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August 30, 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: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action*, dated 27 May 1999.

Dear Ms. Chamberlin:

On behalf of the ITFG/IPAC Collaboration, we are transmitting herewith the following two papers: (i) *Review of In Vivo and In Vitro Tests in FDA's Draft Guidance on Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action and Anticipated Forthcoming Guidance for Orally Inhaled Drugs* and (ii) *Technical Paper on FDA's Bioavailability and Bioequivalence Questions Presented at 26 April 2000 OINDP Advisory Subcommittee Meeting*.

These documents, prepared by the BA/BE Technical Team of the ITFG/IPAC Collaboration, constitute the work described by the BA/BE Technical Team in its presentation to the Orally Inhaled and Nasal Drug Products (OINDP) Subcommittee on 26 April of this year. We request that you circulate these documents to interested persons at the FDA and the members and invited guests of the OINDP Subcommittee. In addition, we ask that these documents be posted on the FDA's website for the OINDP Subcommittee. We hope that these two technical papers are of value to the Agency as it continues to develop guidance on BA/BE studies for OINDP.

Ms. Nancy Chamberlin
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The BA/BE Technical Team would like to discuss with the Agency the enclosed papers and the conclusions contained therein. The BA/BE Team is also willing to address any subsequent BA/BE questions that the Agency may have. Accordingly, we would appreciate an opportunity to meet with appropriate representatives from the Agency. We will contact the Agency in a few weeks discuss the possibility of a meeting.

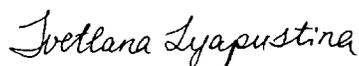
We appreciate the opportunity to submit these papers to the Agency and hope that they will assist the Agency and the OINDP Subcommittee in their consideration of BA/BE issues. Please note that the BA/BE Team would be happy to participate in and contribute to any future meetings of the OINDP Subcommittee.

Please do not hesitate to contact us at the above referenced phone numbers or email addresses if you have any questions.

Sincerely,



Mary Devlin Capizzi
IPAC Secretariat and Legal Counsel



Svetlana Lyapustina, Ph.D.
IPAC Science Advisor

Enclosures

c: Dr. Wallace Adams