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

RE: Docket No. 98D-0785 – Revised Draft Guidance for Industry: Medical Imaging Drugs and Biological Products (May 2003)

Dear Sir/Madam:

The Academy of Molecular Imaging (AMI) respectfully submits comments on the Food and Drug Administration's (FDA's) May 2003 revised draft "Guidance for Industry: Medical Imaging Drug and Biological Products".

AMI is an international scientific and professional organization with 2,000 individual members, as well as 50 institutional members representing major Universities and hospitals in the USA. AMI is dedicated to promoting and enhancing the science, technology and clinical practice of molecular imaging with particular emphasis on positron emission tomography. AMI also carries out cooperative programs with various other societies such as the Society of Nuclear Medicine, the American College of Nuclear Physicians, the American College of Radiology, Radiological Society of North America and various societies and patient advocacy groups in cancer, neurology, psychiatry and cardiology.

Since implementation of FDAMA 97, AMI and the Society of Nuclear Medicine (SNM) have closely worked with the FDA for implementation of new PET radiopharmaceutical regulations. The scientific imaging community under the umbrella of AMI and SNM continues to maintain that regulations applicable to diagnostic radiopharmaceuticals, codified at 21 C.F.R. Part 315, which are the subject of the Draft Guidance, are unnecessarily onerous and burdensome. The FDA needs to provide the Nuclear Medicine community a comprehensive approach that addresses the processes, procedures and mechanisms for development of new radiotracers in order for the community to assess the relevance, appropriateness and applicability of the proposed guidance document. Specifically, FDA needs to streamline the IND process by having Phase I and Phase II studies supervised under local committees, whereas Phase III studies would be conducted pursuant to an IND. This approach would reduce the administrative burden of the Agency and expedite development of new agents at University centers, where the majority of this development activity occurs.

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As long as these regulations go unchanged, the end result will be the continued over-

regulation of radiopharmaceuticals beyond what is scientifically warranted. The constraints imposed by these regulations on

any guidance that attempts to address them would lead to continued stagnation in the development of new imaging diagnostic tracers, in opposition to the intent of FDAMA 1997.

We believe there should be greater recognition that nuclear medicine procedures, including those with PET, are based upon the use of tracers in such extremely low mass amounts that by their nature, and by design, they do not exert significant mass effects on the biological systems of the body. For example, there have been about 2 million PET human procedures performed worldwide with FDG without, to our knowledge, a single reported adverse effect attributable to the tracer.

If an imaging probe qualifies as a tracer, then a scientific evaluation process should be constructed consistent with that. An appropriate FDA process should be designed without requiring a more complicated, costly and time consuming approach than is scientifically justified. This only delays the benefit to patient care that these diagnostic tracers can provide.

Further, we believe that diagnostic imaging using tracers should be cleanly separated away from the use of contrast agents and other imaging probes that do exert significant mass effects with very different risk / benefit ratios.

Respectfully,

Jorge R. Barrio, Ph.D.

Chair, AMI/SNM Radiopharmaceutical Committee

Michael E. Phelps, Ph.D.

President, Academy of Molecular Imaging