stated that more than 3 days were needed for reporting.

FDA agrees. The agency is extending the time period to make such reports from 3 days to 5 days. FDA is also renaming ''imminent hazard reports'' as ''5-day reports'' (defined in § 803.3(k)), and has clarified this requirement in § 803.53.

The purpose of the 5-day report is to alert the agency rapidly to adverse events that may pose an unreasonable risk of substantial harm to the public health. Thus, the definition of ''5-day report'' has been revised to mean a report of an adverse event required by a manufacturer, submitted on FDA Form 3500A or an FDA approved electronic equivalent within 5 work days of: (1) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becoming aware that a reportable MDR event or events, from any information, including any trend analysis, necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or (2) any employee becoming aware of an adverse event, if the manufacturer has received a written request from FDA for the submission of a 5-day report for those types of adverse events. When such a request is made, the manufacturer shall submit a 5-day report for all subsequent adverse events of the same nature that involve substantially similar devices for the time period specified in the written request. The time period stated in the original written request can be extended by FDA if it is in the interest of the public health.

FDA does not intend that a manufacturer delay or interrupt a remedial action in order to submit a 5-day report. The report must be made within 5 days of the manufacturer becoming aware that a reportable event or events necessitate remedial action to prevent unreasonable risk of substantial harm to the public health. Information that would reasonably suggest remedial action is necessary to prevent such risk may, for example, be from one MDR reportable event that makes the manufacturer aware of a serious design flaw that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public. On the other hand, information that would reasonably suggest remedial action is necessary may result from an internal trending analysis of several MDR reports that make the manufacturer aware that serious injuries or deaths occur at a much higher frequency than expected. Further discussion relating to when a manufacturer is considered aware of a reportable event is in section IV.A., comment 2, of this document.

Manufacturers who submit 5-day reports are not required to submit reports of removals and corrections under section 519(f) of the act. Any information not available for reporting under the 5-day reporting timeframe may be submitted in a supplemental report.

FDA does not agree with comments asserting that 5-day reports are beyond the scope of the SMDA or belong in another regulation. Requiring 5-day reports is consistent with FDA's authority under section 519(a)(1) of the act to issue regulations requiring manufacturers to report information that reasonably suggests that one of their marketed devices ''may have caused or contributed to a death or serious injury, or has malfunctioned and that such device * * * would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.'' For the protection of the public health, FDA may limit the time allowed to manufacturers for reporting events of which the agency should be quickly aware.

10. Many comments stated that the requirements relating to user facility incident files (proposed § 803.35(c)) that contain documents related to adverse events that a user facility must maintain are overly burdensome because the definition of ''incident files'' in proposed § 803.3(h) is overly broad. Many of these comments suggested that the definition of incident files be removed or changed in order to clarify or limit the scope of requirements relating to the files. Other comments suggested that FDA's access to the files be limited.

The agency agrees that the definition of these files (which have been renamed ''MDR event files'' in § 803.18 of the final regulation) could be narrowed. Accordingly, FDA has revised the definition of MDR event files to include MDR reports filed with FDA or other entities, and documents related to the adverse event, including documents relating to deliberations and decisionmaking processes used in the evaluation or determination of whether an event is an MDR reportable event. The final rule also allows the reporter to incorporate certain information by reference, such as medical records, patient files, and engineering reports, rather than include them in the MDR event file.

FDA does not agree that agency access to user facility files should be limited. Under § 803.18(b), user facilities shall permit any authorized FDA employee during all reasonable times to have access to, and to copy and verify the records required under part 803. FDA has authority to inspect files under section 704(e) of the act (21 U.S.C. 374(e)). Section 704(e) of the act states that every person required to maintain records under section 519 of the act, and every person who is in charge or custody of such records, shall permit FDA at all reasonable times to have access to and to copy and verify such records. In issuing a regulation stating its authority under section 704(e) of the act to have access to user facility adverse event files, FDA is exercising its duty under the statute to protect the public health by ensuring that user facilities comply with reporting requirements issued under section 519 of the act.

11. Several comments stated that the definition of what kind of information triggers the reporting requirements, specifically, the definition of ''information that reasonably suggests that there is a probability that a device has caused or contributed to a death or serious injury, or serious illness'' (proposed § 803.3(i)), is unclear and requires further definition.

The agency agrees and has clarified this concept in § 803.20(c). As explained in section II.B.1 of this document, section 5 of the 1992 amendments revised section 519(a)(1) of the act, subsequent to FDA's November 1991 tentative final rule, to require the agency to issue regulations that require manufacturers and importers to report to FDA ''whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices: (1) May have caused or contributed to a death or serious injury, or (2) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.'' Similarly, section 5 of the 1992 amendments revised the reporting standard for user facilities under section 519(b)(1) (A) and (B) of the act to require a user facility to submit a report whenever it receives or otherwise becomes aware of information ''that reasonably suggests that a device has or may have caused or contributed to a death * * * or serious illness of, or serious injury to, a patient of the facility * * *.''

Under the revised 1992 amendments' statutory reporting standards, FDA has no discretion to change the reporting standards for manufacturers and user