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Comment On: FDA-2026-N-7129-0001

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Devices: (Medical Product Safety Network (MedSun))

Document: FDA-2026-N-7129-0003

Comment from inventhealth.care

Submitter Information

Organization: inventhealth.care

General Comment

MedSun is an indispensable sentinel network whose targeted, high-precision clinical reporting enables early safety signal detection and proactive device hazard mitigation before patient harm can occur. inventhealth.care requests that the Office of Management and Budget authorize the proposed information collection renewal as submitted.

1. Practical Utility of a Low-Friction Voluntary Program

MedSun's primary value lies in its streamlined, voluntary framework. Because participation is voluntary across the approximately 300 member facilities, keeping the reporting portal simple ensures high ongoing engagement from clinical staff without imposing heavy administrative overhead. MedSun's practical utility stems directly from its nature as a lightweight, low-friction surveillance tool.

2. Accuracy of the Burden Estimate and High Value of the Supplemental Questions

The FDA's estimated average of 0.5 burden hours (30 minutes) and operational costs accurately reflects the standard effort required from respondents. The vast majority of routine MedSun intakes consist of concise, 1-to-2 sentence summaries identifying the device problem. While specialized, complex events occur, they typically require no more than a paragraph or two. Furthermore, the FDA's informal "supplemental follow-up questions" are infrequent, brief administrative clarifications that are already captured within the overall 30-minute average. Creating a separate line item for these occasional follow-up inquiries would add unnecessary paperwork clutter to the OMB filing without offering better accounting accuracy. Evaluating the collection based on this high-volume baseline of straightforward events justifies the estimated burden calculation.

3. Maintaining Regulatory Boundaries and Operational Simplicity

Mandating complex third-party system integrations, such as direct EHR data pulls, would diminish the practical utility of the collection. Section 519 of the FD&C Act, implemented under Part 803, legally

requires user facilities to report incidents directly to the FDA under strict deadlines. This statutory requirement serves as the formal regulatory compliance mechanism with enforcement discretion.

MedSun, on the other hand, is not a regulatory compliance mechanism; rather, it functions as an optional, high-detail sentinel network. MedSun works precisely because it remains a lightweight, direct reporting tool.

inventhealth.care respectfully urges the Office of Management and Budget (OMB) to approve the collection extension as currently proposed.

Respectfully submitted,
inventhealth.care