

December 5, 2005

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

VIA ELECTRONIC SUBMISSION

RE: Docket No. 1998D-0266
Draft Guidance on Current Good Manufacturing Practice for Positron Emission
Tomography Drug Products; Availability [70 **Federal Register** 55145]

Dear Sir or Madam:

P.E.T.Net[®] Pharmaceuticals, Inc., doing business as PETNET Solutions, (PETNET), is a wholly owned subsidiary of Siemens Medical Solutions USA, Malvern Pennsylvania. PETNET is an international health product company dedicated to positron emission tomography (PET) imaging agents and services. We operate 43 cyclotron-based PET nuclear pharmacies in twenty-eight states, and we are a leading producer of radiopharmaceuticals for PET imaging. Additionally, PETNET operates four international PET radiopharmaceutical production facilities in South Korea and the United Kingdom.

As such, PETNET is affected by the draft guidance, and wishes to comment on this draft document. PETNET has provided input on the development of PET cGMP's for several years through participation in previously held public meetings, which intent was for the expert public to assist the Agency in their development of the proposed 21 CFR Part 212 and the associated draft guidance, and by commenting on the previous versions of these documents. PETNET supports the draft guidance and is pleased to provide these comments in an effort to assist in its further development.

Titles of the proposed rule and draft guidance:

We direct the Agency's attention to inconsistencies in the titles of the proposed rule and the draft guidance. Specifically, we note that the title of the draft 21 CFR Part 212 refers to "Positron Emission Tomography *Drugs*," while the title of the draft guidance refers to "PET *Drug Products*." We suggest for sake of clarity and consistency that these titles be consistent with the definitions for "PET Drugs" and "PET Drug Products" as defined in the proposed rule.

