



AULA VIRTUAL de RADIOFARMACIA

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Lectura recomendada

FDA Extends Filing Deadline for PET Radiopharmaceuticals

The Food and Drug Administration (FDA) has issued an extension to the December filing deadline for Positron Emission Tomography (PET) radiopharmaceuticals.

Today, December 6, 2011, the FDA issued a six month extension to the deadline by which all ANDAs and NDAs for PET drugs were to be filed. FDA has received requests to extend the application submission deadline from and on behalf of some PET drug producers trying to comply with the regulation and application submission requirements. concern was expressed that if manufacturers are unable to submit their application by December 12, 2011, they will have to halt production of PET drugs for use in clinical care of patients. Further, although FDA does not anticipate any shortages of PET drugs after December 12, 2011, there is concern that sole producers in isolated areas may halt production if their application has not been submitted and this could create a barrier to access in that particular area. Having considered these points, in addition to the fact that we have yet to issue the two instructive guidances for PET drug producers (Investigational New Drug Applications for PET Drugs and FDA Regulation of PET Drug Products, Questions and Answers) that are currently under development, FDA has decided to exercise enforcement discretion under the following circumstances until June 12, 2012.

For the next six months, until June 12, 2012, FDA does not intend to take enforcement action against a PET facility currently producing PET drugs for clinical use for a failure to submit a new drug application by December 12, 2011, provided that the facility complies with all other FDA requirements, including current good manufacturing practices (CGMPs). FDA will not exercise enforcement discretion after June 12, 2012. Therefore, if a facility wishes to continue to produce PET drugs for clinical use after June 12, 2012, they must have submitted a new drug application (NDA) or an abbreviated new drug application (ANDA) by that date, or be producing the drugs under an investigational new drug exemption (IND). PET producers who are unable to submit an NDA or ANDA by June 12, 2012 or operate under an IND must find a new supplier who has submitted an NDA or ANDA. All PET producers must be operating under an approved NDA or ANDA, or effective IND, by December 12, 2015.

For additional information, please visit the FDA website:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm085783.htm>



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