



## Schering-Plough HealthCare Products

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

**Re: Docket 02N-0359  
Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use  
Proposed Rule**

Dear Sir or Madam:

We refer to the Federal Register of October 4, 2002, which contained a proposed rule (pp. 62218 – 62221) that would establish the conditions under which over-the-counter ingrown toenail relief drug products containing sodium sulfide 1% in a gel vehicle are generally recognized as safe and effective and not misbranded. The rule also proposed to remove sodium sulfide from the regulation that lists non-monograph active ingredients in OTC drug products for ingrown toenail relief.

Schering-Plough HealthCare Products supports the agency's determination that sodium sulfide can be generally recognized as safe and effective as an OTC drug product for ingrown toenail relief. We request that the review of the comments and the publishing of the final rule be completed as expeditiously as possible.

If you have any questions, please call the undersigned at (908) 679-1959.

Sincerely,

Philip Johnson  
Manager, Regulatory Affairs  
Schering-Plough HealthCare Products, Inc.

Filed in triplicate

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