

# Coalition for PET Drug Approval

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March 24, 2014

Ms. Leslie Kux  
Assistant Commissioner for Policy  
U.S. Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**RE: Docket Number 2014-N-0032-0001; Improving the Quality of Abbreviated New Drug Application Submissions to the Food and Drug Administration**

Dear Ms. Kux:

The Coalition for PET Drug Approval was organized in November 2010 to help the PET community understand requirements related to the implementation of 21 CFR part 212, and to communicate with the Food and Drug Administration (FDA) on behalf of this community. It is within this capacity that we write to you in response to the request for comments on the *Establishment of a Public Docket: Improving the Quality of Abbreviated New Drug Application (ANDA) Submissions to the FDA* as published in the *Federal Register* on January 23, 2014. We thank you for this opportunity to submit comments.

As the field of nuclear medicine and molecular imaging has entered a new maturation phase with the FDA as Positron Emission Tomography (PET) drug manufacturers, we have encountered challenges with varying manufacturing standards. In the past, many regulatory issues we experienced were successfully addressed when representatives from our field and the FDA met during public meetings. Unfortunately, due to the changing healthcare climate and budgetary limitations, routine face-to-face meetings have decreased and opportunities to engage in open discussion have been infrequent.

The Coalition for PET Drug Approval supports the goal of expediting the availability of high-quality, lower cost generic drugs by bringing greater predictability to the review times for ANDAs. We encourage the FDA to seek opportunities to engage in routine dialogue with PET drug manufacturers to promote open discussion and increase awareness about issues which impact PET drug manufacturers. Public meetings with the FDA would facilitate discussion to resolve the disproportionate manufacturing standards the PET drug manufacturing community encounters.

American Association of Physicists in Medicine • American Pharmacists Association, Nuclear Pharmacy Practice Section  
Council on Radionuclides and Radiopharmaceuticals • Medical Imaging & Technology Alliance  
National Association of Nuclear Pharmacies • Society of Nuclear Medicine and Molecular Imaging  
Society of Radiopharmaceutical Sciences  
United Pharmacy Partners, LLC • World Molecular Imaging Society

PET drug manufacturers are distinct from larger pharmaceutical manufacturers in that they produce several batches of product every day and subsequently test the entire batch produced. This batch comprehensive testing process is unique to PET drug manufacturers.

In addition, PET drug manufacturers encounter challenges with inconsistent standards based on the size of the manufacturing operation. As many PET drug manufacturers are smaller, unique entities, which distribute products to a network of patients, it is essential that the FDA apply a corresponding standard which appropriately accounts for a manufacturer's product distribution capacity.

One area the FDA could explore amending is the electronic submissions process for small entities. The Coalition for PET Drug Approval supports the primary site registration form, but PET drug manufacturers are currently experiencing issues in completing the package insert labeling requirement. The existing system is, at times, cumbersome and time consuming for smaller entities that lack the necessary resources to complete the gateway process themselves or to employ external vendors to support in the application process. PET drug manufacturers would greatly benefit from the exemptions the FDA states are allowed in the labeling portion of the application process. To date, the Coalition for PET Drug Approval is not aware of any site receiving an exemption after it was requested.

The Coalition for PET Drug Approval supports the goal of streamlining the application process for electronic submissions for the entire application process, including the new drug application, abbreviated new drug application, and investigational new drug application. An electronic submission process which is user-friendly, supports contemporary file formats (MS Word or PDF format), and appropriately accounts for the size of a drug manufacturer, would enhance the overall process for PET drug manufacturers, universities, and other research organizations, and reduce the administrative burden to the FDA.

In summary, the Coalition for PET Drug Approval encourages the FDA to engage with PET drug manufacturers in public meetings to improve dialogue, education, and awareness about critical issues which impact the field. Additionally, the Coalition supports the enhancement of the electronic submission process to improve efficiency and reduce the burden to the Agency.

Please contact Caitlin Kubler, Manager of Regulatory Affairs, if you need additional information. Caitlin can be reached at (703) 326-1190 or [ckubler@snmmi.org](mailto:ckubler@snmmi.org).

Sincerely,



Henry VanBrocklin  
Co-Chair  
Coalition for PET Drug Approval



Sally Schwarz  
Co-Chair  
Coalition for PET Drug Approval

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