February 15, 2012

ALL AGREEMENT STATES

NOTIFICATION OF DRUG SAFETY COMMUNICATION PLANNED RETURN OF CARDIOGEN-82 TO MARKET WITH NEW BOXED WARNING **(FSME-12-017)**

Purpose: To provide the Agreement States with a copy of the U.S. Food and Drug Administration (FDA) Drug Safety Communication (DSC) issued February 15, 2012, notifying healthcare professionals; in particular, the medical imaging community, about the planned return of CardioGen-82 to the U.S. market following the voluntary recall by the manufacturer, Bracco Diagnostics, Inc., on July 25, 2011.

Background: Rubidium-82 is a positron emission tomography (PET) myocardial perfusion imaging (MPI) agent. The manufacturer first sent letters 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 voluntarily recalled the product July 25, 2011. The recall was undertaken while the unexpected radiation exposure was being further investigated. Since that time, FDA, NRC, the Center for Disease Control, the State of Nevada, the State of Florida and Bracco Diagnostics, Inc., have been collecting and analyzing data to determine the extent of condition.

Discussion: Enclosed for your information is a copy of the FDA DSC concerning the revised package labeling. Before the recall there were over 100 users of CardioGen-82 and many were located in Agreement States.

Bracco Diagnostics is now bringing the product back on the market with revised package labeling. FDA has approved revised labeling for CardioGen-82 to include a *Boxed Warning* and enhanced testing information to help minimize the risk for exposure to unintended levels of strontium radiation. The DSC is attached and can also be found at the following link: http://www.fda.gov/Drugs/DrugSafety/ucm265278.htm. The revised package insert may be found at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019414s014lbl.pdf.

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

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Enclosure: FDA Drug Safety Communication

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