

tyco

Healthcare

Mallinckrodt

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 99N-4063: Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Preliminary Draft Proposed Rule

Docket No. 98D-0266: Draft Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drug Products

Dear Sir or Madam:

Tyco Healthcare/Mallinckrodt, a member of CORAR would respectfully like to register the following comment regarding the March 2002 guidance for PET products.

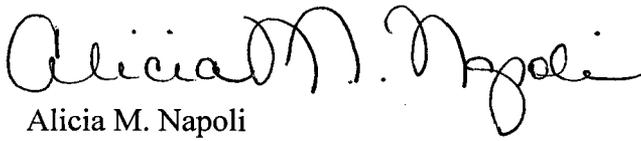
Guidance statements found on pages 4-5 at lines 166-177, under section C. "Distinguishing between PET Drug Production and Practice of Pharmacy" are unclear as to their interpretation and application. Statements contained therein appear to be an infringement on the practice of nuclear pharmacy as regulated by the State Boards of Pharmacy. Dispensing a patient-specific dose by a licensed pharmacist of a drug product manufactured, tested, and released under appropriate CGMP control is performed, without regard for the dosage form container.

The guidance document, as presently written, infers that activities currently regulated by States and performed by a licensed pharmacist will be considered to also fall under CGMP requirements. Such activities would include preparation and distribution of patient-specific doses of a finished drug product pursuant to an order by a licensed physician.

For example, it is Mallinckrodt's position that for PET CGMP, FDA regulation should terminate at the point where finished drug product is obtained from the synthesis unit. Subsequent activities, such as preparation of a patient-specific dose and/or distribution would be considered to be presently regulated by the State Boards of Pharmacy.

It is essential the questionable language in the guidance document does not inhibit the lawful practice of pharmacy. FDA must continue to defer to State and local authorities concerning the regulation of such activities. Finished dosage form radiopharmaceutical products, including PET drugs, produced under the quality assurance of CGMP must continue to be available for dispensing and distribution within the practice of pharmacy.

Respectfully submitted,

A handwritten signature in black ink, reading "Alicia M. Napoli". The signature is written in a cursive style with a large, stylized initial "A".

Alicia M. Napoli
Sr. Director, Imaging Regulatory & Clinical Affairs
Tyco Healthcare/Mallinckrodt

AMN/jwb