CORAR

The Council on Radionuclides and Radiopharmaceuticals, Inc.

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Michael J. Guastella, MS, MBA
Executive Director

May 17, 2022

The Honorable Frank Pallone
U.S. House of Representatives
2107 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Cathy McMorris-Rodgers
U.S. House of Representatives
1035 Longworth House Office Building
Washington, D.C. 20515

The Honorable Anna Eshoo
U.S. House of Representatives
272 Cannon House Office Building
Washington, D.C. 20515

The Honorable Brett Guthrie
U.S. House of Representatives
2434 Rayburn House Office Building
Washington, D.C. 20515

re: Section 803 of the 2022 Food and Drug Amendments (H.R. 7667)

Dear Chairman Pallone, Ranking Member McMorris-Rodgers, Chairwoman Eshoo, and Ranking Member Guthrie,

I am writing on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) to express our support for Section 803 of H.R. 7667, being considered as part of the reauthorization of the Food and Drug Administration (FDA) User Fee Program. CORAR is an association of companies in the United States and Canada that manufacture radiopharmaceuticals, sealed sources, and radionuclides primarily used in nuclear medicine procedures, as well as nuclear pharmacies that dispense these drugs to health care providers for administration to patients in such procedures.

Section 803 would amend the Federal Food, Drug, and Cosmetic Act to provide that "[a]ny contrast agent, radioactive drug, or OTC monograph drug shall be deemed to be a drug under section 201(g) and not a device under section 201(h)." As it applies to radiopharmaceuticals, Section 803 merely continues and reinforces the regulatory paradigm previously established by Congress. In Section 122 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), Congress set forth basic parameters for FDA to use in reviewing and approving diagnostic radiopharmaceuticals. Congress directed FDA to issue regulations providing that the determination of the "safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include consideration of" certain enumerated factors. Section 122 defined a diagnostic radiopharmaceutical as an article that is intended for use in the diagnosis or monitoring of a disease, and that exhibits

spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. **FDC Act section 505 and Public Health Service Act section 351 pertain to the premarket approval of new drugs and the licensing of biologicals, respectively.**

The fact that Congress previously directed FDA to issue regulations governing the determination of safety and effectiveness for diagnostic radiopharmaceuticals under sections 505 and 351 is incontrovertible evidence that Congress intended these products to be regulated and approved as drugs or biologics. Therefore, CORAR supports the inclusion of Section 803 into H.R. 7667 to underscore previous Congressional intent that the FDA regulate diagnostic radiopharmaceuticals as drugs, and not devices. If you have any questions, please don't hesitate to contact me at michael.guastella@corar.org.

Respectfully Submitted,

Michael J. Guastella

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