July 19, 2000

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

Dear Sir or Madam:

In the Agency's recent draft guidance *"FDA Concept Paper: Drug Products That Present Demonstrable Difficulties for Compounding Because of Reasons of Safety or Effectiveness"*, dry powder inhalers (DPIs) are justifiably presented for their difficulties in compounding. Although the paper is thorough, I feel that the compounding obstacle of electrostatic charge warrants *specific* mention within the guidance.

In the Agency's 1998 *"Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products Chemistry, Manufacturing, and Controls Documentation"* the subject of static charge is covered in the following passage:

"Electrostatic charge interactions influence the overall efficiency of a DPI, since such forces are considered to be significant for attraction and adhesion between the drug substance particles, excipient particles, and device surface."

I feel that incorporation of similar verbiage into the DPI section of the more recent guidance (docket number 00N-1357) is necessary to assure its completeness.

Sincerely,

Brent Jones
Validation Consultant

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