DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 15 2012

Susan S. de Mars
General Counsel
United States Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Docket No. FDA-2011-P-0926

Dear Ms. de Mars:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on January 3, 2012. Your petition requests that the Agency amend FDA regulations on current good manufacturing practice (cGMP) for positron emission tomography (PET) drugs (21 CFR 212.5(b)) to incorporate by reference *USP 35/NF 30*, which contains the most current version of United States Pharmacopeia (USP) cGMP standards in *Chapter <823>* that are applicable to compounded, investigational, and research PET drugs.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

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