



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

(FSME-11-076, July, Other, Cardiogen-82 Rubidium-82 Generator)

July 28, 2011

ALL AGREEMENT STATES, MICHIGAN

NOTIFICATION OF ISSUANCE OF IMPORTANT VOLUNTARY RECALL INFORMATION
CONCERNING THE CARDIOGEN-82 RUBIDIUM-82 GENERATOR (**FSME-11-076**)

Purpose: To provide the Agreement States with a copy of the U.S. Food and Drug Administration (FDA) Drug Safety Communication (DSC) issued July 26, 2011, alerting healthcare professionals to stop performing heart scans with CardioGen-82 due to the potential for increased radiation exposure to patients. The DSC is attached and can also be found at the following link: <http://www.fda.gov/Drugs/DrugSafety/ucm265278.htm>. The manufacturer, Bracco Diagnostics, Inc., is voluntarily recalling the CardioGen-82, and the DSC was issued to inform users of the voluntary recall.

Background: Rubidium-82 is a positron emission tomography (PET) myocardial perfusion imaging (MPI) agent. A previous letter was sent to all users providing important information related to the importance of the mandatory strontium-82 and strontium-85 breakthrough checks after two individuals who previously underwent Rb-82 PET MPI imaging triggered radiation detectors when travelling to/from the United States. Radiation analyses indicated the presence of Sr-85 and Sr-82. As a result of further investigations by FDA and the manufacturer, the manufacturer has voluntarily recalled the product.

Discussion: Enclosed for your information is a copy of the FDA DSC concerning the product recall. The U.S. Nuclear Regulatory Commission is coordinating with the FDA on this and will keep you informed as more information becomes available. This recall was initiated following manufacturer discussions with the FDA regarding reports of unexpected radiation exposure in two individuals who underwent cardiac PET scans with CardioGen-82. The recall is being undertaken while the unexpected radiation exposure is being further investigated. There are over 100 users of CardioGen-82 and many are located in Agreement States.

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If you have any questions regarding this communication, please contact me at 301-415-3340, or the individual named below.

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Division of Materials Safety
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Office of Federal and State Materials
and Environmental Management Programs

Enclosure:
FDA Drug Safety Communication



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Drugs

FDA Drug Safety Communication: FDA alerts healthcare professionals to stop performing heart scans with CardioGen-82 due to potential for increased radiation exposure in patients

This update is in follow-up to the Drug Safety Communication: Increased radiation exposure due to undetected strontium breakthrough when using CardioGen-82 for cardiac positron emission tomography (PET) scans¹ issued on 7/15/2011.

[7-26-2011] The U.S. Food and Drug Administration (FDA) is alerting healthcare professionals to stop using CardioGen-82 for cardiac positron emission tomography (PET) scans. The manufacturer, Bracco Diagnostics, Inc. has decided to voluntarily recall CardioGen-82.

CardioGen-82 consists of a generator that is used at clinical sites to produce rubidium (Rb)-82 chloride injection. A CardioGen-82 PET scan is one of a variety of nuclear medicine scans that use radioactive drugs to evaluate the heart.

On July 15, 2011², FDA alerted the public, in particular, the medical imaging community, about the potential for inadvertent, increased radiation exposure in patients who underwent or will be undergoing cardiac PET scans with rubidium (Rb)-82 chloride injection from CardioGen-82. As previously described, FDA has received report of two patients who received more radiation than expected from CardioGen-82. FDA believes that the risk of harm from this exposure is minimal, though exposure to any excessive radiation is undesirable. The estimated amount of excess radiation the two patients received is similar to that other patients may receive with cumulative exposure to certain other types of heart scans.

Based on further investigation, FDA has determined that the current CardioGen-82 manufacturing procedures are not sufficient to ensure reliable performance of the generator used to produce the Rb-82 chloride injection. Reliable generator performance is essential to help prevent strontium breakthrough from CardioGen-82 and to prevent patients from being exposed to excess radiation. FDA is also currently investigating the sufficiency of the testing procedures used to detect strontium breakthrough at the clinical sites that use CardioGen-82.

FDA recommends that healthcare professionals use alternatives to the CardioGen-82 generator when planning nuclear medicine cardiac scans. Patients who have any questions or concerns should talk to their healthcare professional.

FDA continues to work with the Nuclear Regulatory Commission and the CardioGen-82 manufacturer to determine the root cause for the increased radiation exposure detected in the two patients. The extent to which any additional patients may have received inadvertent radiation exposure is also under investigation. FDA plans to notify the public with updates.

Related Information

- [FDA Drug Safety Communication: Increased radiation exposure due to undetected strontium breakthrough when using CardioGen-82 for cardiac positron emission tomography \(PET\) scans³](#)
7/15/2011

Contact Us

- **Report a Serious Problem**

- 1-800-332-1088
- 1-800-FDA-0178 Fax

[MedWatch Online⁴](#)

Regular Mail: Use postage-paid FDA Form 3500⁵

Mail to: MedWatch 5600 Fishers Lane
Rockville, MD 20857

Links on this page:

1. </Drugs/DrugSafety/ucm263112.htm>
2. </Drugs/DrugSafety/ucm263112.htm>
3. </Drugs/DrugSafety/ucm263112.htm>
4. <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
5. <http://www.fda.gov/downloads/Safety/MedWatch/DownloadForms/UCM082725.pdf>