

August 29, 2000

BY OVERNIGHT DELIVERY AND VIA E-MAIL

Nancy Chamberlin
Executive Secretary and Advisory Consultants Staff
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane - Room 1093
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 Particle Size Distribution (PSD) Database by the CMC Specifications Technical Team of the ITFG/IPAC Collaboration*. This document, prepared by the PSD 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. Please post this document on the FDA's website for the OINDP Subcommittee and circulate it to interested persons at the FDA and the members and invited guests of the OINDP Subcommittee. We appreciate the opportunity to provide this report and hope it is of value to the Agency as it develops the relevant Guidances.

The initial assessment is a first step in the analysis of the PSD database compiled by the ITFG/IPAC Collaboration. We would appreciate an opportunity to meet with appropriate representatives from the Agency to discuss the FDA's views on our PSD initial assessment as well as to consider our plans for preparing a more detailed analysis.

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

Sincerely,

A handwritten signature in cursive script that reads "Mary Devlin Capizzi".

Mary Devlin Capizzi
IPAC Secretariat and Legal Counsel

Enclosure