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June 26, 2009

Mr. Michael T. Lesar,
Chief, Rulemaking and Directives Branch
US Nuclear Regulatory Commission, MS TWB-05-B01M
Division of Administrative Services, Office of Administration
Washington, DC 20555-0001

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MERCK
Research Laboratories

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Subject: Comments on Proposed Rulemaking, NRC-2009-042, NRC Staff Assessment of a Proposed Agreement Between the Nuclear Regulatory Commission and the State of New Jersey

5/27/09

74FR 25283

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Dear Mr. Lesar,

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them.

Thank you for the opportunity to comment on the proposed agreement between the US Nuclear Regulatory Commission (NRC) and the State of New Jersey whereby the State is proposed to assume regulatory authority over certain radioactive materials and activities that were previously regulated by the NRC.

Subchapter 64 of the proposed NJ regulations, titled *Radioactive Material License Fees*, unfairly charges exorbitant fees to certain types of NJ licensees. Unlike the NRC, the State has elected to charge independent licensing fees for each "additional use site" on a license. Consider the following comparison of two hypothetical licensees:

	Number & Location of Sites	2009 NRC License Fee	Proposed NJ License Fee
Company "A" - Broad Scope License w/ Irrad	One Large Site in Central NJ	\$14,700	\$14,000
Company "B" - Broad Scope License w/ Irrad	Six Small/Medium Sized Sites in Central NJ, (all within a 30 minute drive)	\$14,700	\$84,000

Clearly the additional amount of administrative work to oversee Company B's license does not justify a 600% fee increase. It is conceivable that the broad scope program for Company "B" could have a smaller radioactive material inventory, fewer laboratories, and fewer scientists working with radioactive material than Company "A." The Proposed NJ Fee structure would levy a fee that is not commensurate with the administrative work associated with that program. Although the information presented in the table above is currently hypothetical, it becomes reality with the upcoming merger of Schering Plough and Merck. Merck supports the rationale whereby states can assume regulatory authority from the NRC when they demonstrate the equivalency of their programs; however charging six times the NRC licensing fees is not justified.

Sincerely,

Gregory R. Reinhard
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