If you have any questions, please call the undersigned me at (908) 679-1560.

Sincerely,

Alan J. Mart  
Associate Director, Regulatory Affairs  
Schering-Plough HealthCare Products, Inc.

Filed in triplicate

96P-0460

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