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# **Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act**

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## **Draft Guidance for Industry and Food and Drug Administration Staff**

### ***DRAFT GUIDANCE***

**This draft guidance document is being distributed for comment purposes only.**

**Document issued on May 27, 2021.**

You should submit comments and suggestions regarding this draft document within 60 calendar days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact OPEQ: Office of Product Evaluation and Quality / OCEA: Office of Clinical Evidence and Analysis / Division of Clinical Science and Quality via email at [MandatedStudiesPrograms@fda.hhs.gov](mailto:MandatedStudiesPrograms@fda.hhs.gov).

**When final, this guidance will supersede “Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act”, issued on May 16, 2016.**



**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

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## **Preface**

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# Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act

## Draft Guidance for Industry and Food and Drug Administration Staff

*This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.*

### I. Introduction

Section 522 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides the Food and Drug Administration (FDA) with the authority to require manufacturers to conduct postmarket surveillance at the time of approval or clearance or at any time thereafter of certain class II or class III devices. Postmarket surveillance is the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device.<sup>1</sup> The data collected under a surveillance order help to address important public health questions on the safety and effectiveness of a device.

This draft guidance document, when finalized, will assist manufacturers of devices subject to section 522 postmarket surveillance orders (522 orders) by providing:

- an overview of section 522 of the FD&C Act;
- information on how to fulfill section 522 obligations,<sup>2</sup> including:
  - when postmarket surveillance should be considered commenced;
  - recommendations for achieving an approved postmarket surveillance plan in a timely manner; and

<sup>1</sup> 21 CFR 822.3(i).

<sup>2</sup> Refer to 21 CFR Part 822 for the full set of procedures and requirements for postmarket surveillance under section 522 of the FD&C Act.

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- 31 ○ recommendations for enrollment schedules to help achieve timely completion  
32 of postmarket surveillance;
- 33 ● recommendations on the format, content, and review of postmarket surveillance plan  
34 and report submissions, including revised FDA review times for postmarket  
35 surveillance-related submissions; and
- 36 ● updated surveillance status categories to better reflect progress.

37  
38 This draft guidance document also aims to increase transparency to stakeholders on FDA’s  
39 approach to the issuance and tracking of 522 postmarket surveillance orders, and expectations  
40 for timely study completion. Our initiative to increase transparency includes posting the  
41 manufacturers’ progress on addressing section 522 orders on FDA’s website.<sup>3</sup>  
42

43 The contents of this document do not have the force and effect of law and are not meant to  
44 bind the public in any way, unless specifically incorporated into a contract. This document is  
45 intended only to provide clarity to the public regarding existing requirements under the law.  
46 FDA guidance documents, including this guidance, should be viewed only as  
47 recommendations, unless specific regulatory or statutory requirements are cited. The use of  
48 the word *should* in Agency guidance means that something is suggested or recommended, but  
49 not required.

50

## 51 **II. Pre-522 Postmarket Surveillance Process**

52

### 53 **A. Legal Background**

54 When FDA identifies a potential issue with a device that could warrant postmarket  
55 surveillance (such as those described in [Section II.B](#) below), the associated review team may  
56 assess whether a 522 order is appropriate and falls within the statutory criteria.

57

58 Section 522 of the FD&C Act, 21 U.S.C. § 360I, authorizes FDA to require postmarket  
59 surveillance in the following instances:

60

- 61 ● a class II or class III device for which failure of the device would be reasonably likely  
62 to have a serious adverse health consequence (section 522(a)(1)(A)(i) of the FD&C  
63 Act);
- 64 ● a class II or class III device expected to have significant use in pediatric populations  
65 (section 522(a)(1)(A)(ii) of the FD&C Act);
- 66 ● a class II or class III device that is intended to be implanted in the human body for more  
67 than one year (section 522(a)(1)(A)(iii)(I) of the FD&C Act); or
- 68
- 69
- 70

---

<sup>3</sup> Section 522 Postmarket Surveillance Program website:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm>.

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- a class II or class III device that is intended to be a life-sustaining or life-supporting device used outside of a device user facility (section 522(a)(1)(A)(iii)(II) of the FD&C Act).

**B. Identification of Issue**

FDA may identify device issues that are appropriate for postmarket surveillance at any point during the life cycle of a class II or III device, which meets statutory criteria identified in section 522(a)(1)(A) of the FD&C Act. Such issues may be identified through a variety of sources including analysis of adverse event reports, a recall or corrective action, post-approval data, review of premarket data, reports from other governmental authorities, or review of scientific literature.

Examples of situations that may raise postmarket questions, during both the premarket and postmarket periods, are listed below. FDA may order postmarket surveillance to:

- better understand the nature, severity, or frequency of suspected problems reported in adverse event reports or in the published literature.
- obtain more information on device performance associated with real-world clinical practice.
- address long term or infrequent safety and effectiveness issues for implantable and other devices for which the premarket testing provided more limited information. For example, premarket evaluation of a device may have been based on surrogate markers. Once the device is actually marketed, postmarket surveillance may be appropriate to assess the effectiveness of the device in detecting or treating the disease or condition, rather than the surrogate. Data collected through postmarket surveillance may include rates of malfunction or failure of a device intended for long-term use or incidents of latent sequelae resulting from device use.
- better define the association between problems and devices when unexpected or unexplained serious adverse events occur after a device is marketed, if there is a change in the nature of serious adverse events (e.g., severity), or if there is an increase in the frequency of serious adverse events.

**C. Team Review of Issue**

In assessing the appropriateness of issuing a 522 order, multiple elements are considered, as indicated below, with the goal of making a determination as to whether or not postmarket surveillance for a class II or class III device should be ordered. In addition, FDA may also choose to engage external stakeholders prior to the issuance of a 522 order.

Some of the elements considered by FDA’s pre-522 team include:

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- 114 • Are the statutory criteria met?  
115
- 116 • What is the public health question? The delineation of the public health question is the  
117 most important element discussed by the team.  
118
- 119 • What is the public health question based on? It should be based on FDA's evaluation of  
120 currently available data. Examples include but are not limited to: scientific/medical  
121 concern from the review of a premarket submission and/or observed issues from the  
122 premarket data, a recall, medical device reports (MDRs), case studies, literature, or  
123 another source.  
124
- 125 • Is the public health issue device-specific or device type-specific?  
126
- 127 • For a device for which a condition of clearance or approval is being considered, can and  
128 should the public health question be addressed premarket rather than as part of a 522  
129 order?  
130
- 131 • Is there any other source of data (e.g., MDR review, published literature, real-world  
132 data sources) or action (e.g., revised labeling, public health notice, recall), or a  
133 combination thereof, that may be used to address the public health question, instead of a  
134 522 order?  
135
- 136 • Does another ongoing study (e.g., premarket approval application (PMA) post-approval  
137 study as described in 21 CFR 814.82(a)(2) and 21 CFR 814.82(a)(9)) address the public  
138 health question?  
139
- 140 • What types of 522 postmarket surveillance design(s) should be recommended?  
141 Feasibility and timeliness of the different types of postmarket surveillance should be  
142 considered.  
143
- 144 • What combination of efforts should be considered to address the public health question?  
145 In addition, when applicable, what changes, if any, are being made with regard to the  
146 premarket review?

## **D. Considerations Regarding Pediatric Population Provisions**

149 As noted above, the statute authorizes postmarket surveillance for class II and III devices that  
150 are “expected to have a significant use in pediatric populations” and also authorizes the  
151 Agency to order postmarket surveillance as a condition of clearance or approval for devices  
152 expected to have significant use in pediatric populations.<sup>4,5</sup> These provisions are not limited to

---

<sup>4</sup> Sections 522(a)(1)(A)(ii) and 522(a)(1)(B)

<sup>5</sup> Since “pediatric populations” is not defined in section 522 of the FD&C Act, for the purposes of 522 orders, FDA

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153 devices labeled for pediatric uses, and therefore specific consideration is given to devices with  
154 anticipated pediatric use.

155  
156 Note that section 402(j)(1)(A)(ii) of the Public Health Service Act (PHS Act) (42 U.S.C. §  
157 282(j)(1)(A)(ii)) also states that any “pediatric postmarket surveillance required under section  
158 522” is considered to be an “applicable device clinical trial.” As such, the pediatric postmarket  
159 surveillance must be in compliance with the registration and results submission requirements  
160 of section 402(j) of the PHS Act (42 U.S.C. § 282(j)). Additional information on these  
161 requirements can be found at <https://clinicaltrials.gov/>.

162  
163 FDA intends to work with the manufacturer to help FDA determine the appropriate timeframe  
164 for a pediatric 522 postmarket surveillance study.

### **E. Issuance of 522 Order**

165  
166 The 522 order will specify the device(s) subject to the surveillance order and the reason that  
167 we are requiring postmarket surveillance (i.e., the public health question(s)).<sup>6</sup> The order will  
168 also typically include any general or specific guidance that is available to assist the  
169 manufacturer subject to the 522 order in preparing the postmarket surveillance plan.<sup>7</sup> FDA  
170 intends to identify the premarket submission involved (i.e., premarket notification [510(k)],  
171 PMA, humanitarian device exemption (HDE) application, or De Novo request) in the 522  
172 order. A 522 order could also include timelines for certain surveillance plan milestones such  
173 as subject enrollment, data accrual, and submission of the final report, depending on the plan  
174 and timing of the order. If a manufacturer disagrees with any order or condition requiring  
175 postmarket surveillance under section 522 of the FD&C Act, a manufacturer may request  
176 review under section 562 of the FD&C Act (see section 522(c) of the FD&C Act) and other  
177 options are further described in 21 CFR 822.7.

178  
179 Section 522(a)(1)(A) of the FD&C Act specifies that the Agency may issue a postmarket  
180 surveillance order at the time of device approval or clearance or any time thereafter. When a  
181 522 order is being considered for issuance at the time of market authorization, FDA may  
182 advise the manufacturer of the potential 522 order and the surveillance plan schedule.  
183 Pursuant to Section 522(b)(1) each manufacturer must develop and submit for FDA approval  
184 a postmarket surveillance plan within 30 days of receiving the order (see also 21 C.F.R. 822.9  
185 and 822.10). Section 522(b)(1) of the FD&C Act provides that a manufacturer must  
186 commence postmarket surveillance not later than 15 months after the day the order is issued.  
187 FDA typically considers postmarket surveillance to have commenced when the first subject is  
188 enrolled as outlined in the approved surveillance plan. For plans that do not involve  
189 enrollment of subjects (e.g., non-clinical studies), FDA considers postmarket surveillance to

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is defining pediatric populations to mean patients who are 21 years of age or younger at the time of diagnosis or treatment, that is, from birth through the twenty-first year of life, up to, but not including the patient’s twenty-second birthday. This definition is consistent with the definition of “pediatric patients” under section 520(m)(6)(E)(i) of the FD&C Act, which was added to the FD&C Act at the same time as the pediatric use criterion in section 522.

<sup>6</sup> 21 CFR 822.5.

<sup>7</sup> *Ibid*



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190 have commenced when data accrual has started as outlined in the approved surveillance plan.<sup>8</sup>  
191 In FDA’s experience, surveillance plans that require enrolling subjects in a prospectively-  
192 targeted manner are more likely to achieve timely completion by following the recommended  
193 schedule below from the date of issuance of the 522 order.  
194

- 195 • Study commenced within 15 months
- 196 • 20% of subjects enrolled within 18 months
- 197 • 50% of subjects enrolled within 21 months
- 198 • 100% of subjects enrolled within 24 months
- 199

### 200 **III. Postmarket Surveillance Plans**

201 FDA will assign a postmarket surveillance (PS) order number (i.e., PS#####) to each 522  
202 order. Manufacturers should cite the assigned PS number when submitting a proposed  
203 postmarket surveillance plan. Surveillance plans are reviewed as supplements to the PS order  
204 number. If there are multiple postmarket surveillance questions in a 522 order that require  
205 different methodologies to address each question, then a separate postmarket surveillance plan  
206 should be submitted for each question, and it is tracked as an individual requirement under the  
207 PS order number. FDA will confirm receipt and identify each plan submission by a unique  
208 document number.<sup>9</sup>  
209

210 A manufacturer must submit a postmarket surveillance plan within 30 calendar days of receipt  
211 of the 522 order.<sup>10</sup> Per Section 522(b)(1) of the FD&C Act and 21 CFR 822.17, FDA will  
212 review postmarket surveillance plans and respond within 60 calendar days of receipt. FDA  
213 intends to promptly review postmarket surveillance plans and work interactively with the  
214 manufacturer in order to issue a decision within 30 calendar days of receiving the plan. The  
215 manufacturer should prioritize resolution of any surveillance plan deficiencies identified by  
216 the Agency and work interactively with the FDA to facilitate that a full surveillance plan  
217 review can be achieved within 60 calendar days from the issuance of the 522 order date.  
218

#### 219 **A. General Information**

220 The general content and format of a postmarket surveillance submission is outlined in 21 CFR  
221 822.9. See [Appendix 1](#) for CDRH’s internal checklist for determining whether a submission is  
222 administratively complete in accordance with 21 CFR 822.9.  
223

#### 224 **B. Elements to Include in a Postmarket Surveillance Plan**

225 As outlined in 21 CFR 822.10, the following sections must be included in your postmarket  
226 surveillance plan:

---

<sup>8</sup> For non-clinical surveillance/studies data, accrual milestone reports may be used to track progress.

<sup>9</sup> See 21 CFR 822.8.

<sup>10</sup> Section 522(b)(1) of the FD&C Act and 21 CFR 822.8

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- 227 • postmarket surveillance plan objectives addressing the surveillance question(s)<sup>11</sup>
- 228 • postmarket surveillance approach (i.e., design) or methodology to be used<sup>12</sup> (see
- 229 [Section III.E.](#) of this guidance), we recommend including the hypothesis(es) and
- 230 success criteria
- 231 • the subject of the study,<sup>13</sup> e.g., the patient population (may include subject inclusion
- 232 and exclusion criteria and definition and source of comparator group)
- 233 • the variables and endpoints for assessing the surveillance question(s),<sup>14</sup> such as the
- 234 primary and secondary endpoints; we recommend including definitions for endpoints, a
- 235 list of expected adverse events/complications, an agreement to collect unexpected
- 236 adverse events, and a plan to assess relatedness of endpoints with the device and/or the
- 237 procedure
- 238 • sample size;<sup>15</sup> we recommend including sample size calculation that is statistically
- 239 justified and based on study hypothesis, where applicable
- 240 • description of the data source (e.g., hospital records, registry data);<sup>16</sup> we recommend
- 241 including description of the data source relevance (e.g., does it capture information to
- 242 address the surveillance question(s) in the order) and of its reliability (e.g., data quality)
- 243 • description of data collection plan<sup>17</sup> (such as procedures, including data management
- 244 and quality control where applicable<sup>18</sup>)
- 245 • data collection forms,<sup>19</sup> informed consent forms,<sup>20</sup> and Institutional Review Board
- 246 (IRB) approval or IRB exemption forms,<sup>21</sup> where applicable
- 247 • patient follow-up plan or schedule;<sup>22</sup> we recommend including length of follow-up, and
- 248 a plan to minimize losses to follow-up assessments, follow-up rates targets, as well as a
- 249 description of baseline and follow-up assessments

---

<sup>11</sup> 21 CFR 822.10(a)

<sup>12</sup> 21 CFR 822.10(d)

<sup>13</sup> 21 CFR 822.10(b)

<sup>14</sup> 21 CFR 822.10(c)

<sup>15</sup> 21 CFR 822.10(e)

<sup>16</sup> 21 CFR 822.10(g)

<sup>17</sup> 21 CFR 822.10(h)

<sup>18</sup> FDA notes that, where appropriate, it may be possible to meet a 522 order requirement through prospective or retrospective analysis of data from real-world data sources, such as device registries and electronic health records. In addition, if real-world data already exist that are of sufficient relevance and reliability and a prospective analysis will be timely performed by a device manufacturer, FDA may decide not to issue a 522 order. For additional information on the use of real-world evidence for medical devices, see FDA Guidance, “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices>.

<sup>19</sup> 21 CFR 822.10(h)

<sup>20</sup> 21 CFR 822.10(i)

<sup>21</sup> 21 CFR 822.10(j)

<sup>22</sup> 21 CFR 822.10(k)

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- 250 • all data analyses and statistical tests planned<sup>23</sup> (such as statistical analysis plan  
251 including interim data release plan, when appropriate, and final data analyses)
- 252 • investigators agreement, if applicable<sup>24</sup>
- 253 • procedures for monitoring conduct and progress of the surveillance<sup>25</sup>, and estimate of  
254 the duration of the surveillance<sup>26</sup>, such as plan milestones/timeline elements, including  
255 (where applicable):
- 256 ○ expected date of study/surveillance initiation
  - 257 ○ expected monthly number of study sites with IRB approvals
  - 258 ○ expected date of initiation of subject enrollment
  - 259 ○ expected date for achieving 20% and 50% enrollment
  - 260 ○ expected date for subject enrollment completion
  - 261 ○ expected date to complete follow-up of all study participants, and
  - 262 ○ if applicable, information related to intermediate milestones (e.g., evaluation of
  - 263 ○ surrogate endpoints in a study that also measures clinical benefits)
- 264 • The content and timing of the Postmarket Surveillance Reports<sup>27</sup>

266 We recommend that you also include in your surveillance plan a background section (e.g., a  
267 brief description of the device, the regulatory history, the indications for use), and enrollment  
268 and recruitment plan (including enrollment targets).

269  
270 In general, section 522(b)(1) of the FD&C Act authorizes FDA to order prospective  
271 postmarket surveillance for duration of up to 36 months unless the manufacturer and FDA  
272 agree to extend that timeframe or, if there is no agreement, after the completion of a dispute  
273 resolution as described in section 562 of the FD&C Act. Further, under section 522(b)(2) of  
274 the FD&C Act FDA may by order require a prospective surveillance period of more than 36  
275 months with respect to a device that is expected to have significant use in pediatric  
276 populations, if such period is necessary in order to assess the impact of the device on growth  
277 and development, or the effects of growth, development, activity level, or other factors on the  
278 safety or efficacy of the device. FDA may work interactively with the manufacturer to help  
279 FDA determine the appropriate time frame for a pediatric 522 postmarket surveillance study.  
280

### **C. FDA and Manufacturer Agreement on Surveillance Plan**

282 FDA will evaluate the proposed surveillance plan to determine whether it is administratively  
283 complete, whether the person designated to conduct the surveillance has appropriate  
284 qualifications and experience to undertake such surveillance, and if the plan will result in the  
285 collection of useful data that can reveal unforeseen adverse events or other information

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<sup>23</sup> 21 CFR 822.10(n)

<sup>24</sup> 21 CFR 822.10(f)

<sup>25</sup> 21 CFR 822.10(l)

<sup>26</sup> 21 CFR 822.10(m)

<sup>27</sup> 21 CFR 822.10(o)

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286 necessary to protect the public health and will answer the surveillance questions.<sup>28</sup>  
287 Accordingly, FDA may issue one of the following letters:<sup>29</sup>  
288

- 289 • **Not Acceptable Letter** – This letter is issued when a submission is found to be  
290 administratively incomplete because it does not include the items required by 21 CFR  
291 822.9 and 822.10 to allow for a substantive review. See [Appendix 1](#) for CDRH’s  
292 internal checklist for determining whether a submission is administratively complete.
- 293 • **Approval Letter** – This letter indicates FDA’s approval of the proposed surveillance  
294 plan as submitted, along with any specific requirements or recommendations related to  
295 the surveillance plan.
- 296
- 297 • **Major Deficiency Letter** – This letter cites serious deficiencies relating to whether the  
298 plan will result in the collection of useful data that will answer the surveillance  
299 questions. The manufacturer must address these deficiencies and/or requests for  
300 specific information within the specified timeframe before the surveillance plan can be  
301 approved.<sup>30</sup>  
302
- 303 • **Disapproval Letter** – This letter indicates FDA’s disapproval of the plan submitted  
304 because FDA has determined it is not likely to result in the collection of useful data that  
305 will address the postmarket surveillance questions in the 522 order. The letter directs  
306 the manufacturer to revise its surveillance plan by submitting an entirely new  
307 submission within the specified timeframe that proposes a new surveillance plan  
308 intended to address the postmarket surveillance questions in the 522 order.  
309

310 If a manufacturer disagrees with FDA about the content of the surveillance plan or if the  
311 surveillance plan is disapproved, possible recourse options are described in 21 CFR 822.22.  
312 These include seeking internal review of FDA’s decision under 21 CFR 10.75; requesting an  
313 informal hearing under 21 CFR Part 16; or requesting review by the Medical Devices Dispute  
314 Resolution Panel of the Medical Devices Advisory Committee. A manufacturer may also  
315 request a meeting with the FDA employee that has signed the 522 order. During the pendency  
316 of such review, FDA does not intend to take enforcement action except as indicated in [Section](#)  
317 [X](#).  
318

319 FDA developed this guidance document, in part, to help facilitate timely discussions with  
320 manufacturers on postmarket surveillance plans, issues and challenges. Early and ongoing  
321 interactions with FDA should be the primary method to ensure the adequacy of 522

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<sup>28</sup> See 522(b)(1) of the FD&C Act and 21 CFR 822.16.

<sup>29</sup> See 21 CFR 822.19. FDA plans to use similar decision letters for supplements submitted by manufacturers proposing changes to approved surveillance plans.

<sup>30</sup> Consistent with FDA’s approach to least burdensome provisions as outlined in the guidance “Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions>) if only minor deficiencies are identified, FDA intends to resolve such outstanding issues interactively.

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322 surveillance plans and to resolve any issues. FDA intends to work with manufacturers on the  
323 development of their surveillance plans, including the timelines and expectations for  
324 commencing and progress of the postmarket surveillance. However, if FDA is unable to  
325 complete the review of the postmarket surveillance plan within 60 calendar days of issuance  
326 of a 522 order due to outstanding deficiencies that the manufacturer needs to address, we  
327 intend for the postmarket surveillance to be categorized as “Plan Overdue” on FDA’s website.  
328 Moreover, once the Secretary issues an order under section 522 requiring a manufacturer to  
329 conduct postmarket surveillance, if a manufacturer fails to submit a plan within 30 calendar  
330 days of the 522 order, fails to have an approved plan, or fails to commence postmarket  
331 surveillance within 15 months of the 522 order, this would constitute a failure to comply with  
332 a requirement under section 522. Failure to comply with a requirement under section 522 of  
333 the FD&C Act may result in enforcement action by FDA, as appropriate.  
334

**D. Changes to an Approved Postmarket Surveillance Plan**

335  
336 If a manufacturer wishes to propose a change to an approved postmarket surveillance plan that  
337 will affect the nature or validity of the data collected, the manufacturer must obtain FDA  
338 approval in writing before making such changes.<sup>31</sup>  
339

340 Also, if a manufacturer wishes to propose a change in the surveillance plan completion dates,  
341 the manufacturer should submit that plan revision as part of a supplement for review and  
342 approval.

343 The manufacturer should not combine a surveillance plan change request, which includes  
344 timeline changes, with any 522 report, but instead should submit the request and the revised  
345 postmarket surveillance plan for FDA review and approval as a standalone supplement to the  
346 postmarket surveillance order number (PS#####). Any submission involving a change to an  
347 approved postmarket surveillance plan is tracked by FDA as a supplement to the PS order and  
348 should be identified by the assigned PS number.  
349

350 In keeping with FDA’s practice of focusing review resources on complete submissions,  
351 requests to change an approved postmarket surveillance plan will first undergo acceptance  
352 review to assess whether a supplement is administratively complete for FDA to conduct a  
353 substantive review.<sup>32</sup> If a supplement does not include the items listed in [Appendix 1](#), a Not  
354 Acceptable letter may be issued identifying the missing items, which the manufacturer would  
355 need to provide in order for FDA to conduct a substantive review of the supplement.  
356

357 Once accepted for substantive review, FDA may also find other deficiencies with a  
358 supplement, and issue a Minor or Major Deficiency letter identifying those issues that the  
359 manufacturer would need to address in order to receive approval. Or, if FDA determines that a  
360 proposed modification to an approved plan is not likely to result in the collection of useful  
361 data that will address the postmarket surveillance question, FDA will issue a Disapproval

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<sup>31</sup> See 21 CFR 822.21.

<sup>32</sup> See 21 CFR 822.16.

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362 letter identifying the reasons for disapproval.<sup>33</sup>

363  
364 Unless FDA approves the revised surveillance plan, the manufacturer remains responsible for  
365 completing the postmarket surveillance following the previously approved surveillance plan.  
366 Failure to meet the milestones and timelines outlined in the approved surveillance plan may  
367 result in enforcement action by FDA (see [Section X](#)).  
368

369 **E. Types of Postmarket Surveillance**

370 FDA may order postmarket surveillance to address a wide variety of device-related public  
371 health questions. When developing a surveillance plan, FDA and the manufacturer should  
372 consider a least burdensome approach that is scientifically appropriate to address the  
373 surveillance question(s).<sup>34</sup> A 522 order may include multiple public health questions. If more  
374 than one postmarket surveillance study is needed to address the postmarket questions, each is  
375 tracked as a unique requirement under the 522 order. FDA also notes that, where appropriate,  
376 it may be possible to meet a 522 order requirement through prospective or retrospective  
377 analysis of data from real-world data sources, such as device registries and electronic health  
378 records.<sup>35</sup> In addition, if real-world data already exist that are of sufficient relevance and  
379 reliability and a prospective analysis will be timely performed by a device manufacturer, FDA  
380 may decide not to issue a 522 order.

381  
382 Table 1 below describes different types of postmarket surveillance designs that could be used  
383 depending on the particular public health question.

384  
385  
386 **Table 1. Types of Postmarket Surveillance Designs**

Type	Design
<b>Randomized Clinical Trial</b>	Prospective study comparing the effects of one or more intervention(s) against a control group. Subjects are assigned randomly to one of the study groups.
<b>Prospective Cohort Study</b>	A study in which the subjects in a defined population are followed prospectively in time to assess the occurrence of outcomes of interest as they occur. Such studies can include one or more groups defined in terms of their exposure to a device. There is no randomization of treatment assignment.
<b>Retrospective Cohort Study</b>	A study in which the subjects in a defined population are followed forward in time; however, unlike a prospective cohort study, the data

<sup>33</sup> See 21 CFR 822.19.

<sup>34</sup> See FDA Guidance, “Least Burdensome Provisions: Concept and Principles”, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles>.

<sup>35</sup> See FDA Guidance, “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices>.

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Type	Design
	records documenting the device exposure and outcomes have been collected in the past relative to the time when the study is initiated. Such studies can include one or more groups defined in terms of their exposure to a device. There is no randomization of treatment assignment.
<b>Cross-Sectional Study</b>	A study in which the presence or absence of an exposure and health outcome are assessed at the same point in time.
<b>Enhanced Surveillance</b>	Continued monitoring of the distribution and trends in the incidence of adverse events through ongoing, <i>passive</i> , but systematic collection, analysis, and interpretation of data. A passive approach to surveillance means that the organization conducting the surveillance does not contact potential reporters and leaves the initial reporting to others. The surveillance may be designed to collect information on events that are both MDR-reportable and MDR non-reportable adverse events or device complaints.
<b>Active Surveillance</b>	Continued monitoring of the distribution and trends in the incidence of adverse events through ongoing, <i>active</i> systematic collection, analysis, and interpretation of data. An active approach means that the organization conducting the surveillance initiates procedures to obtain reports. The surveillance may be designed to collect information on events that are both MDR-reportable and MDR non-reportable adverse events or device complaints.
<b>Meta-Analysis</b>	Systematic review that combines the results of several studies that address a set of related research hypotheses. This is normally done by identification of a common measure of effect size, which is modeled using a form of meta-regression of the published or unpublished study data.
<b>Prospective &amp; Retrospective Study</b>	A hybrid cohort study in which data are collected both retrospectively and prospectively. There is no randomization of the treatment assignment.
<b>Case Control Study</b>	Study in which subjects are identified on the basis of the presence of an outcome (cases) and compared to an appropriate comparison group (non-cases). The proportions with the exposure of interest are compared and Odds Ratios for the outcome(s) of interest are calculated.
<b>Non-Clinical Study</b>	A study that involves testing on the bench or laboratory setting (e.g., wear testing, fatigue testing).
<b>Animal Study<sup>36</sup></b>	A study that involves animal testing (e.g., device or material implanted in animal).

<sup>36</sup> FDA supports the principles of the “3Rs,” to reduce, refine, and replace animal use in testing when feasible. We encourage manufacturers to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

Type	Design
Other Design	A surveillance methodology that does not fit one of the other categories.

387  
388  
389

#### 390 IV. When and How to Submit Postmarket Surveillance 391 Reports

392 Per 21 CFR 822.38, manufacturers must submit interim and final reports as specified in an  
393 approved postmarket surveillance plan. A 522 order can include the timing of reports. FDA  
394 recommends submitting two types of interim reports: “Enrollment Reports” and “Interim  
395 Postmarket Surveillance Status Reports.” An Enrollment Report provides the progress  
396 towards meeting the enrollment milestones outlined in the surveillance plan. For Enrollment  
397 Reports, the timing can be based on the expected completion dates for enrollment milestones.  
398 An Interim Postmarket Surveillance Status Report includes subject accountability as well as  
399 device performance data. There may be instances in which the timing for submission of an  
400 Enrollment Report coincides with the timing for an Interim Postmarket Surveillance Status  
401 Report. In such instances, a manufacturer can submit one report labeled as “Enrollment and  
402 Interim Postmarket Surveillance Status Report.”

403

404 The Final Postmarket Surveillance Report is a written report of a postmarket surveillance  
405 requirement that has been completed or terminated.

406

407 Unless otherwise specified in the 522 order, for each postmarket surveillance requirement,  
408 manufacturers should submit an Interim Postmarket Surveillance Status Report every 6  
409 months for the first 2 years of the postmarket surveillance and annually, thereafter, from the  
410 date of the 522 postmarket surveillance plan approval or other agreed-upon starting date,  
411 separately for each unique requirement. Manufacturers should continue this reporting  
412 schedule, for each unique requirement, until the Final Postmarket Surveillance Report(s) are  
413 submitted. In accordance with the 522 order, the Final Postmarket Surveillance Report is  
414 required to be submitted no later than three months after study/surveillance completion for the  
415 particular postmarket surveillance requirement, which FDA considers to have occurred when  
416 the last data point is collected during the surveillance period (e.g., when the last subject  
417 completes the last follow-up visit).<sup>37</sup>

418

419 In order to ensure proper review, the manufacturer should indicate the type of report and the  
420 time span on the report cover letter in **bold** letters (e.g., **Enrollment Report, 6-Month**  
421 **Interim Postmarket Surveillance Status Report, 12-Month Interim Postmarket**  
422 **Surveillance Status Report, Final Postmarket Surveillance Report**). For final reports,  
423 FDA also recommends that manufacturers clearly identify the postmarket surveillance  
424 requirement (i.e., public health question(s)) for which the report is being submitted.

<sup>37</sup> For non-clinical surveillance/studies submission of final report is expected no later than three months from the date the last datapoint was captured.



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425  
426 Section 522 is not subject to section 745A(b) of the FD&C Act [21 U.S.C. § 379k-1(b)],  
427 regarding electronic copy (eCopy) requirements. However, submission of an eCopy is  
428 recommended for all postmarket surveillance plan submissions. If you choose to submit an  
429 eCopy, the eCopy should be accompanied by a single paper copy of your signed cover letter and  
430 should be sent to the current address displayed on the website  
431 <http://www.fda.gov/cdrhsubmissionaddress>. Refer to FDA Guidance, “[eCopy Program for](#)  
432 [Medical Device Submissions](#)”, for additional information on the eCopy program.<sup>38</sup>  
433

434 **V. Content and Format of Postmarket Surveillance**  
435 **Reports**

436 FDA’s ability to adequately track and evaluate postmarket surveillance depends on the quality  
437 and timeliness of information provided. The recommendations in this section are intended to  
438 help ensure that Postmarket Surveillance Reports contain adequate information for the  
439 Agency to identify the device being studied, the specific postmarket surveillance being  
440 conducted, the status of that postmarket surveillance, and, if applicable, the reasons for any  
441 delays or failures to complete the postmarket surveillance.  
442

443 FDA recommends that Postmarket Surveillance Reports (interim and final) include the  
444 information listed below, clearly identified, and in separate sections. All reports should  
445 contain the data listed below and submitted per the timeline in the Postmarket Surveillance  
446 Plan.  
447  
448

449 **A. General Information**

450 FDA recommends all reports include a section that contains the following general  
451 information:  
452

- 453 • Postmarket surveillance tracking number (i.e., PS#####)
- 454 • Manufacturer name and contact information (name of the individual or entity holding  
455 the approved PMA, or HDE, cleared 510(k), or De Novo order):
  - 456 ○ Company Name/Institution Name
  - 457 ○ Street Address
  - 458 ○ City
  - 459 ○ State/Province
  - 460 ○ ZIP/Postal Code
  - 461 ○ Phone Number (include area code)
  - 462 ○ Contact name and title
  - 463 ○ Contact e-mail address

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<sup>38</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>

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- 464 • Date of issuance of the 522 order
- 465 • Date of postmarket surveillance plan approval and, if applicable, dates of approval of
- 466 any plan revisions
- 467 • Device trade name(s), subject to the 522 order
- 468 • Device model number(s) , subject to the 522 order
- 469 • Report information:
  - 470 ○ Date of the report
  - 471 ○ Description of the data included in the report, including:
    - 472 ■ Enrollment data
    - 473 ■ Clinical study data
    - 474 ■ Non-clinical data (e.g., bench/laboratory)
    - 475 ■ Animal<sup>39</sup> study data
    - 476 ■ Other
  - 477 ○ Type of submission (choose one):
    - 478 ○ Enrollment Report
    - 479 ○ Interim Postmarket Surveillance Status Report
    - 480 ○ Final Postmarket Surveillance Report
    - 481 ○ Response to FDA correspondence for a deficient report or another reason
    - 482 (specify)

### **B. Postmarket Surveillance Enrollment Reports**

484 FDA intends to review Enrollment Reports to assess progress towards the surveillance plan  
485 milestones. If the postmarket surveillance plan involves new enrollment of subjects<sup>40</sup>, FDA  
486 may request a manufacturer to submit Enrollment Reports until enrollment is completed. The  
487 Enrollment Reports should include sufficient information to allow FDA and the manufacturer  
488 to track progress towards the enrollment milestones, including:

- 490 • Date of approval of the surveillance plan
- 491 • Start and completion date for clinical site(s) recruitment
- 492 • Number of IRB approvals and number of clinical sites at which the surveillance was
- 493 initiated
- 494 • Subject enrollment start date and expected completion date
- 495 • Number of subjects enrolled (if applicable, this information should be presented for the
- 496 entire subject population and for each subgroup)
- 497 • Comparison of target versus actual enrollment dates (e.g., First subject enrolled, 20%
- 498 of subjects enrolled, 50% of subjects enrolled, 100% of subjects enrolled)

---

<sup>39</sup> FDA supports the principles of the “3Rs,” to reduce, refine, and replace animal use in testing when feasible. We encourage manufacturers to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

<sup>40</sup> For non-clinical surveillance data, accrual milestone reports may be used to track progress.

501 **C. Interim Postmarket Surveillance Status Report**

502 FDA recommends Interim Postmarket Surveillance Status Reports include (as applicable):

- 503
- 504 • purpose of the postmarket surveillance, including goals, objectives, and primary and
  - 505 secondary endpoints
  - 506 • begin and end dates of period covered by the report
  - 507 • date of database closure for the report (should not exceed three months prior to the
  - 508 deadline for submission of report)
  - 509 • If clinical study:
    - 510 ○ description of the patient population being studied, including:
      - 511 • specific illness or condition
      - 512 • whether the postmarket surveillance targets subpopulations (e.g., pediatric,
      - 513 geriatric)
      - 514 • total number of subjects to be studied
      - 515 • schedule of subject follow-up
    - 516 ○ subject accountability data stratified by each follow-up time point for the entire
    - 517 population and for each subgroup. To limit the potential bias in safety and
    - 518 effectiveness data, manufacturers should make every effort to reduce the
    - 519 number of subjects lost to follow-up.
    - 520 ○ if applicable, an explanation for:
      - 521 • subjects lost to follow-up, as well as any measure to minimize such future
      - 522 events
      - 523 • subject and physician-initiated discontinuations
      - 524 • any deaths, including reports from post-mortem examinations
  - 525 • summary and interpretation of results
    - 526 ○ interim safety/effectiveness findings, as identified in the Postmarket
    - 527 Surveillance Plan

528 **D. Final Postmarket Surveillance Reports**

529 FDA recommends Final Postmarket Surveillance Reports include (as applicable):

- 530
- 531 • purpose of the postmarket surveillance, including goals, objectives, and primary and
  - 532 secondary endpoints
  - 533 • begin and end dates of period covered by the final report
  - 534 • date of database closure for the final report (should not exceed three months prior to
  - 535 the deadline for submission of report)
  - 536 • If clinical study:
    - 537 ○ patient population being studied, including:
      - 538 • specific illness or condition
      - 539 • whether the postmarket surveillance targets subpopulations (e.g., pediatric,
      - 540 geriatric)
      - 541 • total number of subjects to be studied
      - 542 • schedule of subject follow-up

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- 543 ○ final accountability of enrolled subjects, compared to target
- 544 ○ final accountability of number of subjects followed for surveillance, stratified
- 545 by each follow-up time point for the entire population and for each subgroup.
- 546 ○ if applicable, an explanation for:
- 547 • subjects lost to follow-up
- 548 • subject and physician-initiated discontinuations
- 549 • any deaths, including reports from post-mortem examinations
- 550 • assessment of potential bias introduced by losses to follow-up (e.g. are
- 551 subjects lost to follow-up different from those that remain under
- 552 surveillance, is the loss to follow-up differential by study group) and impact
- 553 on interpretation of results
- 554 • summary and interpretation of results
- 555 ○ final safety/effectiveness findings

## 556 **VI. Evaluation of Interim Postmarket Surveillance Reports**

557 FDA intends to consider multiple factors when evaluating an Interim Postmarket Surveillance  
558 Study Report, including:

- 559 • the completeness of the report content (especially in regard to progress towards
- 560 achieving primary and secondary endpoints and performance goals, or sufficient
- 561 individual endpoint data to infer progress in the case of composite endpoints)
- 562 • the expected versus actual status of the study at the time of the report (especially
- 563 timeliness in recruitment of subjects and sites to the study and adherence to timeline in
- 564 the Postmarket Surveillance Plan)
- 565 • the causes for and solutions to delays in postmarket surveillance progress
- 566 • adherence to methodology in the Postmarket Surveillance Plan and reasons for
- 567 deviations from the methodology
- 568 • whether information in the reports address the public health question(s)
- 569
- 570

571 FDA intends to review Interim Postmarket Surveillance Reports within 30 calendar days from  
572 submission receipt. If FDA has questions regarding the data provided in the report, or  
573 believes that the data are incomplete or insufficient, FDA will generally request additional  
574 information interactively and/or through a deficiency letter. If an interim report includes  
575 insufficient data or includes data that raise new concerns regarding the safety and/or  
576 effectiveness of a device, FDA may take compliance or enforcement action, as appropriate.  
577

## 578 **VII. Evaluation of Postmarket Surveillance Final Reports** 579 **and Possible FDA Actions After 522 Order Completion**

580 FDA recommends the Final Postmarket Surveillance Report describe the methodology and  
581 results and explain how it fulfills the public health questions identified in the 522 order.

582  
583 FDA will consider several factors in its evaluation of the Final Postmarket Surveillance

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- 584 Report, including:
- 585 • the completeness of the report content;
  - 586 • adherence to methodology in the Postmarket Surveillance Plan and reasons for
  - 587 deviations from the methodology;
  - 588 • evaluation of information in the report to assess the performance of the device; and
  - 589 • evaluation of fulfillment of the 522 order (i.e., have the public health questions been
  - 590 addressed).

591

592 FDA intends to complete its review of a manufacturer’s Final Postmarket Surveillance Report

593 submission and respond within 60 calendar days. If FDA concludes that the manufacturer has

594 fulfilled the obligations in the 522 order, FDA will send a letter to the manufacturer reflecting

595 that decision. However, if the results of the postmarket surveillance raise new issues or

596 questions, additional actions may be warranted. In such circumstances, FDA could, for

597 example:

- 598
- 599 • request changes to the labeling of the device to reflect additional information learned
- 600 from the postmarket surveillance;
- 601 • issue a new postmarket surveillance order to address new issues; or
- 602 • consider administrative or regulatory actions to protect the public health (e.g., request an
- 603 update to a device’s indications for use statement).
- 604

## 605 **VIII. Manufacturer’s Reporting Status**

606 Upon receipt of an Interim or Final Postmarket Surveillance Report, FDA determines your

607 reporting status based on the schedule in the Postmarket Surveillance Plan. The reporting

608 status categories are included in Table 2 below. The reporting status for each postmarket

609 surveillance study is posted in the 522 Postmarket Surveillance Program webpage.<sup>41</sup>

610 **Table 2. Reporting Status Categories**

<b>Status</b>	<b>Definition</b>
<b>Report on Time</b>	FDA has received the scheduled Interim or Final Postmarket Surveillance Report by the due date set in the agreed-upon schedule.
<b>Report Overdue</b>	FDA has not received the Interim or Final Postmarket Surveillance Report by the due date set in the agreed-upon schedule.
<b>Report Overdue/Received</b>	FDA has received the Interim or Final Postmarket Surveillance Report, although receipt was after the due date set in the agreed-upon schedule.

612

613

614

<sup>41</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm>

615

## 616 IX. Postmarket Surveillance Status

617 After the review of a supplement with a postmarket surveillance study plan, or of an interim<sup>42</sup>  
618 or final report, FDA will consider the manufacturer’s progress with completing the postmarket  
619 surveillance. Factors in considering the postmarket surveillance status include, as applicable:

- 620 1. Assessing the status of surveillance plan approval
- 621 2. After surveillance plan approval, assessing the following:
  - 622 a. Whether the surveillance plan milestones are met
  - 623 b. Progress with data accrual
  - 624 c. Submission of a final report

625

626 Based on the above, FDA will review the potential progress categories (see Table 3 below)  
627 and consider the appropriate progress status to be posted on the section 522 Postmarket  
628 Surveillance Program public webpage.<sup>43</sup> Refer to [Section III. D](#) for information on how to  
629 handle changes to surveillance timelines. Of note, there may be circumstances in which a  
630 postmarket surveillance requirement may be put on a temporary hold, be redesigned, or  
631 terminated. A manufacturer’s progress status is considered based on current information  
632 available to the agency and may be revised accordingly based on the availability of new  
633 information. Each of these status categories are described in Table 3 below.

634

635

636

**Table 3. Postmarket Surveillance Status Categories<sup>1</sup>**

Overall Status	Description
<b>Plan Pending</b>	FDA is reviewing the manufacturer’s proposed Postmarket Surveillance Plan, and it has been less than 60 calendar days since issuance of the 522 order.
<b>Plan Overdue</b>	FDA is unable to complete its review of the proposed Postmarket Surveillance Plan due to outstanding deficiencies that the manufacturer needs to address, and it has been more than 60 calendar days since issuance of the 522 order.
<b>Surveillance Pending</b>	This status category is used from the time the Postmarket Surveillance Plan is approved to the completion of the review of the first Interim Postmarket Surveillance Report.
<b>Ongoing</b>	The surveillance is proceeding according to, or is ahead of, the original schedule. The FDA considers the surveillance to be ongoing until a final report is submitted to the FDA, as long as the activities are proceeding according to the approved surveillance plan.

<sup>42</sup> See [Section IV](#) for types of Postmarket Surveillance Reports

<sup>43</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm>

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<b>Overall Status</b>	<b>Description</b>
<b>Delayed</b>	The progression of the surveillance is behind the original schedule. For example, the enrollment of subjects (or data accrual) may or may not have started but the projected date for completion of that milestone has passed. Delays can occur in any phase of the surveillance, including subject enrollment, analysis of data, or submission of the final report to the FDA. While the milestones in the originally approved plan serve as the basis for defining the surveillance as delayed, each phase of the surveillance will be considered on its own right. If the manufacturer has one delayed phase, but gets back on schedule during the next phase, the delayed status will no longer apply.
<b>Non-compliant</b>	The surveillance fails to comply with a requirement under section 522, e.g., it has been more than 15 months since the 522 order date and the surveillance has not commenced.
<b>Completed</b>	The manufacturer has fulfilled the postmarket surveillance requirement(s) and FDA considers the requirement(s) under the 522 order to be satisfied.
<b>Terminated</b>	The manufacturer has not fulfilled or cannot fulfill the postmarket surveillance requirement identified in the 522 order, i.e. postmarket surveillance questions are no longer relevant, dataset cannot address public health question(s) in 522 order) and after all appropriate efforts to fulfill the requirement have been exhausted, FDA has terminated the postmarket surveillance requirement.
<b>Redesigned/Replaced</b>	The manufacturer has not fulfilled or cannot fulfill the surveillance requirement in the 522 order as originally designed. All appropriate efforts to fulfill the postmarket surveillance requirement have been exhausted, and FDA has agreed to allow the manufacturer to revise or replace the original Postmarket Surveillance Plan with a new surveillance plan to address the public health question(s) in the 522 order. The new plan supersedes the previous plan.
<b>Hold</b>	<p>This status reflects when a postmarket surveillance requirement has been placed on a hold temporarily. Examples of situations when a postmarket surveillance requirement might be temporarily paused include the following examples:</p> <ul style="list-style-type: none"><li>• while a change in ownership is completed, a pending separate study is being used to address the public health question(s) in the 522 order,</li><li>• redesigning the device and it needs prior premarket authorization to use in study,</li><li>• device has been authorized for marketing in US, but is not</li></ul>

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Overall Status	Description
	<p>currently marketed by manufacturer,</p> <ul style="list-style-type: none"><li>• ceased device sales, but regulatory submission that received the order has not been withdrawn.</li></ul> <p>When the circumstances supporting the hold have resolved, the manufacturer is responsible for implementing the surveillance plan. The progress is assessed against the milestones in the surveillance plan and time since issuance of the revised order.</p>
<b>Consolidated</b>	<p>The manufacturer has requested to consolidate multiple 522 orders for devices of a particular device type into one consolidated 522 order. FDA has agreed to have the multiple 522 orders consolidated under one order.</p>

637 <sup>1</sup> See [Section III.C](#) and [Section X](#)

638 **X. Failure to Comply with Postmarket Surveillance**  
639 **Requirements under Section 522 of the FD&C Act**

640 Failure or refusal to comply with a requirement under section 522, including failure to  
641 commence surveillance within 15 months of a 522 order, is a prohibited act under section  
642 301(q)(1)(C) of the FD&C Act, 21 U.S.C. § 331(q)(1)(C), and renders the device misbranded  
643 under section 502(t)(3) of the FD&C Act, 21 U.S.C. § 352(t)(3). Note that violations of  
644 sections 301(q)(1)(C) and 502(t)(3) may lead to enforcement actions including seizure of  
645 product, injunction, prosecution, and/or civil money penalties, as appropriate.<sup>44</sup>  
646

647 Furthermore, the failure to have an approved post market surveillance plan could also be the  
648 basis of enforcement action, as appropriate, because such constitutes failure to comply with  
649 section 522 of the FD&C Act, which is a prohibited act under section 301(q)(1)(C) of the  
650 FD&C Act and the device would be misbranded under section 502(t)(3) of the FD&C Act (21  
651 CFR 820.20).  
652

653 There may be instances in which it is impossible or inappropriate for a manufacturer to  
654 complete a particular postmarket surveillance order, and manufacturers may request  
655 exemption from the requirement to conduct postmarket surveillance for their devices, which  
656 FDA will consider under 21 CFR 822.30. Unless an exemption is granted, manufacturers must  
657 comply with the 522 order.<sup>45</sup> If a manufacturer stops marketing the device subject to the  
658 postmarket surveillance order, it still must continue to conduct postmarket surveillance in  
659 accordance with the approved plan unless notified otherwise by the Agency.<sup>46</sup> Requests to  
660 terminate or modify postmarket surveillance in such instances will be decided on a case-by-  
661 case basis but are less likely to be granted for devices that are implanted long-term. FDA  
662 recommends that manufacturers initiate early communication with FDA if they intend to

<sup>44</sup> 21 CFR 822.20

<sup>45</sup> 21 CFR 822.30

<sup>46</sup> 21 CFR 822.28



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663 terminate postmarket surveillance prior to fulfilling the postmarket surveillance commitment.

664  
665 Alternatively, if FDA determines a surveillance plan will no longer answer or adequately  
666 address questions in a 522 order, for example because of the postmarket surveillance design or  
667 data inadequacies, or due to a discontinuation in marketing or manufacturing of the device,  
668 but the 522 order objectives remain important, FDA intends to discuss the establishment of a  
669 new Postmarket Surveillance Plan and schedule with the manufacturer.

670

## 671 **XI. Public Disclosure of Postmarket Surveillance Plan** 672 **Information and Reports**

673 After approval of the manufacturer’s plan, FDA may disclose the contents of the original  
674 submission and any amendments, supplements, or reports, in accordance with applicable  
675 disclosure laws, such as the Freedom of Information Act. When FDA discloses such  
676 information, FDA will continue to protect any trade secret or confidential commercial  
677 information, as well as any personal privacy information of patients.<sup>47</sup>

678  
679 Any postmarket surveillance study that is an “applicable device clinical trial” as defined in  
680 section 402(j)(1)(A)(ii) of the PHS Act must comply with registration and results submission  
681 requirements for such clinical trials. Certain information on clinical trials is publicly available  
682 on the [Clinical Trials webpage](#).<sup>48</sup> Additional information on these requirements can be found  
683 at <https://clinicaltrials.gov/ct2/manage-recs/background>.

684  
685

### 686 **A. FDA Website**

687 To increase transparency to FDA stakeholders, including consumers, physicians, and industry,  
688 FDA posts information about postmarket surveillance on the [FDA 522 webpage](#).<sup>49</sup> As noted  
689 above, this information is posted in compliance with applicable disclosure statutes and  
690 regulations. Postmarket surveillance details that may be posted include:

691

#### 692 General Information

- 693 • postmarket surveillance application number (i.e., PS#####)
- 694 • manufacturer name
- 695 • device name
- 696 • medical specialty (e.g., cardiovascular, orthopedic)
- 697 • date of issuance of the 522 order
- 698 • study/surveillance name
- 699 • most recent surveillance plan approval date
- 700 • study/surveillance plan overall status (see [Section IX](#), Table 3 of this guidance)

701

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<sup>47</sup> 21 CFR 822.23

<sup>48</sup> <http://www.clinicaltrials.gov>

<sup>49</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm>

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#### 702 General Surveillance Plan Parameters

- 703 • postmarket surveillance design
- 704 • data source(s)
- 705 • comparison group
- 706 • analysis type
- 707 • patient population

708

#### 709 Detailed Surveillance Plan Parameters (where applicable)

- 710 • postmarket surveillance design detailed description
- 711 • surveillance milestones
- 712 • sample size (number of subjects and sites)
- 713 • study population detailed description
- 714 • data collection detailed description
- 715 • follow-up visits and length of follow-up

716

#### 717 Interim Postmarket Surveillance Status Report Information

718 FDA intends to post on its website or otherwise make public postmarket surveillance interim  
719 summary data and/or FDA analyses thereof when appropriate to protect the public health, for  
720 example, when interim results raise safety concerns or may otherwise impact treatment. FDA  
721 generally considers such information to be publicly releasable in accordance with applicable  
722 disclosure laws, such as the Freedom of Information Act. Examples of interim report  
723 information that FDA publicly discloses include:

- 724 • number of subjects enrolled
- 725 • number of sites enrolled
- 726 • interim safety/effectiveness findings, as identified in the postmarket surveillance  
727 plan

728

#### 729 Final Postmarket Surveillance Report Results (where applicable)

- 730 • actual number of subjects enrolled
- 731 • actual number of sites enrolled
- 732 • subject follow-up rate
- 733 • final safety/effectiveness findings and results
- 734 • FDA's interpretation and summation of the study/surveillance strengths and  
735 weaknesses

736

#### 737 Reporting Information

- 738 • Interim and Final Postmarket Surveillance Report(s) schedule
- 739 • due date(s) for Interim and Final reports (based on postmarket surveillance plan)
- 740 • FDA receipt date(s) of Interim and Final Postmarket Surveillance Report(s)
- 741 • receipt status category for Interim and Final Postmarket Surveillance Report(s)

742

743 Additional elements may be posted on FDA's website, as permitted by applicable disclosure  
744 statutes and regulations.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

## **APPENDIX 1: Section 522 Administrative Checklist Review (Per 21 CFR 822.9 & 822.10)**

The following is an internal checklist for use by FDA staff to determine whether a postmarket surveillance submission is administratively complete. The checklist can be used by manufacturers as a reference when preparing their postmarket surveillance submissions.

<b>Items required</b>	<b>Circle Yes or No or N/A</b>
<b>21 CFR 822.9 – The submission must include:</b>	
(a) Organizational/administrative information	
(1) Name and address	<b>Yes or No or N/A</b>
(2) Generic and trade names of the device	<b>Yes or No or N/A</b>
(3) Name and address of the contact person for the submission	<b>Yes or No or N/A</b>
(4) Premarket application/submission number and device identifiers for the device	<b>Yes or No or N/A</b>
(5) Table of contents identifying page numbers for each section of the submission	<b>Yes or No or N/A</b>
(6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission)	<b>Yes or No or N/A</b>
(7) Product codes and list of all relevant model numbers	<b>Yes or No or N/A</b>
(8) Indications for use and claims for the device	<b>Yes or No or N/A</b>
(b) Postmarket surveillance plan	<b>Yes or No or N/A</b>
(c) Designated person information	
(1) Name, address, and telephone number	<b>Yes or No or N/A</b>
(2) Experience and qualifications	<b>Yes or No or N/A</b>
<b>21 CFR 822.10 – The surveillance plan must include:</b>	
(a) The plan objective(s) addressing the surveillance questions identified in the 522 order	<b>Yes or No or N/A</b>
(b) The subject of the study, e.g., patients, the device, animals	<b>Yes or No or N/A</b>
(c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes	<b>Yes or No or N/A</b>
(d) The surveillance approach or methodology to be used	<b>Yes or No or N/A</b>
(e) Sample size and units of observation	<b>Yes or No or N/A</b>
(f) The investigator agreement, if applicable	<b>Yes or No or N/A</b>
(g) Sources of data, e.g. hospital records	<b>Yes or No or N/A</b>
(h) The data collection plan and forms	<b>Yes or No or N/A</b>

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

<u>Items required</u>	<u>Circle Yes or No or N/A</u>
(i) The consent document, if applicable	Yes or No or N/A
(j) Institutional review board information, if applicable	Yes or No or N/A
(k) The patient follow-up plan, if applicable	Yes or No or N/A
(l) The procedures for monitoring conduct and progress of the surveillance	Yes or No or N/A
(m) An estimate of the duration of surveillance, e.g., timeline for milestones	Yes or No or N/A
(n) All data analysis and statistical test planned	Yes or No or N/A
(o) The content and timing of reports, e.g., reporting schedule	Yes or No or N/A

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