DEPARTMENT OF HE TH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 1 2006

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

Re: Docket No. 2005P-0358/CP1

Dear Mr. Kirschenbaum:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on September 1, 2005, on behalf of the Council on Radionuclides and Radiopharmaceuticals. Your petition requests that FDA exempt the sponsors of human drug applications for positron emission tomography drugs from paying certain user fees assessed pursuant to the Prescription Drug User Fee Act, or assess only a single establishment fee for each approved human drug application.

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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