you receive such a written request from us, you must submit, without fur-
ther requests, a 5-day report for all
subsequent events of the same nature
that involve substantially similar de-
vices for the time period specified in
the written request. We may extend
the time period stated in the original
written request if we determine it is in
the interest of the public health.

§ 803.56 If I am a manufacturer, in
what circumstances must I submit a
supplemental or followup report
and what are the requirements for
such reports?

If you are a manufacturer, when you
obtain information required under this
part that you did not provide because
it was not known or was not available
when you submitted the initial report,
you must submit the supplemental in-
fomation to us within 1 month of the
day that you receive this information.
On a supplemental or followup report,
you must:
(a) Indicate on the envelope and in
the report that the report being sub-
mitted is a supplemental or followup
report. If you are using FDA form
3500A, indicate this in Block Item H–2;
(b) Submit the appropriate identi-
fication numbers of the report that you
are updating with the supplemental in-
fomation (e.g., your original manufac-
turer report number and the user facil-
ity or importer report number of any
report on which your report was based),
if applicable; and
(c) Include only the new, changed, or
corrected information in the appro-
priate portion(s) of the respective
form(s) for reports that cross reference
previous reports.

§ 803.58 Foreign manufacturers.
(a) Every foreign manufacturer
whose devices are distributed in the
United States shall designate a U.S.
agent to be responsible for reporting in
accordance with §807.40 of this chapter.
The U.S. designated agent accepts re-
sponsibility for the duties that such
designation entails. Upon the effective
date of this regulation, foreign manu-
facturers shall inform FDA, by letter,
of the name and address of the U.S.
agent designated under this section
and §807.40 of this chapter, and shall
update this information as necessary.
Such updated information shall be sub-
mitted to FDA, within 5 days of a
change in the designated agent in-
formation.
(b) U.S.-designated agents of foreign
manufacturers are required to:
(1) Report to FDA in accordance with
§§803.50, 803.52, 803.53, 803.55, and 803.56;
(2) Conduct, or obtain from the for-
.eign manufacturer the necessary in-
formation regarding, the investiga-
tion and evaluation of the event to com-
port with the requirements of §803.50;
(3) Forward MDR complaints to the
foreign manufacturer and maintain
documentation of this requirement;
(4) Maintain complaint files in ac-
cordance with §803.18; and
(5) Register, list, and submit pre-
market notifications in accordance
with part 807 of this chapter.

EFFECTIVE DATE NOTE: At 61 FR 38347, July
23, 1996, §803.58 was stayed indefinitely. At 73
FR 33695, June 13, 2008, §803.58(b)(1) was
amended, but the amendment could not be
incorporated because the section is stayed.

PART 806—MEDICAL DEVICES; RE-
PORTS OF CORRECTIONS AND
REMOVALS

Subpart A—General Provisions

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806.1 Scope.
806.2 Definitions.

Subpart B—Reports and Records
806.10 Reports of corrections and removals.
806.20 Records of corrections and removals
not required to be reported.
806.30 FDA access to records.
806.40 Public availability of reports.

AUTHORITY: 21 U.S.C. 332, 360, 360i, 360j, 371,
374.

SOURCE: 62 FR 27191, May 19, 1997, unless
otherwise noted.

Subpart A—General Provisions
§ 806.1 Scope.
(a) This part implements the provi-
sions of section 519(f) of the Federal
Food, Drug, and Cosmetic Act (the act)
requiring device manufacturers and
importers to report promptly to the
Food and Drug Administration (FDA)
§ 806.2 Definitions.

As used in this part:


(b) Agency or FDA means the Food and Drug Administration.

(c) Consignee means any person or firm that has received, purchased, or used a device subject to correction or removal.

(d) Correction means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.

(e) Correction or removal report number means the number that uniquely identifies each report submitted.

(f) Importer means, for the purposes of this part, any person who imports a device into the United States.

(g) Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(h) Market withdrawal means a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves no violation of the act, e.g., normal stock rotation practices.

(i) Removal means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

(j) Risk to health means

(1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or

(2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

(k) Routine servicing means any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.

(l) Stock recovery means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit...
Subpart B—Reports and Records
§ 806.10 Reports of corrections and removals.
(a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:
(1) To reduce a risk to health posed by the device; or
(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under §806.1(b).
(b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.
(c) The manufacturer or importer shall include the following information in the report:
(1) The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation “C” or “R”. For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567–6/1/97–001–C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567–7/1/97–002–C etc. For removals, the number will appear as follows: 1234567–6/1/97–001–R and 1234567–7/1/97–002–R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000–6/1/97–001–C for corrections and 0000000–7/1/97–001–R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.
(2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.
(3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.
(4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.
(5) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
(6) The manufacturer’s name, address, telephone number, and contact person if different from that of the person submitting the report.
(7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.
(8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.
(9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.
(10) The date of manufacture or distribution and the device’s expiration date or expected life.
(11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.
(12) A copy of all communications regarding the correction or removal and
§ 806.20 Records of corrections and removals not required to be reported.

(a) Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under §806.10 shall keep a record of such correction or removal.

(b) Records of corrections and removals not required to be reported to FDA under §806.10 shall contain the following information:

(1) The brand name, common or usual name, classification, name and product code if known, and the intended use of the device.

(2) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

(3) A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

(4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any followups, and be reviewed and evaluated by a designated person.

(5) A copy of all communications regarding the correction or removal.

(c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.


§ 806.30 FDA access to records.

Each device manufacturer or importer required under this part to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

[63 FR 42233, Aug. 7, 1998]

§ 806.40 Public availability of reports.

(a) Any report submitted under this part is available for public disclosure
Food and Drug Administration, HHS

in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under § 20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

Subpart A—General Provisions

Sec. 807.3 Definitions.

807.65 Exemptions for device establishments.

Subpart B—Procedures for Device Establishments

807.20 Who must register and submit a device list?

807.21 Times for establishment registration and device listing.

807.22 How and where to register establishments and list devices.

807.25 Information required or requested for establishment registration and device listing.

807.26 Amendments to establishment registration.

807.30 Updating device listing information.

807.31 Additional listing information.

807.35 Notification of registrant.

807.37 Inspection of establishment registration and device listings.

807.39 Misbranding by reference to establishment registration or to registration number.

Subpart C—Registration Procedures for Foreign Device Establishments

807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

Subpart E—Premarket Notification Procedures

807.81 When a premarket notification submission is required.

807.85 Exemption from premarket notification.

807.87 Information required in a premarket notification submission.

807.90 Format of a premarket notification submission.

807.92 Content and format of a 510(k) summary.

807.93 Content and format of a 510(k) statement.

807.94 Format of class III certification.

807.95 Confidentiality of information.

807.97 Misbranding by reference to premarket notification.

807.100 FDA action on a premarket notification.


SOURCE: 42 FR 42526, Aug. 23, 1977, unless otherwise noted.