

3701:1-40-39

**Radioactive drug: capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.**

- (A) Except as provided in paragraphs (B) and (C) of this rule, any person is exempt from the requirements for a license set forth in this chapter and Chapter 3701:1-58 of the Administrative Code, provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing thirty-seven kilobecquerels (one microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.
- (B) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license under Chapter 3701:1-58 of the Administrative Code.
- (C) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license under Chapter 3701:1-46 of the Administrative Code.
- (D) Nothing in this rule relieves persons from complying with applicable United States food and drug administration, other federal, and state requirements governing receipt, administration, and use of drugs.

Five Year Review (FYR) Dates: 04/08/2015 and 04/01/2020

CERTIFIED ELECTRONICALLY

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Certification

04/08/2015

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Date

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Statutory Authority: 3748.02, 3748.04  
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