LIFE FROM INSIDE

September 14, 2011

Dear Valued Customer,

The purpose of this letter is to provide you with the most recent information regarding the voluntary recall of CardioGen-82® (Rubidium Rb 82 Generator). We continue to focus on activities surrounding patient safety including on-site CardioGen-82 use that is consistent with product labeling and federal regulations, and our generator production processes.

The radiation detection investigation is not complete. We have, however, received information concerning the two patients who had previously undergone Rb 82 PET MPI and in whom, when crossing the U.S. border, radiation detectors detected gamma radiation. The additional testing results for both individuals indicated lower than originally reported exposure levels to Sr-82 and Sr-85. One individual's radiation exposure was less than what would be expected from a Thallium SPECT MPI procedure, and the other individual's slightly higher than a Thallium SPECT MPI study. We have been notified of a third individual that was detained at a U.S. border due to radiation detection similar to that of the two other individuals. It was determined that the third individual was imaged at the same site in Florida as one of the other two individuals. We are seeking to have additional testing on this individual as well, in order to evaluate exposure levels. We continue to work with the respective sites, state authorities, and federal authorities, including the FDA, throughout the process, in order to facilitate conclusion of the investigation.

As mentioned in previous communications, we implemented several additional initiatives to facilitate our review and outcome efforts.

- ***CardioGen-82 Generator Voluntary Recall Process:*** We appreciate your cooperation in expeditiously shipping the recalled generators back to LANL and submitting the completed generator return paperwork. As a requirement of the recall process, it is critical that each facility fully complies with the return request. Of note, we have completed the functional and breakthrough testing of the recalled generators, and are in the process of compiling the data for a full report for the FDA. The generator testing demonstrated that each and every generator had Sr-82 and Sr-85 levels well within specification limits set forth in the prescribing information.

- ***Clinical Assessment Program***: As stated, Bracco is conducting a clinical study at all institutions that have administered CardioGen-82 to patients from January 2011 through July 2011. Bracco is asking CardioGen-82 users to participate in this study (designated CGEN-105) to capture important information. Details about this study have been sent to your institution. If you have additional questions regarding this study, or if you have not received the information, please contact the Clinical Research Team (Scott Rauscher 609-514-2315, Kathleen Bensel 609-514-2286 or Marie Morris 609-514-2577).

- ***Rb82 Generator Quality Review Program***:
  In addition to the functional testing of the generators that were in clinical use, we are continuing our on-site review of each facility's daily quality control records, using the Quality Review process. This is an opportunity to reinforce customer training and education. The objectives of both of these efforts are focused on evaluating generator quality control processes. We anticipate completion of this review by the end of September.

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- ***Customer Outreach***:
  We have been working closely with industry societies and directly with customers during this time. The Society of Nuclear Medicine (SNM), the American Society of Nuclear Cardiology (ASNC) and MedAxiom continue to post updated information on the recall, as new information becomes available. We continue to collaborate with the industry societies, to discuss areas of opportunities for Bracco, have the societies work together during the product recall, and, ultimately, to re-introduce the product to the market.

Bracco has agreed with the FDA to engage in various follow-up activities regarding the CardioGen-82 generators to effectuate a return to the marketplace. The timing of the completion of these efforts is not clear, but it will unlikely be before 2012. At this time, Bracco cannot provide the specific timing of a 2012 return, but will continue to provide you with updates. Bracco is committed to continuing the 22-year history of the safe and effective use of CardioGen-82, because we know that PET MPI is a clinically significant diagnostic procedure for use in your practice, and of great value to the patients you serve.

We will continue to provide regular updates regarding the status of our investigation. There are several sources to access information during this challenging time:

- Your local Bracco representative is updated on new information as it becomes available. Please contact him/her if you have any specific questions or concerns.
- Bracco Professional Services Hotline: 800-257-5181
- www.cardiogen.com has the latest information and most recent Q & A regarding the voluntary recall.
- ASNC and SNM have posted materials and resources relating to the CardioGen-82 recall.

We are committed to providing you with timely information and working with you throughout this process. If you have any questions regarding this matter or require additional assistance, please contact us. Thank you for your ongoing support of Bracco, CardioGen-82 and the cardiac PET MPI modality.

Regards,

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