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TITLE 21--FOOD AND DRUGS

标题21--食品和药品

CHAPTER I--FOOD AND DRUG ADMINISTR

第I章--食品和药品管理局

ATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

卫生与公众服务部

SUBCHAPTER H - MEDICAL DEVICES

H分章-医疗器械

PART 806 - MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

第806部分 医疗器械更正和移除报告

Content（目录）

Subpart A - General Provisions	**A** 分部 **-** 一般规定
§ 806.1 Scope.	**§** 806.1 范围。
(a) This part implements the provisions of section 519(g) 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) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.	(a) 本部分实施联邦食品、药品和化妆品法案（法案）第 519(g) 节的规定，要求器械制造商和进口商及时向食品药品监督管理局 (FDA) 报告有关器械更正的某些行动和移除，并保存所有更正和移除的记录，无论此类更正和移除是否需要向 FDA 报告。
(b) The following actions are exempt from the reporting requirements of this part:	(b) 以下行为不受本部分报告要求的约束：
(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device. (2) Market withdrawal as defined in § 806.2(i) (3) Routine servicing as defined in § 806.2(l). (4) Stock recovery as defined in § 806.2(m).	(1) 器械制造商或进口商为提高器械的性能或质量而采取的行动，但并未降低器械对健康造成的风险或补救器械造成的违法行为。 (2) § 806.2(i) 中定义的市场退出 (3) § 806.2(l) 中定义的例行服务。 (4) § 806.2(m) 中定义的库存回收。
[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 84 FR 12083, Apr. 1, 2019]	[62 FR 27191，1997 年 5 月 19 日，经 63 FR 42232，1998 年 8 月 7 日修订；84 FR 12083，2019 年 4 月 1 日]
§ 806.2 Definitions.	**§** 806.2 定义。
As used in this part:	如本部分中所述：
(a) Act means the Federal Food, Drug, and Cosmetic Act. (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) Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in	(a)法案 是指联邦食品、药品和化妆品法案。 (b)机构 或FDA 是指食品和药物管理局。 (c)收货人 是指接收、购买或使用需要更正或移除的设备的任何个人或公司。 (d)更正 是指对设备进行维修、修改、调整、重新贴标签、销毁或检查（包括患者监测），而无需将其从使用点物理移至其他位置。 (e)更正或移除报告编号 是指唯一标识提交的每份报告的编号。 (f)作为器械监管的人体细胞、组织或基于细胞或组织的产品 (HCT/P) 是 指本章 § 1271.3(d) 中定义的不符合 § 1271.10(a) 并且这也作为

§ 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device. (g) Importer means, for the purposes of this part, any person who imports a device into the United States.	一种设备进行监管。 (g)进口商 就本部分而言是指将设备进口到美国的任何人。
(h) 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:	(h)制造商 是指通过化学、物理、生物或其他程序制造、制备、繁殖、复合、组装或加工设备的任何人。该术语包括以下任何人：
(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.	(1) 重新包装或以其他方式更改器械的容器、包装或标签，以促进器械从原始制造地分配给最终交付或销售给最终用户或消费者的人； (2) 为由第二方制造的设备发起规范，以供发起规范的人随后分发；或者 (3) 制造的组件或附件是准备好使用并打算进行商业销售并打算按原样使用的设备，或由有执照的从业人员或其他合格人员加工以满足特定需求的设备病人。
(i) 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. (j) 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.	(i)市场退出 是指对分布式设备的更正或移除，其中涉及轻微违反该法案的行为，不会受到 FDA 的法律诉讼或不违反该法案，例如正常的库存周转做法。 (j)移除 是指将设备从其使用点物理移除到其他位置以进行维修、修改、调整、重新贴标签、销毁或检查。
(k) Risk to health means	(k)健康风险 指
(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.	(1) 使用或接触产品会导致严重不良健康后果或死亡的合理可能性；或者 (2) 使用或接触该产品可能会导致暂时或医学上可逆的不良健康后果，或严重不良健康后果的可能性很小的结果。

(l) 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. (m) 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 involved in the corrective or removal action has been released for sale or use.	(l)日常维护 是指对设备进行的任何定期维护，包括在其正常预期寿命结束时更换部件，例如校准、更换电池以及对正常磨损的响应。意外性质的维修、比正常预期寿命更早的部件更换、或相同的维修或更换设备的多个单元都不是常规维修。 (m)库存回收 是指更正或移除尚未上市或未离开制造商直接控制的设备，即设备位于制造商拥有或控制的场所，涉及更正或移除行动的批次、型号、代码或其他相关单元的任何部分均未发布出售或使用。
(n) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A UDI is composed of:	(n)唯一设备标识符 (UDI) 是指通过满足本章第 830.20 条的要求，通过其分发和使用充分识别设备的标识符。UDI 由以下部分组成：
(1) A device identifier - a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and	(1)器械标识符 ——UDI 的强制性、固定部分，用于标识器械的特定版本或型号以及器械的标签；和
(2) A production identifier - a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:	(2)生产标识符 - UDI 的一个有条件的可变部分，当包含在设备标签上时，它标识以下一项或多项：
(i) The lot or batch within which a device was manufactured; (ii) The serial number of a specific device; (iii) The expiration date of a specific device; (iv) The date a specific device was manufactured. (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.	(i) 制造设备的批次； (ii) 特定设备的序列号； (iii) 特定设备的到期日期； (iv) 特定设备的制造日期。 (v) 对于作为设备监管的 HCT/P，本章第 1271.290(c) 节要求的独特识别码。
[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 78 FR 58821, Sept. 24, 2013]	[62 FR 27191，1997 年 5 月 19 日，经 63 FR 42232，1998 年 8 月 7 日修订； 78 FR 58821，2013 年 9 月 24 日]
Subpart B - Reports and Records	**B** 子部分 **-** 报告和记录
§ 806.10 Reports of corrections and removals.	**§** 806.10 更正和移除报告。
(a) Each device manufacturer or importer shall submit a	(a) 每个器械制造商或进口商应向 FDA 提交一

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:	份书面报告，说明该制造商或进口商对器械进行的任何更正或移除，如果更正或移除是在以下情况下启动的：
(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).	(1) 降低设备对健康造成的风险；或者 (2) 纠正由设备引起的可能对健康构成风险的违规行为，除非该信息已按照本节 (f) 段的规定提供，或者更正或移除行动免于报告§ 806.1(b) 的要求。
(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.	(b) 制造商或进口商应在开始此类更正或移除后的 10 个工作日内提交本节 (a) 段要求的任何报告。
(c) The manufacturer or importer shall include the following information in the report:	(c) 制造商或进口商应在报告中包括以下息：
(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.	(1) 负责提交更正或移除行动报告的实体的七位数注册号（如适用）、报告的月、日和年，以及序列号（即，001 表示第一个报告，002 表示第二个报告，003 等），以及报告类型名称“C”或“R”。例如，对于注册号为 1234567 的公司，1997 年 6 月 1 日提交的第一份更正报告的完整编号如下所示：1234567-6/1/97-001-C。同一公司于 1997 年 7 月 1 日提交的第二次更正报告编号为 1234567-7/1/97-002-C 等。对于移除，编号将显示为：1234567-6/1/97-001 -R 和 1234567-7/1/97-002-R 等。没有七位注册号的公司可以使用七个零，后跟月份、日期、年份和序列号（即 0000000-6/1/97-001-C 用于更正，0000000-7/1/97-001-R 用于移除）。收到的没有七位数注册号的报告将由审查报告的地区办公室分配一个七位数的中央档案号。
(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	(2) 制造商或进口商的名称、地址和电话号码，以及负责进行设备更正或移除的制造商或进口商代表的名称、职务、地址和电话号码。 (3) 器械的品牌名称和通用名称、分类名称或

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 unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), 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 the names and addresses of all recipients of the communications not provided in accordance with paragraph	常用名称以及器械的预期用途。 (4) 器械的营销状态，即任何适用的上市前通知号、上市前批准号或器械是预先修订器械的指示，以及器械清单号。没有 FDA 机构注册号的制造商或进口商应在报告中说明其是否曾在FDA 注册。 (5) 出现在设备标签或设备包装上的唯一设备标识符 (UDI)，或设备标识符、通用产品代码 (UPC)、型号、目录或设备代码以及制造批号或序列号设备编号或其他标识号。 (6) 制造商的名称、地址、电话号码和联系人，如果与提交报告的人不同的话。 (7) 对导致所报告信息的事件的描述，以及已经采取和预计将采取的纠正或消除行动。 (8) 因使用该设备而发生的任何疾病或伤害。如果适用，包括医疗器械报告编号。 (9) 生产或者销售的纠正或者下架器械的总数，以及同一批次、批次或者同等生产单位中需要更正或者下架的器械数量。 (10) 制造或分销日期以及设备的到期日期或预期寿命。 (11) 设备的所有国内外收货人的名称、地址和电话号码，以及分发给每个此类收货人的设备的日期和数量。 (12) 有关更正或移除的所有通信的副本，以及未根据本节 (c)(11) 段提供的所有通信接收人的姓名和地址。 (13) 如果任何所需信息无法立即获得，说明为何无法获得以及何时提交。

(c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.	
(d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available.	(d) 如果在根据本部分提交报告后，制造商或进口商确定应将相同的更正或移除扩大到同一器械的额外批次或批次，制造商或进口商应在启动后的 10 个工作日内延长更正或移除，通过提交修改来修改报告，引用根据本节 (c)(1) 段分配的原始报告编号、(c)(2) 段要求的所有信息，以及任何信息本节 (c)(3) 至 (c)(12) 段要求的与原始报告中提交的信息不同的信息。制造商或进口商还应根据本节 (c)(13) 段的规定，就任何不易获得的所需信息提供一份声明。
(e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.	(e) 制造商或进口商根据本节提交的报告（以及 FDA 对该报告或信息的任何发布）不一定反映制造商、进口商或 FDA 的结论，即该报告或信息构成承认该报告或信息设备造成或促成死亡或重伤。制造商或进口商无需承认也可以否认根据本节提交的报告或信息构成承认该设备导致或促成了死亡或严重伤害。
(f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.	(f) 如果需要更正或移除报告并且已根据本章第 803 或 1004 部分提交，则本部分不需要更正或移除报告。
[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 58821, Sept. 24, 2013]	[62 FR 27191，1997 年 5 月 19 日，经 63 FR 42232，1998 年 8 月 7 日修订；69 FR 11311，2004 年 3 月 10 日；78 FR 58821，2013 年 9 月 24 日]
§ 806.20 Records of corrections and removals not required to be reported.	§ 806.20 不需要报告的更正和移除记录。

(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.	(a) 根据 § 806.10 无需向 FDA 报告的器械的更正或移除，每个器械制造商或进口商应保留此类更正或移除的记录。
(b) Records of corrections and removals not required to be reported to FDA under § 806.10 shall contain the following information:	(b) 根据§ 806.10 不需要向 FDA 报告的更正和移除记录应包含以下信息：
(1) The brand name, common or usual name, classification, name and product code if known, and the intended use of the device. (2) The unique device identifier (UDI) of the device, or the device identifier, universal product code (UPC), 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.	(1) 品牌名称、通用名称或常用名称、分类、名称和产品代码（如果已知）以及设备的预期用途。 (2) 设备的唯一设备标识符（UDI），或设备标识符、通用产品代码（UPC）、型号、目录或设备代码以及设备的制造批号或序列号或其他标识号. (3) 对导致所报告信息的事件的描述，以及已经采取和预计将采取的纠正或消除行动。 (4) 不向FDA报告更正或移除行动的理由，应包含结论和任何后续行动，并由指定人员进行审查和评估。 (5) 有关更正或移除的所有通信的副本。
(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.	(c) 制造商或进口商应将本节要求的记录保留超过设备的预期寿命 2 年，即使制造商或进口商已停止制造或进口该设备。根据本节 (b) 段要求保存的记录必须转移给设备的新制造商或进口商，并保存规定的时间。
[62 FR 27191, May 19, 1997, as amended at 63 FR 42233, Aug. 7, 1998; 78 FR 58821, Sept. 24, 2013]	[62 FR 27191，1997 年 5 月 19 日，经 63 FR 42233，1998 年 8 月 7 日修订； 78 FR 58821，2013 年 9 月 24 日]
§ 806.30 FDA access to records.	**§** 806.30 FDA 访问记录。
Each device manufacturer or importer required under this part	根据本部分要求保存记录的每个设备制造商或

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.	进口商以及负责或保管此类记录的每个人都应根据 FDA 指定的官员或员工的要求并根据该法案的第 704(e) 节允许该官员或员工在所有合理时间访问、复制和验证此类记录和报告。
[63 FR 42233, Aug. 7, 1998]	[63 FR 42233，1998 年 8 月 7 日]
§ 806.40 Public availability of reports.	**§** 806.40 报告的公开可用性。
(a) Any report submitted under this part is available for public disclosure in accordance with part 20 of this chapter.	(a) 根据本章第 20 部分提交的任何报告均可公开披露。
(b) Before public disclosure of a report, FDA will delete from the report:	(b) 在公开披露报告之前，FDA 将从报告中删除：
(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.	(1) 构成本章第 20.61 条规定的商业秘密或机密商业或财务信息的任何信息；和 (2) 根据本章第 20.63 条或 5 USC 552(b)(6)，任何人员、医疗或类似信息，包括植入设备的序列号，显然构成对个人隐私的无理侵犯；前提是，除了本章§ 20.61 或 5 USC 552(b)(4) 规定的信息外，FDA 将向要求报告的患者披露报告中有关该患者的所有信息。