

July 12, 2004

Dockets Management Branch
Food and Drug Administration
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To Whom It May Concern:

School of Pharmacy

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I would like to offer some comments regarding the recently released "Draft Guidances for Industry on Medical Imaging Drug and Biological Products; Availability" (Docket No. 98D-0785), specifically on the "Guidance for Industry: Medical Imaging Drug and Biological Products Part 1: Conducting Safety Assessments" (<http://www.fda.gov/cber/gdlns/medimagesaf.pdf>).

On Page 5 of this document it states:

66 **B. Diagnostic Radiopharmaceuticals**

67 As used in this guidance, a *diagnostic radiopharmaceutical* is (1) an article that is intended for
68 use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans and that
69 exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or
70 photons

and then on page 6:

77 Diagnostic radiopharmaceuticals are generally radioactive drug or biological products that
78 contain a radionuclide that typically is linked to a ligand or carrier.

The key comment is that we have evolved well beyond the stage of radiopharmaceuticals being used solely for diagnostic purposes, which are probably well defined in lines #77-#78. However, this definition is not fully suitable for radiolabeled pharmaceuticals that are used for monitoring the kinetics of drug biodistribution and targeting of approved drugs or new pharmaceutical drug products in development, and where the intent is to ascertain what should be the proper dose of the drug to be used in order to optimize/personalize its effectiveness.

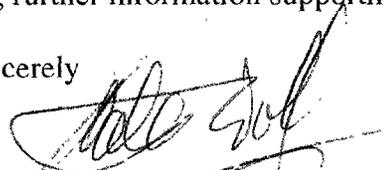
Thus, when we radiolabel a drug intrinsically (e.g., with no chemical modifications), the radionuclide used is the radioactive isotope of an atom present in that molecule. Examples are ¹⁸F-radiolabeling of 5-fluorouracil or ^{195m}Pt-radiolabeling of cisplatin. This does not fall properly within the definition of #77-#78.

Let me suggest the following addition to the above wording:

78b Monitoring radiopharmaceuticals are radiolabeled forms of existing drugs or biological products,
78c where one or more of its non-radioactive atoms have been replaced by one of its radioisotopes.

I would be delighted in providing further information supporting this proposed change.

Sincerely



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98D-0785

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