

§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for “in vivo” diagnostic use for humans to persons exempt from licensing; Requirements for a license.

(a) An application for a specific license to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for “in vivo” diagnostic use, to persons exempt from licensing under § 30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter, provided that the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under § 32.27(a)(2) of this part;

(3) The applicant provides evidence that each capsule contains 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

(5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

[62 FR 63640, Dec. 2, 1997]

§ 32.21a Same: Conditions of license.

Each license issued under § 32.21 of this part is subject to the following conditions:

(a) The immediate container of the capsule(s) must bear a durable, legible label which:

(1) Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

(2) Bears the words “Radioactive Material.”

(b) In addition to the labeling information required by paragraph (a) of this section, the label affixed to the immediate container, or an accompanying brochure also must:

(1) State that the contents are exempt from NRC or Agreement State licensing requirements; and

(2) Bears the words “Radioactive Material. For ‘In Vivo’ Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash.”

[62 FR 63640, Dec. 2, 1997]

§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

(a) An application for a specific license to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use pursuant to § 30.19 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, or produced pursuant to a license issued by an Agreement State.

(2) The applicant submits sufficient information relating to the design,

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manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in §32.23. The information should include:

(i) A description of the product and its intended use or uses.

(ii) The type and quantity of byproduct material in each unit.

(iii) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

(iv) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2)(iii) and (xii) of this section.

(v) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

(vi) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

(vii) Degree of access of human beings to the product during normal handling and use.

(viii) Total quantity of byproduct material expected to be distributed in the product annually.

(ix) The expected useful life of the product.

(x) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

(xi) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

(xii) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be

released to the environment, any increase in external radiation levels, and any other changes in safety features.

(xiii) The estimated external radiation doses and dose commitments relevant to the safety criteria in §32.23 and the basis for such estimates.

(xiv) A determination that the probabilities with respect to the doses referred to in §32.23(d) meet the criteria of that paragraph.

(xv) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

(xvi) Any additional information, including experimental studies and tests, required by the Commission.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

[34 FR 9026, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978]

§ 32.23 Same: Safety criteria.

An applicant for a license under §32.22 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in §32.24 of this part.

(b) In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the