BRACCO

LIFE FROM INSIDE

December 29, 2011

Dear Valued Customer,

As you know, Bracco Diagnostics Inc. ("Bracco") initiated a voluntary recall of CardioGen-82 on July 29, 2011. During the past five months since the voluntary recall was initiated, Bracco, has implemented actions listed below. By the end of 2011, Bracco will close out the product recall process.

- ***CardioGen-82 Generator Voluntary Recall Process:*** All recalled generators were sent to LANL for functional and breakthrough testing. 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***: Bracco continues to gather data in a clinical study (designated CGEN-105) at all participating institutions that have administered CardioGen-82 to patients from January 2011 through July 2011. To date, there have been no patients identified at these sites with higher than expected radiation levels.

- ***Rb82 Generator Quality Review Program***:
  Bracco Diagnostics Inc. initiated an on-site review of each facility's daily quality control records, using the Quality Review process. This review was an opportunity to reinforce customer training and education and will be the basis for our enhanced CardioGen-82 training Quality Control assessment and monitoring upon reintroduction of CardioGen-82 to the market.

- ***Manufacturing Process Review:***:
  At FDA's request, Bracco initiated the re-qualifying of all CardioGen components and revalidating the manufacturing process.

- ***Enhanced Labeling and User Training***
  Bracco Diagnostics Inc. continues to work with FDA on enhancing the CardioGen-82 prescribing information and user training parameters to ensure proper field use. We will initiate a new Quality Control data repository and monitoring program upon the reintroduction of Cardiogen-82 to the market.

We proposed to FDA a controlled and phased reintroduction of CardioGen-82 generators to user facilities, with data collection and evaluation of the actual field use of each generator beginning Q1 2012. The FDA expressed support for this plan. The first step in this effort will be to implement customer requirements in advance of commercial generator availability. Our field Nuclear Medicine team will begin to contact each facility toward the end of January, discussing the compliance training and site preparation expectations. Specific customer generator delivery schedules are not available at this time. However, you can anticipate receiving additional information regarding generator availability by February 1, 2012.

We are looking forward to once again providing you with CardioGen-82 in 2012. We appreciate your loyalty and support.

Regards,

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