

Docket Management Branch
HFA-305
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20857

December 16, 2005

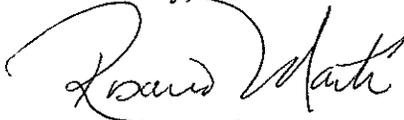
Re: Docket No. 2004N-0439
Positron Emission Tomography Drugs; Current Good Manufacturing Practice

Dear Sir/Madam:

International Cyclotrons, Inc. is a nationwide health product company in Puerto Rico dedicated to Positron Emission Tomography. We operate the only cyclotron, based in PET nuclear pharmacies and we are the first to bring this advanced technology to Puerto Rico and the Caribbean. International Cyclotrons Inc. has the commitment to serve F 18 Fludeoxyglucose (FDG) to the Pet Community in Puerto Rico.

At present, we are engaged in sending promptly our Master Validation Plan (MVP) draft to FDA and obtain some feedback from FDA representative in our intention to execute a full validation process following the United State Pharmacopeias (USP) chapter 813 and the latest cGMP that has been published on September 19 in the Federal Register. It is very important for us submit our application in order to comply with the regulations before the final rule of the cGMP is published in the Federal Register.

Sincerely,

A handwritten signature in cursive script that reads "Rosario Marti". The signature is written in black ink and is positioned above the printed name and title.

Rosario Marti, R.Ph
Quality Assurances