



May 13, 2005

Food and Drug Administration  
Division of Dockets Management  
5630 Fishers Lane, room 1061  
Rockville, MD 20852

REFERENCE: **[Docket No. 2004N-0527]**

Dear Sir or Madam:

Following are comments in regard to the proposed regulation changing the Medical Device Reporting, 21 CFR 803.

- Refer to §803.18 (e)  
The text of the regulation states, '... unless you evaluate an event in accordance with the quality system requirements described in part 820 of this chapter.' This sentence or sub-section (e) should be clarified with the intent to investigate the event according to corrective action principles and root cause analysis techniques. The assumption is being made that the intent of the paragraph is to follow those principles of corrective action and root cause analysis as outlined in §820.100. Modify the sentence to detail intent on corrective action principles or clarify the actual intent of the evaluation being performed according to specific requirements in part 820.
- Refer to §803.20 (b)(2)(ii)  
The first sentence stating, 'The manufacturer, no later than 30 days calendar after receiving ...' should be, 'The manufacturer, no later than 30 calendar days after receiving ...' This is consistent with the remainder of the text.
- Refer to §803.32 (a)(1) and §803.42 (a)(1) and §803.52 (a)(1)  
The FDA Form 3500A states to enter the patient name or other identifier. This comment is in regard to the HIPAA Act of 1996 and protection of patient privacy and medical information. The user facility, manufacturer, or importer to keep with the spirit of the HIPAA Act should only use a patient identifier. As this document may be transmitted to multiple persons or multiple organizations, it is important to protect the privacy of the patient identity. The form should be updated to reflect recording only a patient identification.
- Refer to §803.56  
The first paragraph states, '... you must submit the supplemental information to us within 1 month of the day that you receive this information.' This sentence portion should be, '... you must submit the supplemental information to us within 30 days of the day that you receive this information.' This is consistent with the remainder of the text.

Sincerely,

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Director of Regulatory Affairs

*"Innovative Molecular Diagnostic Solutions"*

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