

1 use radiopharmaceuticals, and the regulated in-
2 dustry, shall issue proposed regulations govern-
3 ing the approval of radiopharmaceuticals de-
4 signed for diagnosis and monitoring of diseases
5 and conditions. The regulations shall provide
6 that the determination of the safety and effec-
7 tiveness of such a radiopharmaceutical under
8 section 505 of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 355) or section 351 of
10 the Public Health Service Act (42 U.S.C. 262)
11 shall include (but not be limited to) consider-
12 ation of the proposed use of the
13 radiopharmaceutical in the practice of medicine,
14 the pharmacological and toxicological activity of
15 the radiopharmaceutical (including any carrier
16 or ligand component of the
17 radiopharmaceutical), and the estimated ab-
18 sorbed radiation dose of the
19 radiopharmaceutical.

20 (B) FINAL REGULATIONS.—Not later than
21 18 months after the date of enactment of this
22 Act, the Secretary shall promulgate final regu-
23 lations governing the approval of the
24 radiopharmaceuticals.

1 (2) SPECIAL RULE.—In the case of a
2 radiopharmaceutical intended to be used for diag-
3 nostic or monitoring purposes, the indications for
4 which such radiopharmaceutical is approved for mar-
5 keting may, in appropriate cases, refer to manifesta-
6 tions of disease (such as biochemical, physiological,
7 anatomic, or pathological processes) common to, or
8 present in, 1 or more disease states.

9 (b) DEFINITION.—In this section, the term
10 “radiopharmaceutical” means—

11 (1) an article—

12 (A) that is intended for use in the diag-
13 nosis or monitoring of a disease or a manifesta-
14 tion of a disease in humans; and

15 (B) that exhibits spontaneous disintegra-
16 tion of unstable nuclei with the emission of nu-
17 clear particles or photons; or

18 (2) any nonradioactive reagent kit or nuclide
19 generator that is intended to be used in the prepara-
20 tion of any such article.

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