



2/19/2007

Citizen Petition

I, Jon Woodward, representing PFI LLC, submit this petition under section 505 (j) (2) (C) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food to amend an existing regulation.

Action Requested

Concerning NDA 20-306 (Fludeoxyglucose F 18 Injection), I request the Commissioner to amend the present regulation for Strength from 4.0-90 mci/mL at end of synthesis to 0.9-475 mci/mL at end of synthesis.

	Generic Drug Product	Downstate Clinical Pet Center NDA 20-306
Conditions of use:	Fludeoxyglucose F 18 (FDG) Injection is indicated in positron emission tomography (PET) imaging: <ol style="list-style-type: none">1. for assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities or in patients with an existing diagnosis of cancer2. in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging, for the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function	Fludeoxyglucose F 18 (FDG) Injection is indicated in positron emission tomography (PET) imaging: <ol style="list-style-type: none">1. for assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities or in patients with an existing diagnosis of cancer2. in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging, for the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function

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	3. in patients for the identification of regions of abnormal glucose metabolism associated with foci in epileptic seizures.	3. in patients for the identification of regions of abnormal glucose metabolism associated with foci in epileptic seizures.
Active Ingredient:	2-Deoxy-2[18]fluoro-D-glucose	2-Deoxy-2[18]fluoro-D-glucose
Route of Administration	Intravenous	Intravenous
Dosage form:	Injection	Injection
Strength:	Specific Concentration 0.9-475 mci/mL at EOS. (End of Synthesis)	Specific Concentration 4.0-90 mci/mL at EOS. (End of Synthesis)

Statement of Grounds

The justification for the proposed variance of strength is based on our internal stability studies for the strength mentioned above. The strength range is requested due to varying production levels based on patient demand.

In regards to other parameters: active ingredient, route of administration and dosage form, our generic drug will be identical to that of the RLD.

Environmental Impact

In accordance with the regulations of 21 CFR 25.31, no code violations will transpire.

Economic Impact

Analysis will be provided upon request.

Certification

I, Jon Woodward, PFI LLC, certify that to my best knowledge and belief that this petition includes all information and views on which the petition relies, and that it includes no unfavorable data known to the petitioner which is unfavorable to the petition.



Jon Woodward, R.Ph.



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To Whom It May Concern:

I have Enclosed three copies of an ANDA suitability petition for our proposed drug, 2-Deoxy-2[18]fluoro-D-glucose. If you have any questions, do not hesitate to call me.

Thank you,

Jon Woodward, R.Ph.