



Food and Drug Administration
Rockville, MD 20857

September 1, 2005

Alan Kirschenbaum
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, District of Columbia 20005-5929

Dear Mr. Kirschenbaum:

Your petition, on behalf of Council on Radionuclides and Radiopharmaceuticals, requesting the Food and Drug Administration to determine that sponsors of human drug applications for positron emission tomography (PET) drug be exempt from paying certain user fees assessed pursuant to the Prescription Drug User Fee Act of 1992, was received by this office on 09/01/2005. It was assigned docket number 2005P-0358/CP1 and it was filed on 09/01/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Lyle D. Jaffe".

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P.0358

ACK 1