



Schering-Plough

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

Re: Docket No. 02D-0254; Draft Guidance for Industry on Inhalation Drug Products
Packaged in Semipermeable Container Closure Systems

Dear Sir/Madam:

Schering-Plough has reviewed the Draft Guidance for Industry on Inhalation Drug Products Packaged in Semipermeable Container Closure Systems, and we are providing the following comments for your consideration.

1. In the Introduction (lines 30-31) it is stated that the recommendations in the draft guidance apply to inhalation drug products both in development, and those that are already approved and marketed in the United States. The guidance is not clear, however, on what should be done for products that are already approved. Will companies be required to add secondary packaging, change from paper labels to embossing, or implement new controls?

2. In the Chemistry, Manufacturing, and Controls Considerations section (lines 142-144) the Agency recommends alternative approaches to paper labels, such as embossing or debossing or "other means to display the requisite labeling information." It would be helpful if the Agency provided examples of "other means."

Schering Plough appreciates the opportunity to comment on this draft guidance and hopes you will consider our comments when finalizing the guidance document.

Sincerely,

Gretchen Trout
Director, Regulatory Relations and Policy
Worldwide Regulatory Affairs

02D-0254

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