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Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

JUN 7 2005

FDA RADIOLOGICAL HEALTH PROGRAM

Dear Colleague,

We are writing to tell you that FDA has set a new direction for our Radiological Health Program which renews our commitment to safeguarding the public health in this area. In May 2004, FDA's Center for Devices and Radiological Health (CDRH) began an effort to examine how our Program can best adapt to current public health needs. This effort culminated in a report we would like to share with you. The report outlines the key elements of the Program and how our new direction will impact the most pressing public health problems in the radiological health arena and anticipate the evolution of medical radiation systems.

We determined that we must shift the focus of our resources to the products and procedures with the highest risks to the public, including those that affect the greatest number of people or cause the most severe harm. There are five program areas we will be concentrating our efforts on: standards, monitoring, education, research, and program management. The benefits that we expect are that the new Program will:

- Align CDRH efforts with current and evolving public health needs.
- Expand focus on patient and consumer protection.
- Allow for a more targeted approach to regulation.
- Increase information dissemination and training.
- Improve coordination across the radiological health community.

These changes to the Radiological Health Program will offer us exciting opportunities to work together to improve the safe operation of radiation-emitting medical equipment and electronic products. You can find the complete report, *The CDRH Radiological Health Program – Adapting to Current Public Health Needs* at www.fda.gov/cdrh/radhlth/initiative.html. We hope to meet with you and our other stakeholders this fall to discuss how we can work together to maximize the benefits of the Center's Radiological Health Program.

Sincerely,

Daniel G. Schultz, M.D.
Director
Center for Devices and Radiological Health

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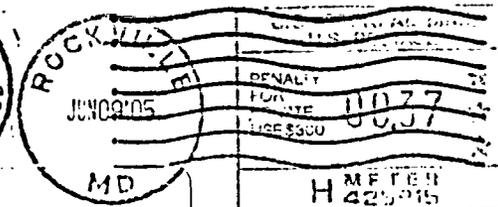
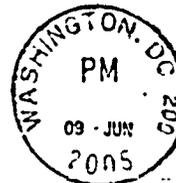
SISP Review Complete

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