



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Office of the Regional
Food and Drug Director

Mid-Atlantic Region
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106-2973

April 7, 1997

John Motzi, Ph.D.
Director, Process Development
Novartis Pharmaceuticals
59 Rt. 10
East Hanover, NJ 07936-1080

Dear Dr. Motzi:

In November 1995, the Food and Drug Administration (FDA) issued its first SUPAC (Scale-Up and Post Approval Changes) Guidance for immediate release solid oral dosage form pharmaceutical products. The intent of that guidance was to grant the industry substantial regulatory relief in filing when changes were made while safeguarding the safety and efficacy of the drug products.

In that guidance was a reference to the use of "similar equipment" in changes as one criteria for reduced filing. The Agency quickly realized there was a real need to develop a listing of "similar equipment" based on design and operating principle.

We opted to seek assistance from ISPE (International Society for Pharmaceutical Engineering). This non profit society of about 9,000 engineers agreed to assist us. They brought the industries' expertise to the issue and on a strictly voluntary basis collaborated with us to develop the similar equipment list.

Dr. Russell Somma of your staff has served as chairperson of the ISPE team tasked to develop the equipment guidance. I have committed Joseph Phillips, my deputy, and Paul D'Eramo of my staff to serve on this team. My staffers inform me that Dr. Somma has provided executive leadership to this team. Through his untiring efforts, the first "similar equipment listing" is now out for public comment. Dr. Somma has consistently managed to bring the diverse opinions of his team members to a logical conclusion and, in record time, had a document to turn over to FDA. His performance was outstanding and reflects positively on your company. You can be proud to have persons of this caliber represent you.

I realize that without the support of your firm and yourself, Dr. Somma could not have served in this vital role. We need this level of support to continue our efforts to streamline our operations. Please accept our gratitude for a job well done and thank Dr. Somma for his continuing efforts.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan M. Setterberg". The signature is fluid and cursive, with the first name "Susan" being the most prominent.

Susan M. Setterberg
Regional Food and Drug Director
Mid-Atlantic Region

cc: Mr. Robert Best/ISPE