The Food and Drug Administration allows that a radioactive drug prepared, packaged, distributed, and primarily intended for use in accordance with the requirements of 21 CFR 361.1 shall be exempt from the Food, Drugs and Cosmetic Act and the requirements for labeling set forth under the regulations found at 21 CFR 201.100 if either separate from or as part of any label and labeling required for radioactive materials by the Nuclear Regulatory Commission or by State or local radiological health authorities bear the following:

(1) The statement “Rx only.”
(2) The statement “To be administered in compliance with the requirements of Federal regulations regarding radioactive drugs for research use (21 CFR 361.1
(3) The established name of the drug, if any;
(4) The established name and quantity of each active ingredient;
(5) The name and half-life of the radionuclide, total quantity of radioactivity in the drug product’s immediate container, and amount of radioactivity per unit volume or unit mass at a designated referenced time;
(6) The route of administration, if it is for other than oral use.
(7) The net quantity of contents;
(8) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug.
(9) The name and address of the manufacturer, packet, or distributor;
(10) The expiration date, if any;
(11) If the drug is intended for parenteral use, a statement as to whether the contents are sterile
(12) If the drug is for other than oral use, the names of all inactive ingredients, except that:
    i. Trace amounts of harmless substances added solely for individual product identification need not be named.
    ii. If the drug is intended for parenteral use, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust pH or to make the drug isotonic may be declared by name and a statement of their effect; if the vehicle is water for injection, it need not be named. Provided, however, that in the case of containers too
small or otherwise unable to accommodate a label with sufficient space to bear all such
information, the information required of this section may be placed on the shielded
container only.

Contents of this report are available for public disclosure unless confidentiality is
requested by the investigator and it is adequately shown by the investigator that the
report constitutes a trade secret or confidential commercial information as defined in
21 CFR 20.61.

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<thead>
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<th>History of SOP</th>
<th>Date</th>
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<tr>
<td>Initial approval</td>
<td>12/16/15</td>
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<td>Review by the RDRC</td>
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<td>Re-review:</td>
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