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July 31, 2000

BY OVERNIGHT DELIVERY AND VIA E-MAIL

Nancy Chamberlin
Executive Secretary and Advisory Consultants Staff
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857

Re: FDA's draft *Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products: Chemistry, Manufacturing, and Controls Documentation*, dated November 13, 1998; and FDA's draft *Guidance for Industry: Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products; Chemistry, Manufacturing, and Controls Documentation*, dated June 2, 1999

Dear Ms. Chamberlin:

On behalf of the ITFG/IPAC Collaboration, I am transmitting herewith the *Initial Assessment of the ITFG/IPAC Dose Content Uniformity (DCU) Database by the CMC Specifications Technical Team of the ITFG/IPAC Collaboration*. This document, prepared by the DCU Working Group of the ITFG/IPAC Collaboration, constitutes part of the work described by the ITFG/IPAC Collaboration in its presentation to the Orally Inhaled and Nasal Drug Products (OINDP) Subcommittee on April 26 of this year. We ask that this initial assessment be posted on the FDA's website for the OINDP Subcommittee and circulated to interested persons at the FDA and the members and invited guests of the OINDP Subcommittee. We hope this report is of value to the Agency as it continues its work to finalize the Guidances, referred to above.

The initial assessment constitutes a first step in the analysis of the DCU database compiled by the ITFG/IPAC Collaboration. We believe that the database provides an important opportunity to investigate relationships between the DCU standards proposed in the Guidances and the capabilities of today's development and manufacturing technology. In the coming weeks, we will be finalizing our plan for this further investigation.

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We would find it of great value to hear FDA's views on the results of our initial assessment as well as to discuss our plans for further detailed analysis. Accordingly, we would appreciate an opportunity to meet with appropriate representatives from the Agency prior to the execution of our detailed analysis plans so that this second phase of the data analysis meets the needs of all parties.

We anticipate that the details of our next steps will be finalized by mid-September and would like to suggest that a meeting be scheduled at this time for the latter part of September. We would plan to send the Agency our plans for follow-up work prior to the meeting to give the Agency adequate review time prior to the meeting.

Thank you for your consideration. I will be contacting the Agency in a few weeks to discuss the possibility of a meeting. Please do not hesitate to contact me (202-408-7101) if you have any questions.

Sincerely,



Mary Devlin Capizzi
IPAC Secretariat and Legal Counsel

Enclosure