



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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July 31, 2000

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

Dear Sir or Madam:

I am writing in reference to Docket No. 96N-0393 regarding the solicitation of public comments to "MedWatch: The FDA Medical Products Reporting Program" forms (3500 and 3500A).

My comment relates to improving form 3500A to increase its utility to FDA by helping FDA achieve proper performance of its function.

I suggest adding a block to the form that requires manufacturers to state the date the report was forwarded to the FDA. Blocks F8 and F11 require a User Facility to provide the date a report is forwarded to the FDA (when applicable), however the 3500A does not contain a similar block requiring the manufacturer to provide this information. Providing this information will make the FDA Investigator's job more efficient. Currently, when verifying that the reporting timeframe requirements of 21 CFR 803 are being met, the Investigator must rely on some other evidence (if available) that the reports were submitted within the timeframes or contact FDA Headquarters staff to confirm that the timeframes are being met. If a block containing the date the report was forwarded by the manufacturer to the FDA was provided on the 3500A (similar to the requirement that User Facilities must meet), it would be more efficient for the Investigator to verify that submission timeframes are being met. For example, regarding 30 day reports, the Investigator could compare the date submitted to the FDA to the date the manufacturer became aware of the event (block G4) and verify that there are no significant problems with the implementation of procedures that ensure timely transmission of reports to the FDA.

Thank you for allowing me the opportunity to comment.

Sincerely,

Robert G. Ruff
Consumer Safety Officer

96N-0393

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