Notice of FDA Exercise of Enforcement Discretion for PET Drugs

In 1997, Congress passed the Food and Drug Administration Modernization Act (Public Law 105-115) (the Modernization Act). Section 121 of the Modernization Act directed FDA to establish appropriate approval procedures and Current Good Manufacturing Practices (CGMP) for PET drugs. These procedures were published on December 9, 2009, triggering an implementation timeline. Under the requirements of section 121, within 2 years of that publication date, a new drug application (NDA) or abbreviated new drug application (ANDA) must be submitted for any PET drug marketed for clinical use in the United States.

Recently, 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. Some firms have expressed concern that if they 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 we do not anticipate any shortages of PET drugs after December 12, 2011, we are concerned 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 application (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.**

We know that many PET producers, both large companies and small academic centers, have been making a good faith effort to comply with the regulations and submit their applications by the original December 12, 2011 deadline, and it would be unfair to extend the deadline indefinitely. Therefore, we are establishing a firm deadline, June 12, 2012, after which FDA will no longer exercise enforcement discretion.