

# Kidney ~~Cancer~~ Association

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August 13, 2001

Dockets Management Branch  
HFA-305  
Food & Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville MD 20854

RE: Docket # 00D-1033

To Whom It May Concern:

On behalf of the 203,000 Americans who have kidney cancer, the Kidney Cancer Association, a patient and survivor led voluntary health agency, is pleased to offer these comments on the proposed Draft Guidance relating to the Clinical Trials Data Base mandated by Section 1033 of the Food and Drug Administration Modernization Act.

- Sponsors should be required to update the information they have posted on clinical trials in a timely fashion, which the Association believes should be within not more than 30 days after the occurrence of the reportable event or change. The Association believes that it might be appropriate to allow sponsors to batch updates within this time frame.
- Sponsors should be encouraged to post the results of the trials as soon as they are made available in abstract or similar form.

Respectfully submitted,



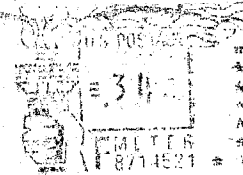
Carl F. Dixon  
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