



European Pharmaceutical Aerosol Group

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## Inhalation Drug Products Packaged in Semipermeable Container Closure Systems

The European Pharmaceutical Aerosol Group (EPAG) is pleased to have the opportunity to comment on this guidance for industry. EPAG is a voluntary non-profit making consortium of member companies open to "European Pharmaceutical Companies that develop new products for human use utilising the Pulmonary or Nasal route of delivery"

We submit the following specific comments:

- **Section I. Introduction.** We ask that clarification be added that the guidance does not apply to dry powder inhalers or pressurised metered dose inhalers.
- **Section I. Introduction.** We ask that definition of "semipermeable" be added to the document in order to clarify applicability of the guidance to new packaging materials.
- **Section I. Introduction (lines 30-31).** We ask that time frame and details on information required to adopt the guidance be added for products already approved and marketed in the United States.
- **Section III. Chemistry, Manufacturing and Controls Considerations (lines 125-128).** We ask that additional information be added to clarify the type and extent of study that should be performed to demonstrate that the secondary packaging can provide adequate protection from reactive gases, volatile compounds and foreign chemicals from the local environment.
- **Section III. Chemistry, Manufacturing and Controls Considerations (lines 129-132).** We ask that guidance be added for concentrations at which chemical contaminants from the secondary packaging components should be identified, quantified and qualified.

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Yours sincerely,  
On behalf of EPAG

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## Comments on

Draft Guidance for Industry  
Inhalation Drug Products Packaged in  
Semipermeable Container Closure Systems

Docket Number 02D-0254

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3M, AstraZeneca, Aventis, Bepak, Boehringer Ingelheim, Chiesi, Clinical Designs, GlaxoSmithKline, Hovione, Innovata Biomed, Ivax Pharmaceuticals, Novartis, Orion, Pharmachemie, Pfizer, SkyePharma, Sofotec, Trudell Medical International, Vectura.