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February 11, 2000

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

**RE: Federal Register Notice December 1, 1999 (FR Vol. 64, No. 230,  
Pages 67207-67216)**

**Docket No. 99N-1852**

Dear Colleague:

Baxter Healthcare Corporation appreciates the opportunity to submit comments on the Proposed Rule: "*Postmarketing Studies for Human Drugs and Licensed Biological Products; Status Reports.*"

Baxter supports FDA's efforts to implement the requirements of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and recognizes that the proposed changes to 21 CFR Parts 314 and 601 have been initiated to address specific requirements of Section 130(a) of FDAMA. While we agree that FDA's proposed rule addresses the requirements put forth in Section 130(a) of FDAMA, we believe that it goes beyond the scope and intent of the law with respect to the requirement for reporting the status of postmarketing studies.

Section 130(a) of FDAMA amended the Federal Food, Drug, and Cosmetic Act and added new provisions for reporting postmarketing studies (Section 506B). FDAMA required that "a sponsor of a drug that has entered into an *agreement* with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study..."

Baxter believes that FDAMA clearly specifies that a firm is only required to submit reports of the progress of postmarketing studies for which a firm has *committed* to FDA to perform. FDAMA does not require the submission of

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status reports for postmarketing studies that a firm has not committed to FDA to perform. Requiring such reports goes beyond the letter and intent of the law and represents an unnecessary regulatory burden that does not assist FDA toward its stated goal of effective oversight of the increased number of postmarketing study *commitments*.

In addition, relevant postmarketing information on studies that are not subject to a commitment to FDA is already being reported under 21 CFR Parts 314.81(b)(2)(iv) through 314.81(b)(2)(vi), e.g., new information regarding chemistry, manufacturing and controls that may affect FDA's previous conclusions about the safety or effectiveness of the drug product. We feel that reporting the status of these studies is not pertinent and that repeating this information under 314.81(b)(2)(viii) is redundant and unnecessary.

Therefore, Baxter recommends that proposed regulation 21 CFR Part 314.81(2)(viii) "*Status of other postmarketing studies*" be removed from the final rule.

Thank you for your consideration of our comments on the proposed rule.

Sincerely,



FOR

Marcia Marconi  
Vice President  
Regulatory Affairs  
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