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TITLE 21--FOOD AND DRUGS

标题21--食品和药品

CHAPTER I--FOOD AND DRUG ADMINISTRATION

第I章--食品药品监督管理局

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 822 POSTMARKET SURVEILLANCE

第822部分 上市后监督

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Subpart A - General Provisions	A 分部 - 一般规定
Sec. 822.1 What does this part cover?	822.1 这部分包括什么？
This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:	本部分通过提供符合以下任何标准的 II 类和 III 类器械的上市后监督程序和要求，实施了《联邦食品、药品和化妆品法案》（该法案）的第522条：
(a) Failure of the device would be reasonably likely to have serious adverse health consequences;	(a) 设备故障很可能对健康造成严重的不利后果；
(b) The device is intended to be implanted in the human body for more than 1 year; or	(b) 装置拟植入人体1年以上；或者
(c) The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the act and this part, your device is considered misbranded under section 502(t)(3) of the act and you are in violation of section 301(q)(1)(C) of the act.	(c) 该设备旨在在用户设施之外使用以支持或维持生命。如果您未能遵守我们根据该法案第 522 条和本部分规定的要求，您的设备将根据该法案第 502(t)(3) 条被视为贴错标签，并且您违反了第 301(q)(1) 条)(C) 的法案。
Sec. 822.2 What is the purpose of this part?	822.2 这部分的目的是什么？
The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.	这部分的目的是实施我们的售后监督权限，以最大限度地提高售后监督计划收集有用数据的可能性。这些数据可以揭示不可预见的不良事件、预期不良事件的实际发生率或保护公众健康所需的其他信息。
Sec. 822.3 How do you define the terms used in this part?	822.3 您如何定义本部分中使用的术语？
Some of the terms we use in this part are specific to postmarket surveillance and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section of the part defines the following terms:	我们在这一部分中使用的一些术语是特定于上市后监督的，并反映了法规（法律）中使用的语言。其他术语更为笼统，反映了我们对法律的解释。该部分的这一部分定义了以下术语：
(a) Act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., as amended.	(a)法案：是指经修订的联邦食品、药品和化妆品法案， 21 U.S.C 301 et seq .。
(b) Designated person means the individual who conducts or supervises the conduct of your postmarket surveillance. If your postmarket surveillance plan includes a team of investigators, as defined below, the designated person is the responsible leader of that team.	(b)指定人员：是指进行或监督您进行上市后监督的个人。如果您的上市后监督计划包括如下定义的调查员团队，则指定人员是该团队的负责领导。
(c) Device failure means a device does not perform or function as intended, and includes any deviation from the device's performance specifications or intended use.	(c)设备故障：是指设备未按预期执行或运行，包括与设备性能规格或预期用途的任何偏差。

<p>(d) General plan guidance means agency guidance that provides information about the requirement to conduct postmarket surveillance, the submission of a plan to us for approval, the content of the submission, and the conduct and reporting requirements of the surveillance.</p>	<p>(d)总体计划指南：是指提供有关进行上市后监督的要求、向我们提交计划以供批准、提交的内容以及监督的实施和报告要求等信息的机构指南。</p>
<p>(e) Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.</p>	<p>(e)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) 并且这也作为一种设备进行监管。</p>
<p>(f) Investigator means an individual who collects data or information in support of a postmarket surveillance plan.</p>	<p>(f)调查员：是指收集数据或信息以支持上市后监督计划的个人。</p>
<p>(g) Life-supporting or life-sustaining device used outside a device user facility means that a device is essential to, or yields information essential to, the restoration or continuation of a bodily function important to the continuation of human life and is used outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. A physician's office is not a device user facility.</p>	<p>(g)在器械使用者设施之外使用的生命支持或维持生命的器械：是指器械对于恢复或延续对人类生命延续很重要的身体机能是必不可少的或产生必要的信息，并在户外使用医院、疗养院、门诊手术设施或诊断或门诊治疗设施。医生办公室不是设备用户设施。</p>
<p>(h) Manufacturer means any person, including any importer, repacker, and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, processes a device, or engages in any of the activities described in § 807.3(d) of this chapter.</p>	<p>(h)制造商：是指任何人，包括任何进口商、再包装商和/或再贴标签商，他们制造、准备、传播、合成、组装、加工设备，或从事本§ 807.3(d) 中所述的任何活动章节。</p>
<p>(i) Postmarket surveillance means the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device.</p>	<p>(i)上市后监督：是指对已上市器械的数据或其他信息进行主动、系统、科学有效的收集、分析和解释。</p>
<p>(j) Prospective surveillance means that the subjects are identified at the beginning of the surveillance and data or other information will be collected from that time forward (as opposed to retrospective surveillance).</p>	<p>(j)前瞻性监测：是指在监测开始时确定受试者，并从那时起收集数据或其他信息（与回顾性监测相反）。</p>
<p>(k) Serious adverse health consequences means any significant adverse experience related to a device, including device-related events that are life-threatening or that involve permanent or long-term injuries or illnesses.</p>	<p>(k)严重的不良健康后果：是指与器械相关的任何重大不良经历，包括与器械相关的危及生命或涉及永久性或长期伤害或疾病的事件。</p>
<p>(l) Specific guidance means guidance that provides information regarding postmarket surveillance for specific types or categories of devices or specific postmarket surveillance issues. This type of guidance may be used to supplement general guidance and may address such topics as the type of surveillance approach that is</p>	<p>(l)特定指南：是指针对特定类型或类别的器械或特定上市后监督问题提供有关上市后监督信息的指南。这种类型的指南可用于补充一般指南，并可能涉及适用于器械</p>

appropriate for the device and the postmarket surveillance question, sample size, or specific reporting requirements.	的监测方法类型和上市后监测问题、样本量或特定报告要求等主题。
(m) Surveillance question means the issue or issues to be addressed by the postmarket surveillance.	(m)监督问题：是指上市后监督要解决的一个或多个问题。
(n) Unforeseen adverse event means any serious adverse health consequence that either is not addressed in the labeling of the device or occurs at a rate higher than anticipated.	(n)不可预见的不良事件：是指任何严重的不良健康后果，要么未在器械标签中提及，要么发生率高于预期。
(o) 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:	(o)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;	(i) 制造设备的批次；
(ii) The serial number of a specific device;	(ii) 特定设备的序列号；
(iii) The expiration date of a specific device;	(iii) 特定设备的到期日期；
(iv) The date a specific device was manufactured.	(iv) 特定设备的制造日期。
(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.	(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。
[67 FR 38887, June 6, 2002, as amended at 78 FR 58823, Sept. 24, 2013] [67 FR 38887, 2002 年 6 月 6 日, 经 78 FR 58823, 2013 年 9 月 24 日修订]	
Sec. 822.4 Does this part apply to me?	822.4 这部分适用于我吗?
If we have ordered you to conduct postmarket surveillance of a medical device under section 522 of the act, this part applies to you. We have the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:	如果我们根据该法案第522条命令您对医疗器械进行上市后监督，则本部分适用于您。我们有权下令对任何符合以下任何标准的 II 类或 III 类医疗器械进行上市后监督，包括根据《公共卫生服务法》第 351 条许可条款审查的器械：
(a) Failure of the device would be reasonably likely to have serious	(a) 设备故障很可能对健康造成严重的不利

adverse health consequences;	后果;
(b) The device is intended to be implanted in the human body for more than 1 year; or	(b) 装置拟植入人体1年以上; 或者
(c) The device is intended to be used to support or sustain life and to be used outside a user facility.	(c) 该设备旨在用于支持或维持生命, 并在用户设施之外使用。
Subpart B - Notification	B 部分 - 通知
Sec. 822.5 How will I know if I must conduct postmarket surveillance?	822.5 我如何知道我是否必须进行上市后监督?
We will send you a letter (the postmarket surveillance order) notifying you of the requirement to conduct postmarket surveillance. Before we send the order, or as part of the order, we may require that you submit information about your device that will allow us better to define the scope of a surveillance order. We will specify the device(s) subject to the surveillance order and the reason that we are requiring postmarket surveillance of the device under section 522 of the act. We will also provide you with any general or specific guidance that is available to help you develop your plan for conducting postmarket surveillance.	我们将向您发送一封信函(上市后监管令), 通知您进行上市后监管的要求。在我们发送订单之前, 或作为订单的一部分, 我们可能会要求您提交有关您的设备的信息, 以便我们更好地定义监控订单的范围。我们将根据法案第 522 条指定受监管令约束的设备以及我们要求对设备进行上市后监管的原因。我们还将为您提供任何一般或具体的指导, 以帮助您制定进行上市后监督的计划。
Sec. 822.6 When will you notify me that I am required to conduct postmarket surveillance?	822.6 您何时会通知我需要进行售后监督?
We will notify you as soon as we have determined that postmarket surveillance of your device is necessary, based on the identification of a surveillance question. This may occur during the review of a marketing application for your device, as your device goes to market, or after your device has been marketed for a period of time.	一旦我们确定有必要对您的设备进行上市后监控, 我们将根据监控问题的识别通知您。这可能发生在审核您设备的营销申请期间、您的设备上市时或您的设备已上市一段时间后。
Sec. 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?	822.7 如果我不同意上市后监督是适当的, 我应该怎么做?
(a) If you do not agree with our decision to order postmarket surveillance for a particular device, you may request review of our decision by:	(a) 如果您不同意我们为特定设备订购上市后监督的决定, 您可以通过以下方式请求审查我们的决定:
(1) Requesting a meeting with the Director, Office of Surveillance and Biometrics, who generally issues the order for postmarket surveillance;	(1) 要求与监督和生物识别办公室主任会面, 后者通常会发布上市后监督令;
(2) Seeking internal review of the order under § 10.75 of this chapter;	(2) 根据本章第 10.75 条寻求对命令进行内部审查;
(3) Requesting an informal hearing under part 16 of this chapter; or	(3) 根据本章第 16 部分要求举行非正式听证会; 或者
(4) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.	(四) 请求医疗器械咨询委员会医疗器械争议解决小组审查。

<p>(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHombudsman/default.htm).</p>	<p>(b) 您可以从器械和放射健康中心 (CDRH) 的网站 (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHombudsman/default.htm) 获得讨论这些机制的指导文件。) 。</p>
<p>[67 FR 38887, June 6, 2002, as amended at 72 FR 17399, Apr. 9, 2007; 78 FR 18233, Mar. 26, 2013] [67 FR 38887, 2002 年 6 月 6 日, 经 72 FR 17399, 2007 年 4 月 9 日修订; 78 FR 18233, 2013 年 3 月 26 日]</p>	
<p>Subpart C - Postmarket Surveillance Plan</p>	<p>C部分 - 上市后监督计划</p>
<p>Sec. 822.8 When, where, and how must I submit my postmarket surveillance plan?</p>	<p>822.8 我必须何时、何地以及如何提交我的上市后监督计划?</p>
<p>You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Biologics Evaluation and Research, send your submission to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002. For devices regulated by the Center for Drug Evaluation and Research, send your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B, Ammendale Rd., Beltsville, MD 20705-1266. For devices regulated by the Center for Devices and Radiological Health, send your submission to the Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993-0002. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.</p>	<p>您必须在收到上市后监管令之日起 30 天内提交您的上市后监管计划。对于受生物制品评估和研究中心监管的器械, 请将您的提交提交给食品和药物管理局, 生物制品评估和研究中心, 文件控制中心, 10903 New Hampshire Ave., Bldg. 71 室。G112, 银弹簧, MD 20993-0002。对于受药物评估和研究中心监管的设备, 请将您的提交提交至中央文件室, 药物评估和研究中心, 食品和药物管理局, 5901-B, Ammendale Rd., Beltsville, MD 20705-1266。对于受设备和放射健康中心监管的设备, 请将您提交的文件发送至 Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, 室。G609, 银弹簧, MD 20993-0002。当我们收到您提交的原始文件后, 我们将向您发送一封确认信, 确认分配给您提交的唯一文件编号。您必须在与此提交相关的任何通信中使用此号码。</p>
<p>[87 FR 17950, Mar. 29, 2022] [87 FR 17950, 2022 年 3 月 29 日]</p>	
<p>Sec. 822.9 What must I include in my submission?</p>	<p>822.9 我必须在我的提交中包括什么?</p>
<p>Your submission must include the following:</p>	<p>您的提交必须包括以下内容:</p>
<p>(a) Organizational/administrative information:</p>	<p>(a) 组织/行政信息:</p>
<p>(1) Your name and address;</p>	<p>(1) 您的姓名和地址;</p>
<p>(2) Generic and trade names of your device;</p>	<p>(2) 您设备的通用名称和商品名称;</p>

(3) Name and address of the contact person for the submission;	(3) 投稿联系人姓名、地址；
(4) Premarket application/submission number and device identifiers for your device;	(4) 您设备的上市前申请/提交编号和设备标识符；
(5) Table of contents identifying the page numbers for each section of the submission;	(5) 标明投稿各部分页码的目录；
(6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission);	(6) 设备描述（这可以通过参考适当的上市前申请/提交来合并）；
(7) Product codes and a list of all relevant model numbers; and	(7) 产品代码和所有相关型号的清单；和
(8) Indications for use and claims for the device;	(8) 器械的使用说明和权利要求；
(b) Postmarket surveillance plan;	(b) 上市后监督计划；
(c) Designated person information;	(c) 指定人员信息；
(1) Name, address, and telephone number; and	(1) 姓名、地址、电话号码；和
(2) Experience and qualifications.	(2) 经验和资格。
[67 FR 38887, June 6, 2002, as amended at 78 FR 58823, Sept. 24, 2013] [67 FR 38887, 2002 年 6 月 6 日, 经 78 FR 58823, 2013 年 9 月 24 日修订]	
Sec. 822.10 What must I include in my surveillance plan?	822.10 我的监视计划中必须包括什么？
Your surveillance plan must include a discussion of:	您的监督计划必须包括对以下内容的讨论：
(a) The plan objective(s) addressing the surveillance question(s) identified in our order;	(a) 解决我们订单中确定的监督问题的计划目标；
(b) The subject of the study, e.g., patients, the device, animals;	(b) 研究对象，例如患者、装置、动物；
(c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;	(c) 将用于回答监测问题的变量和终点，例如临床参数或结果；
(d) The surveillance approach or methodology to be used;	(d) 将使用的监测方法或方法；
(e) Sample size and units of observation;	(e) 样本量和观察单位；
(f) The investigator agreement, if applicable;	(f) 调查员协议（如适用）；
(g) Sources of data, e.g., hospital records;	(g) 数据来源，例如医院记录；
(h) The data collection plan and forms;	(h) 数据收集计划和表格；
(i) The consent document, if applicable;	(i) 同意文件（如适用）；
(j) Institutional Review Board information, if applicable;	(j) 机构审查委员会信息（如适用）；
(k) The patient followup plan, if applicable;	(k) 患者随访计划（如适用）；
(l) The procedures for monitoring conduct and progress of the surveillance;	(l) 监督监督行为和进展的程序；

(m) An estimate of the duration of surveillance;	(m) 监测持续时间的估计；
(n) All data analyses and statistical tests planned;	(n) 计划进行所有数据分析和统计测试；
(o) The content and timing of reports.	(o) 报告的内容和时间。
Sec. 822.11 What should I consider when designing my plan to conduct postmarket surveillance?	822.11 在设计进行上市后监督的计划时，我应该考虑什么？
You must design your surveillance to address the postmarket surveillance question identified in the order you received. You should consider what, if any, patient protection measures should be incorporated into your plan. You should also consider the function, operating characteristics, and intended use of your device when designing a surveillance approach.	您必须设计您的监控以解决您收到的订单中确定的售后监控问题。您应该考虑应将哪些患者保护措施（如果有）纳入您的计划。在设计监视方法时，您还应该考虑设备的功能、操作特性和预期用途。
Sec. 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?	822.12 您是否有任何信息可以帮助我准备提交或设计我的上市后监督计划？
Guidance documents that discuss our current thinking on preparing a postmarket surveillance submission and designing a postmarket surveillance plan are available on the Center for Devices and Radiological Health's website, the Food and Drug Administration main website, and from the Food and Drug Administration, Center for Devices and Radiological Health, Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. They do not establish legally enforceable rights or responsibilities and do not legally bind you or FDA. You may choose to use an approach other than the one set forth in a guidance document, as long as your alternative approach complies with the relevant statutes (laws) and regulations. If you wish, we will meet with you to discuss whether an alternative approach you are considering will satisfy the requirements of the act and regulations.	指导文件讨论了我们目前关于准备上市后监督提交和设计上市后监督计划的想法，可在器械和放射健康中心的网站、食品和药物管理局的主网站以及食品和药物管理局的器械中心获得和放射健康，政策，指导和政策制定办公室，设备和放射健康中心，食品和药物管理局，10903 New Hampshire Ave., Bldg. 66，室。5431，银泉，MD 20993-0002。它们不确立具有法律效力的权利或责任，也不对您或 FDA 具有法律约束力。您可以选择使用指导文件中规定的方法以外的方法，只要您的替代方法符合相关法规（法律）和法规。
[75 FR 20915, Apr. 22, 2010, as amended at 87 FR 17950, Mar. 29, 2022] [75 FR 20915, 2010 年 4 月 22 日，经 87 FR 17950, 2022 年 3 月 29 日修订]	
Sec. 822.13 [Reserved]	822.13 [保留]
Sec. 822.14 May I reference information previously submitted instead of submitting it again?	822.14 我可以参考之前提交的信息而不是再次提交吗？
Yes, you may reference information that you have submitted in premarket submissions as well as other postmarket surveillance submissions. You must specify the information to be incorporated and the document number and pages where the information is located.	是的，您可以参考您在上市前提交以及其他上市后监督提交中提交的信息。您必须指定要合并的信息以及信息所在的文件编号和页码。
Sec. 822.15 How long must I conduct postmarket surveillance of my device?	822.15 我必须对我的设备进行多长时间的后市场监督？
The length of postmarket surveillance will depend on the postmarket surveillance question identified in our order. We may order prospective surveillance for a period up to 36 months; longer periods require your agreement. If we believe that a prospective period of	上市后监督的时长将取决于我们订单中确定的上市后监督问题。我们可能会下令进行长达 36 个月的前瞻性监视；更长的时

<p>greater than 36 months is necessary to address the surveillance question, and you do not agree, we will use the Medical Devices Dispute Resolution Panel to resolve the matter. You may obtain guidance regarding dispute resolution procedures from the Center for Devices and Radiological Health's (CDRH') Web site (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHombudsman/default.htm). The 36-month period refers to the surveillance period, not the length of time from the issuance of the order.</p>	<p>间需要您的同意。如果我们认为解决监控问题需要超过 36 个月的预期期限，而您不同意，我们将使用医疗器械争议解决小组来解决问题。您可以从设备和放射健康中心 (CDRH') 网站 (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHombudsman/default.htm.) 获得有关争议解决程序的指导。36 个月是指监督期，而不是命令发出后的时间长度。</p>										
<p>[72 FR 17400, Apr. 9, 2007, as amended at 78 FR 18233, Mar. 26, 2013] [72 FR 17400, 2007 年 4 月 9 日, 经 78 FR 18233, 2013 年 3 月 26 日修订]</p>											
<p>Subpart D - FDA Review and Action</p>	<p>D 部分 - FDA 审查和行动</p>										
<p>Sec. 822.16 What will you consider in the review of my submission?</p>	<p>822.16 在审查我的提交时，您会考虑什么？</p>										
<p>First, we will determine that the submission is administratively complete. Then, in accordance with the law, we must determine whether the designated person has appropriate qualifications and experience to conduct the surveillance and whether the surveillance plan will result in the collection of useful data that will answer the surveillance question.</p>	<p>首先，我们将确定提交在管理上是否完整。然后，根据法律，我们必须确定指定人员是否具有适当的资格和经验来进行监视，以及监视计划是否会导致收集有用的数据来回答监视问题。</p>										
<p>Sec. 822.17 How long will your review of my submission take?</p>	<p>822.17 您审核我提交的内容需要多长时间？</p>										
<p>We will review your submission within 60 days of receipt.</p>	<p>我们将在收到后 60 天内审核您的提交。</p>										
<p>Sec. 822.18 How will I be notified of your decision?</p>	<p>822.18 我将如何获知您的决定？</p>										
<p>We will send you a letter notifying you of our decision and identifying any action you must take.</p>	<p>我们将向您发送一封信函，通知您我们的决定并确定您必须采取的任何行动。</p>										
<p>Sec. 822.19 What kinds of decisions may you make?</p>	<p>822.19 你可以做出什么样的决定？</p>										
<table border="1"> <thead> <tr> <th data-bbox="175 1350 565 1392">If your plan:</th> </tr> </thead> <tbody> <tr> <td data-bbox="175 1392 565 1623">(a) Should result in the collection of useful data that will address the postmarket surveillance question (a) 应收集有用的数据以解决上市后监督问题</td> </tr> <tr> <td data-bbox="175 1623 565 1913">(b) Should result in the collection of useful data that will address the postmarket surveillance question after specific revisions are made or specific information is provided</td> </tr> </tbody> </table>	If your plan:	(a) Should result in the collection of useful data that will address the postmarket surveillance question (a) 应收集有用的数据以解决上市后监督问题	(b) Should result in the collection of useful data that will address the postmarket surveillance question after specific revisions are made or specific information is provided	<table border="1"> <thead> <tr> <th data-bbox="613 1350 959 1392">Then we will send you:</th> </tr> </thead> <tbody> <tr> <td data-bbox="613 1392 959 1623">An approval order, identifying any specific requirements related to your postmarket surveillance 批准令，确定与您的售后监督相关的任何具体要求</td> </tr> <tr> <td data-bbox="613 1623 959 1913">An approvable letter identifying the specific revisions or information that must be submitted before your plan can be approved</td> </tr> </tbody> </table>	Then we will send you:	An approval order, identifying any specific requirements related to your postmarket surveillance 批准令，确定与您的售后监督相关的任何具体要求	An approvable letter identifying the specific revisions or information that must be submitted before your plan can be approved	<table border="1"> <thead> <tr> <th data-bbox="1008 1350 1490 1392">And you must:</th> </tr> </thead> <tbody> <tr> <td data-bbox="1008 1392 1490 1623">Conduct postmarket surveillance of your device in accordance with the approved plan 根据批准的计划对您的设备进行上市后监督</td> </tr> <tr> <td data-bbox="1008 1623 1490 1913">Revise your postmarket surveillance submission to address the concerns in the approvable letter and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit</td> </tr> </tbody> </table>	And you must:	Conduct postmarket surveillance of your device in accordance with the approved plan 根据批准的计划对您的设备进行上市后监督	Revise your postmarket surveillance submission to address the concerns in the approvable letter and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit
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<p>(b) 在进行具体修订或提供具体信息后，应收集有用的数据以解决上市后监管问题</p>	<p>一封可批准的信函，指明在您的计划获得批准之前必须提交的具体修订或信息</p>	<p>修改您的上市后监督提交以解决批准信中的问题，并在指定的时间范围内将其提交给我们。我们将根据您必须提交的修订或信息的类型，逐案确定时间表</p>
<p>(c) Does not meet the requirements specified in this part</p> <p>(c) 不符合本部分规定的要求</p>	<p>A letter disapproving your plan and identifying the reasons for disapproval</p> <p>一封不批准您的计划并说明不批准原因的信函</p>	<p>Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit</p> <p>修改您的上市后监督提交，并在指定的时间范围内提交给我们。我们将根据您必须提交的修订或信息的类型，逐案确定时间表</p>
<p>(d) Is not likely to result in the collection of useful data that will address the postmarket surveillance question</p> <p>(d) 不太可能收集到解决上市后监督问题的有用数据</p>	<p>A letter disapproving your plan and identifying the reasons for disapproval</p> <p>一封不批准您的计划并说明不批准原因的信函</p>	<p>Revise your postmarket surveillance submission and submit it to us within the specified timeframe. We will determine the timeframe case-by-case, based on the types of revisions or information that you must submit</p> <p>修改您的上市后监督提交，并在指定的时间范围内提交给我们。我们将根据您必须提交的修订或信息的类型，逐案确定时间表</p>
<p>Sec. 822.20 What are the consequences if I fail to submit a postmarket surveillance plan, my plan is disapproved and I fail to submit a new plan, or I fail to conduct surveillance in accordance with my approved plan?</p>		<p>822.20 如果我没有提交上市后监督计划，我的计划被拒绝并且我没有提交新计划，或者我没有按照我批准的计划进行监督，会有什么后果？</p>
<p>The failure to have an approved postmarket surveillance plan or failure to conduct postmarket surveillance in accordance with the approved plan constitutes failure to comply with section 522 of the act. Your failure would be a prohibited act under section 301(q)(1)(C) of the act, and your device would be misbranded under section 502(t)(3) of the act. We have the authority to initiate actions against products that are adulterated or misbranded, and against persons who commit prohibited acts. Adulterated or misbranded devices can be seized. Persons who commit prohibited acts can be enjoined from committing such acts, required to pay civil money penalties, or prosecuted.</p>		<p>没有获得批准的上市后监督计划或未能按照批准的计划进行上市后监督构成不遵守该法案第 522 条。根据该法案第 301(q)(1)(C) 条，您的失败将是一项被禁止的行为，并且您的设备将根据该法案第 502(t)(3) 条被贴错标签。我们有权对掺假或贴错标签的产品以及从事违禁行为的人采取行动。可以没收掺假或贴错标签的设备。实施违禁行为的人可被禁止实施此类行为、被要求支付民事罚款或被起诉。</p>
<p>Sec. 822.21 What must I do if I want to make changes to my postmarket surveillance plan after you have approved it?</p>		<p>822.21 如果我想在您批准后对我的售后监督计划进行更改，我必须怎么做？</p>
<p>You must receive our approval in writing before making changes in your plan that will affect the nature or validity of the data collected in accordance with the plan. To obtain our approval, you must submit the request to make the proposed change and revised postmarket surveillance plan to the applicable address listed in § 822.8. You</p>		<p>在对您的计划做出将影响根据计划收集的数据的性质或有效性的更改之前，您必须获得我们的书面批准。要获得我们的批准，您必须向第 822.8 条中列出的适用地</p>

<p>may reference information already submitted in accordance with § 822.14. In your cover letter, you must identify your submission as a supplement and cite the unique document number that we assigned in our acknowledgment letter for your original submission, specifically identify the changes to the plan, and identify the reasons and justification for making the changes. You must report changes in your plan that will not affect the nature or validity of the data collected in accordance with the plan in the next interim report required by your approval order.</p>	<p>址提交提出变更和修订后的上市监督计划的请求。您可以参考已根据 § 822.14 提交的信息。在您的求职信中，您必须将您的提交标识为补充，并引用我们在确认信中为您的原始提交指定的唯一文件编号，具体标识对计划的更改，并确定进行更改的原因和理由。</p>
<p>[87 FR 17950, Mar. 29, 2022] [87 FR 17950, 2022 年 3 月 29 日]</p>	
<p>Sec. 822.22 What recourse do I have if I do not agree with your decision?</p>	<p>822.22 如果我不同意你的决定，我有什么追索权？</p>
<p>(a) If you disagree with us about the content of your plan or if we disapprove your plan, or if you believe there is a less burdensome approach that will answer the surveillance question, you may request review of our decision by:</p>	<p>(a) 如果您不同意我们对您的计划内容的看法，或者如果我们不批准您的计划，或者如果您认为有一种不那么繁琐的方法可以回答监督问题，您可以通过以下方式要求审查我们的决定：</p>
<p>(1) Requesting a meeting with the individual who issued the order for postmarket surveillance;</p>	<p>（一）要求会见发布上市后监管令的个人；</p>
<p>(2) Seeking internal review of the order under § 10.75 of this chapter;</p>	<p>(2) 根据本章第 10.75 条寻求对命令进行内部审查；</p>
<p>(3) Requesting an informal hearing under part 16 of this chapter; or</p>	<p>(3) 根据本章第 16 部分要求举行非正式听证会；或者</p>
<p>(4) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.</p>	<p>（四）请求医疗器械咨询委员会医疗器械争议解决小组审查。</p>
<p>(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site.</p>	<p>(b) 您可以从设备和放射健康中心 (CDRH) 的网站获取讨论这些机制的指导文件。</p>
<p>[67 FR 38887, June 6, 2002, as amended at 72 FR 17400, Apr. 9, 2007; 85 FR 18443, Apr. 2, 2020]</p>	
<p>Sec. 822.23 Is the information in my submission considered confidential?</p>	<p>822.23 我提交的信息是否被视为机密信息？</p>
<p>We consider the content of your submission confidential until we have approved your postmarket surveillance plan. After we have approved your plan, the contents of the original submission and any amendments, supplements, or reports may be disclosed in accordance with the Freedom of Information Act. We will continue to protect trade secret and confidential commercial information after your plan is approved. We will not disclose information identifying</p>	<p>在我们批准您的上市后监督计划之前，我们认为您提交的内容是保密的。在我们批准您的计划后，原始提交的内容以及任何修改、补充或报告可能会根据《信息自由法》进行披露。在您的计划获得批准后，我们将继续保护商业秘密和机密商业</p>

individual patients. You may wish to indicate in your submission which information you consider trade secret or confidential commercial.	信息。我们不会披露识别个别患者的信息。您可能希望在提交的内容中说明您认为哪些信息是商业机密或机密商业信息。
Subpart E - Responsibilities of Manufacturers	E部分 - 制造商的责任
Sec. 822.24 What are my responsibilities once I am notified that I am required to conduct postmarket surveillance?	822.24 一旦我被告知我需要进行上市后监督，我的责任是什么？
You must submit your plan to conduct postmarket surveillance to us within 30 days from receipt of the order (letter) notifying you that you are required to conduct postmarket surveillance of a device.	您必须在收到通知您需要对设备进行售后监控的订单（信件）后 30 天内向我们提交您的售后监控计划。
Sec. 822.25 What are my responsibilities after my postmarket surveillance plan has been approved?	822.25 在我的上市后监督计划获得批准后，我的责任是什么？
After we have approved your plan, you must conduct the postmarket surveillance of your device in accordance with your approved plan. This means that you must ensure that:	在我们批准您的计划后，您必须按照您批准的计划对您的设备进行上市后监督。这意味着您必须确保：
(a) Postmarket surveillance is initiated in a timely manner;	(a) 及时启动上市后监督；
(b) The surveillance is conducted with due diligence;	(b) 监督是在尽职的情况下进行的；
(c) The data identified in the plan is collected;	(c) 收集计划中确定的数据；
(d) Any reports required as part of your approved plan are submitted to us in a timely manner; and	(d) 作为您批准的计划的一部分所需的任何报告都及时提交给我们；和
(e) Any information that we request prior to your submission of a report or in response to our review of a report is provided in a timely manner.	(e) 我们在您提交报告之前或为响应我们对报告的审查而要求的任何信息都会及时提供。
Sec. 822.26 If my company changes ownership, what must I do?	822.26 如果我的公司更改所有权，我必须做什么？
You must notify us within 30 days of any change in ownership of your company. Your notification should identify any changes to the name or address of the company, the contact person, or the designated person (as defined in § 822.3(b)). Your obligation to conduct postmarket surveillance will generally transfer to the new owner, unless you and the new owner have both agreed that you will continue to conduct the surveillance. If you will continue to conduct the postmarket surveillance, you still must notify us of the change in ownership.	您必须在公司所有权发生任何变化后 30 天内通知我们。您的通知应指明公司名称或地址、联系人或指定人员（如 § 822.3(b) 中所定义）的任何更改。您进行上市后监督的义务通常会转移给新所有者，除非您和新所有者都同意您将继续进行监督。如果您将继续进行上市后监督，您仍必须将所有权变更通知我们。
Sec. 822.27 If I go out of business, what must I do?	822.27 如果我倒闭了，我该怎么办？
You must notify us within 30 days of the date of your decision to close your business. You should provide the expected date of closure and discuss your plans to complete or terminate postmarket surveillance of your device. You must also identify who will retain the records related to the surveillance (described in subpart G of this part) and where the records will be kept.	您必须在决定关闭业务之日起 30 天内通知我们。您应该提供预期的关闭日期，并讨论您完成或终止对您的设备进行上市后监督的计划。您还必须确定谁将保留与监视相关的记录（在本部分的 G 小节中描述）以及记录将保存在哪里。

Sec. 822.28 If I stop marketing the device subject to postmarket surveillance, what must I do?	822.28 如果我停止销售受售后监管的设备，我该怎么办？
You must continue to conduct postmarket surveillance in accordance with your approved plan even if you no longer market the device. You may request that we allow you to terminate postmarket surveillance or modify your postmarket surveillance because you no longer market the device. We will make these decisions on a case by-case basis, and you must continue to conduct the postmarket surveillance unless we notify you that you may stop your surveillance study.	即使您不再销售该设备，您也必须继续按照您批准的计划进行上市后监督。您可以要求我们允许您终止售后监管或修改您的售后监管，因为您不再销售该设备。我们将根据具体情况做出这些决定，您必须进行上市后监督，除非我们通知您可以停止监督研究。
Subpart F - Waivers and Exemptions	F部分 – 弃权 and 豁免
Sec. 822.29 May I request a waiver of a specific requirement of this part?	822.29 我可以要求放弃本部分的特定要求吗？
You may request that we waive any specific requirement of this part. You may submit your request, with supporting documentation, separately or as a part of your postmarket surveillance submission to the address in § 822.8.	您可以要求我们放弃这部分的任何特定要求。您可以单独或作为上市后监督提交的一部分向第 822.8 节中的地址提交您的请求以及支持文件。
Sec. 822.30 May I request exemption from the requirement to conduct postmarket surveillance?	822.30 我可以申请豁免进行上市后监管的要求吗？
You may request exemption from the requirement to conduct postmarket surveillance for your device or any specific model of that device at any time. You must comply with the requirements of this part unless and until we grant an exemption for your device. Your request for exemption must explain why you believe we should exempt the device or model from postmarket surveillance. You should demonstrate why the surveillance question does not apply to your device or does not need to be answered for the device for which you are requesting exemption. Alternatively, you may provide information that answers the surveillance question for your device, with supporting documentation, to the address in § 822.8.	您可以随时请求免除对您的设备或该设备的任何特定型号进行售后监督的要求。您必须遵守本部分的要求，除非我们为您的设备授予豁免权。您的豁免请求必须解释为什么您认为我们应该免除该设备或型号的上市后监管。您应该说明为什么监控问题不适用于您的设备或不需要为您申请豁免的设备回答。或者，您可以向第 822.8 节中的地址提供回答设备监控问题的信息以及支持文档。
Subpart G - Records and Reports	G部分 - 记录和报告
Sec. 822.31 What records am I required to keep?	822.31 我需要保留哪些记录？
You must keep copies of:	您必须保留以下副本：
(a) All correspondence with your investigators or FDA, including required reports;	(a) 与您的调查人员或 FDA 的所有通信，包括所需的报告；
(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;	(b) 如果您的监测计划使用调查员，则您的每个调查员签署的协议，说明承诺根据批准的计划、任何适用的 FDA 法规以及批准您的计划的任何条件（例如报告要求）进行监测；
(c) Your approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan;	(c) 您批准的上市后监督计划，并附有日期

	和偏离计划的原因的文件；
(d) All data collected and analyses conducted in support of your postmarket surveillance plan; and	(d) 为支持您的上市后监督计划而收集和分析的所有数据；和
(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.	(e) 我们根据法规或命令要求保存的任何其他记录，例如签署的同意文件副本、机构审查委员会审查和批准的证据等。
Sec. 822.32 What records are the investigators in my surveillance plan required to keep?	822.32 我的监督计划中的调查人员需要保留哪些记录？
Your investigator must keep copies of:	您的调查员必须保留以下副本：
(a) All correspondence between investigators, FDA, the manufacturer, and the designated person, including required reports.	(a) 调查人员、FDA、制造商和指定人员之间的所有通信，包括所需的报告。
(b) The approved postmarket surveillance plan, with documentation of the date and reason for any deviation from the plan.	(b) 经批准的上市后监督计划，并记录任何偏离计划的日期和原因。
(c) All data collected and analyses conducted at that site for postmarket surveillance.	(c) 在该站点收集和进行分析的所有数据，用于上市后监督。
(d) Any other records that we require to be maintained by regulation or by order.	(d) 我们要求按规定或命令保存的任何其他记录。
Sec. 822.33 How long must we keep the records?	822.33 我们必须保存记录多久？
You, the designated person, and your investigators must keep all records for a period of 2 years after we have accepted your final report, unless we specify otherwise.	除非我们另有说明，否则您、指定人员和您的调查员必须在我们接受您的最终报告后将所有记录保存 2 年。
Sec. 822.34 What must I do with the records if the sponsor of the plan or an investigator in the plan changes?	822.34 如果计划的发起人或计划中的调查员发生变化，我必须如何处理这些记录？
If the sponsor of the plan or an investigator in the plan changes, you must ensure that all records related to the postmarket surveillance have been transferred to the new sponsor or investigator and notify us within 10 working days of the effective date of the change. You must provide the name, address, and telephone number of the new sponsor or investigator, certify that all records have been transferred, and provide the date of transfer.	如果计划的申办者或计划中的研究者发生变化，您必须确保与上市后监督相关的所有记录已转移给新的申办者或研究者，并在变更生效之日起 10 个工作日内通知我们。您必须提供新申办者或研究者的姓名、地址和电话号码，证明所有记录已被转移，并提供转移日期。
Sec. 822.35 Can you inspect my manufacturing site or other sites involved in my postmarket surveillance plan?	822.35 您能否检查我的生产场所或参与我的售后监督计划的其他场所？
We can review your postmarket surveillance programs during regularly scheduled inspections, inspections initiated to investigate recalls or other similar actions, and inspections initiated specifically to review your postmarket surveillance plan. We may also inspect any other person or site involved in your postmarket surveillance, such as investigators or contractors. Any person authorized to grant access to a facility must permit authorized FDA employees to enter and inspect any facility where the device is held or where records	我们可以在定期安排的检查、为调查召回或其他类似行动而发起的检查以及专门为审查您的上市后监督计划而发起的检查期间审查您的上市后监督计划。我们还可能检查参与您的售后监督的任何其他人或场所，例如调查员或承包商。任何被授权进入设施的人必须允许经授权的 FDA 员工进

regarding postmarket surveillance are held.	入并检查任何存放该设备或存放有关上市后监督记录的设施。
Sec. 822.36 Can you inspect and copy the records related to my postmarket surveillance plan?	822.36 你能检查和复制与我的售后监督计划相关的记录吗?
We may, at a reasonable time and in a reasonable manner, inspect and copy any records pertaining to the conduct of postmarket surveillance that are required to be kept by this regulation. You must be able to produce records and information required by this regulation that are in the possession of others under contract with you to conduct the postmarket surveillance. Those who have signed agreements or are under contract with you must also produce the records and information upon our request. This information must be produced within 72 hours of the initiation of the inspection. We generally will redact information pertaining to individual subjects prior to copying those records, unless there are extenuating circumstances.	我们可以在合理的时间以合理的方式检查和复制与本法规要求保存的售后监督行为有关的任何记录。您必须能够提供本法规要求的记录和信息，这些记录和信息由与您签订合同的其他人拥有，以进行上市后监督。与您签订协议或签订合同的人也必须根据我们的要求提供记录和信息。该信息必须在检查开始后 72 小时内提供。我们通常会在复制这些记录之前编辑与个别主题有关的信息，除非有情有可原。
Sec. 822.37 Under what circumstances would you inspect records identifying subjects?	822.37 在什么情况下你会检查识别对象的记录?
We can inspect and copy records identifying subjects under the same circumstances that we can inspect any records relating to postmarket surveillance. We are likely to be interested in such records if we have reason to believe that required reports have not been submitted, or are incomplete, inaccurate, false, or misleading.	我们可以在与我们可以检查与售后监督有关的任何记录相同的情况下检查和复制识别对象的记录。如果我们有理由相信要求的报告尚未提交，或者不完整、不准确、虚假或具有误导性，我们可能会对此类记录感兴趣。
Sec. 822.38 What reports must I submit to you?	822.38 我必须向您提交哪些报告?
You must submit interim and final reports as specified in your approved postmarket surveillance plan. In addition, we may ask you to submit additional information when we believe that the information is necessary for the protection of the public health and implementation of the act. We will also state the reason or purpose for the request and how we will use the information.	您必须按照您批准的上市后监督计划中的规定提交中期和最终报告。此外，当我们认为信息对于保护公众健康和实施该法案是必要的时，我们可能会要求您提交额外信息。我们还将说明请求的原因或目的以及我们将如何使用这些信息。
<p>Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374. Source: 67 FR 38887, June 6, 2002, unless otherwise noted. 权威： 21 USC 331、352、360i、360l、371、374。 来源： 67 FR 38887，2002 年 6 月 6 日，除非另有说明。</p>	



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