

Record Retention for Device Manufacturers

Medical device manufacturers regulated by FDA perform many activities as stipulated in various parts of the regulations. Many of these activities generate records. Records may include internal activities only or reports to FDA.

In general, records have the following attributes:

- Requirement – Where do the FDA Regulations require the record?
- Trigger – What activity initiates a record?
- Content – What information belongs in the record?
- Retention – How long to keep the record?
 - In some cases the retention clock starts with a specific activity, not the trigger
- Custody – Who must retain custody of the records?
- Access – Under what conditions may FDA access and copy the records?

Reports have the same attributes as records, and a few more:

- Timing – How long is the time from the trigger until the report is due?
- Transmission – Does FDA specify the method to send the report?

In some sections there are recording keeping requirements for specific device types. For example, Part 801 requires distribution records for impact resistant lenses. This report does not include those types of device specific records.

In some cases, there are multiple criteria. These are usually a disjunction between two choices. This document uses the following convention: <Criterion #1> OR <Criterion #2>.

Part 803 Medical Device Reporting

MDR Event file §803.18

An MDR Event file contains all of the manufacturer's information related to an adverse event, any reports sent to the FDA, and any electronic acknowledgements from FDA.

Record Retention:

Source: §803.18(c)

Clock Starts: Date of the event

Retention Period: The longer of <2 years> OR <a period of time equivalent to the expected life of the device>

Note: *Expected life of a device* means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified "end of life" (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time. [§803.3(f)]

Part 807 Establishment Registration and Device Listing

Labeling and Advertisements File §807.26

The Labeling and Advertisements File contains the labeling and advertisements a) in use on the date of initial listing, b) in use after October 10, 1978, but before the date of initial listing, and c) for which a material change has been made any time after initial listing.

Record Retention:

Source: §807.26(c)

Clock Starts: The date of the last shipment of a discontinued device by an owner or operator

Retention Period: 3 years

Notes: *Material change* includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for devices where the biological activity or known composition differs with each lot produced, the labeling containing the actual values for each lot. [§807.3(n)]

An owner or operator who *discontinues commercial distribution* of a device shall discontinue the device listing using the FDA electronic device registration and listing system. A device listing is considered discontinued if: (1) All devices under an exempt product code have been discontinued or (2) All devices associated with an FDA premarket submission number have been discontinued. [§807.28(d)]

Part 812 Investigational Device Exemptions

Investigator Records §812.140(a)

A participating investigator maintains accurate, complete, and current records relating to the investigator's participation in an investigation.

Record Retention:

Source: §812.140(d)

Clock Starts: The longer of <the date on which the investigation is terminated or completed> OR <the date that the records are no longer required to support a premarket approval application or a notice of completion of a product development protocol>

Retention Period: 2 years

Sponsor Records §812.140(b)

A sponsor maintains accurate, complete, and current records relating to an investigation:

Record Retention:

Source: §812.140(d)

Clock Starts: The longer of <the date on which the investigation is terminated or completed> OR <the date that the records are no longer required to support a premarket approval application or a notice of completion of a product development protocol>
Retention Period: 2 years

IRB Records §812.140(c)

An IRB shall maintain records in accordance with part 56 of this chapter.

Record Retention:

Source: §56.115(b)
Clock Starts: Completion of the research
Retention Period: 3 years

Investigator Reports §812.150(a)

An investigator prepares and submits complete, accurate, and timely reports to the parties specified in 812.150(a). Depending on the report type, it could go to the sponsor, the IRB, FDA, *etc.* Investigator reports are also Investigator Records.

Record Retention:

Source: §812.140(d)
Clock Starts: The longer of <the date on which the investigation is terminated or completed> OR <the date that the records are no longer required to support a premarket approval application or a notice of completion of a product development protocol>
Retention Period: 2 years

Sponsor Reports §812.150(b)

A sponsor prepares and submits complete, accurate, and timely reports to the parties specified in 812.150(b). Depending on the report type, it could go to the investigator, the IRB, FDA, *etc.* Sponsor reports are also Sponsor Records.

Record Retention:

Source: §812.140(d)
Clock Starts: The longer of <the date on which the investigation is terminated or completed> OR <the date that the records are no longer required to support a premarket approval application or a notice of completion of a product development protocol>
Retention Period: 2 years

Part 820 Quality System Regulation

QSR requires multiple records, but they all have the same record retention period.

Record Retention:

Source: §820.180(b)
Clock Starts: Date of release for commercial distribution by the manufacturer
Retention Period: The longer of <the period of time equivalent to the design and expected life of the device> OR <2 years>

Part 821 Medical Device Tracking Requirements

Information prior to the distribution of a tracked device §821.25(a)(1)

A manufacturer provides the information listed in §821.25(a)(1) to FDA within 3 days of a request.

Record Retention:

Source: §821.25(b)

Clock Starts: Tracked device released for distribution

Retention Period: <as long as the device is in use> OR < as long as the device is in distribution for use>

Information for tracked devices that are intended for use by a single patient over the life of the device §821.25(a)(2)

A manufacturer provides the information listed in §821.25(a)(2) to FDA within 10 working days of a request.

Record Retention:

Source: §821.25(b)

Clock Starts: Tracked device released for distribution

Retention Period: <as long as the device is in use> OR < as long as the device is in distribution for use>

Information for tracked devices that are intended for use by more than one patient §821.25(a)(3)

A manufacturer provides the information listed in §821.25(a)(3) to FDA within 10 working days of a request.

Record Retention:

Source: §821.25(b)

Clock Starts: Tracked device released for distribution

Retention Period: <as long as the device is in use> OR <as long as the device is in distribution for use>

Part 822 Postmarket Surveillance

Records to Keep §822.31

§822.31 lists five types of records to maintain:

- (a) All correspondence with your investigators or FDA, including required reports;
- (b) Signed agreements from each of your investigators, if your surveillance plan uses investigators, stating the commitment to conduct the surveillance in accordance with the approved plan, any applicable FDA regulations, and any conditions of approval for your plan, such as reporting requirements;
- (c) Your approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan;

(d) All data collected and analyses conducted in support of your postmarket surveillance plan; and

(e) Any other records that we require to be maintained by regulation or by order, such as copies of signed consent documents, evidence of Institutional Review Board review and approval, *etc.*

Record Retention:

Source: §822.33

Clock Starts: When FDA accepts the final report

Retention Period: <2 years> OR <as specified by FDA>

Part 830 Unique Device Identification

Relabeling of a device §830.60

§830.60 a record showing the relationship of the prior device identifier to your new device identifier.

Record Retention:

Source: §830.360(a)

Clock Starts: The date the labeler ceases to market the version or model

Retention Period: 3 years

Unique device identifiers (UDIs) §830.360(a)

§830.360(a) requires records showing all unique device identifiers (UDIs) used to identify devices that must bear a UDI on their label, and the particular version or model associated with each device identifier.

Record Retention:

Source: §830.360(a)

Clock Starts: The date the labeler ceases to market the version or model

Retention Period: 3 years