CGMP for PET Drugs: Important Steps to Take Now

The U.S. Food and Drug Administration (FDA), taking into consideration the unique nature of PET drugs and PET drug production, published the final rule 21 CFR Part 212, “Current Good Manufacturing Practice (CGMP) for Positron Emission Tomography Drug Products,” on December 10, 2009 (Fed Reg. 2009;74:65409). This regulation contains binding requirements for CGMP for PET drugs and is enforceable in court. The guidance “PET Drugs. . .CGMP,” published at the same time as Part 212, describes FDA’s current thinking on specific approaches to comply with Part 212 requirements (Fed Reg. 2009;74:65538).

Part 212 requires that producers of PET drugs for clinical use be compliant with the rule by December 12, 2011—only 1 year away. Any facility that produces PET drugs for clinical use is required to submit either a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) for each of its clinical PET drugs, whether or not the drugs are produced for commercial distribution. The following requirements apply to all PET drug producers.

**Step 1: Establish an electronic portal with the FDA.**

All PET drug producers are required to electronically register their establishments as manufacturing facilities. Electronic Drug Registration and Listing Instructions are available at www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm177328, where the list of requirements can be downloaded. In addition, FDA Guidance, “Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration & Drug Listing,” is available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.

Producers are required to e-mail the FDA, then submit a letter of nonrepudiation. Response from the FDA allowing the set-up of a test account will take approximately 1 month, followed by the set-up of a Web trader account. This account will be used for submission of all communications with the FDA, including NDA or ANDA submission. Completing the electronic connection with the FDA could require up to 6 months, so starting early is advised.

**Step 2: Submit an NDA or ANDA for each clinical PET drug.**

SNM is working toward facilitating the process for submission of the NDA or ANDA for all manufacturers, as all sites manufacturing diagnostic FDG will need to submit these as a requirement of the FDA. Because NDAs have been approved by the FDA for 18F-FDG injection and 13N-ammonia, ANDAs may be submitted.

SNM has established an FDA Part 212 Working Group to support the community and facilitate submission of ANDAs. Over the coming months, the society will be providing information via the SNM Web site at http://interactive.snm.org/index.cfm?PageID59740 and through other outreach tools.

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