Renal

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Baxter

October 14, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Comments to the Proposed Safety Reporting Requirements for Human Drug and Biological Products; Proposed Rule

Dear Sir or Madam:

Attached are Baxter Healthcare Corporation's written comments to the proposed changes to 21 CFR Parts 310, 312, 314, 320, 600, 601, and 606, Docket Number 00N-1484, concerning Safety Reporting Requirements for Human Drugs and Biological Products; Proposed Rule, published in the Federal Register on March 14, 2003.

Baxter Healthcare appreciates the FDA's efforts to update the safety reporting regulations in the United States. We would like to suggest that the final rule be similar to the current ICH Guidelines: E2A, E2B and E2C in order to be more consistent with safety reporting requirements worldwide.

If you have any questions or comments regarding our response, please do not hesitate to contact me.

Sincerely,

Linda J. Peters

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