

1 **Public Notification of Emerging**
2 **Postmarket Medical Device Signals**
3 **(“Emerging Signals”)**
4

5 **Draft Guidance for Industry and**
6 **Food and Drug Administration Staff**
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8 ***DRAFT GUIDANCE***
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13

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22 796-5660 or the Office of Surveillance and Biometrics, 301-796-6006.
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Preface

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42

DRAFT

Public Notification of Emerging Postmarket Medical Device Signals (“Emerging Signals”)

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

The Food and Drug Administration (FDA) is issuing this draft guidance to describe the Agency’s policy for notifying the public about medical device “emerging signals.” For the purposes of this guidance, an emerging signal is new information about a medical device used in clinical practice: 1) that the Agency is monitoring or analyzing, 2) that has the potential to impact patient management decisions and/or alter the known benefit-risk profile of the device, 3) that has not yet been fully validated or confirmed, and 4) for which the Agency does not yet have specific recommendations.

At the time a medical device is approved or cleared, it has a benefit-risk profile that health care providers, patients, and consumers use to make treatment decisions. Once a medical device is on the market, new information, including unanticipated problems, may change the benefit-risk profile of a device. Timely communication of emerging signals may help health care providers, patients, and consumers make informed treatment choices based on the most current available information. This draft guidance document proposes criteria, timeframes, a method of communication, and follow-up for FDA communications for emerging signals. This document does NOT address findings of postmarket safety or reduced benefit that are confirmed, or for which the Agency has specific recommendations for consumers, patients, health care providers, health care facilities, or industry.

Historically, the FDA has communicated important medical device postmarket information after having completed an analysis of available data and, in most cases, after having reached a

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79 decision about relevant recommendations for the device user community and about whether
80 further regulatory action is warranted. For such safety or effectiveness issues, FDA generally will
81 provide new or amended advice or instructions for patients, practitioners, and/or consumers
82 regarding the safe and effective use of the device, based on the new data. In these cases, the
83 Agency uses a variety of mechanisms to communicate publicly, including recall notices, safety
84 communications, and press releases.

85
86 However, in addition to these types of public communications, we believe there also is a need to
87 notify the public about emerging signals that the Agency is monitoring or analyzing, even when
88 the information has not been fully analyzed, validated or confirmed, and for which the Agency
89 does not yet have specific recommendations.

90
91 Because of the evolving nature of this information, FDA would be sharing it with the public at an
92 early stage of the Agency's assessment and evaluation of the signal. Further, in contrast to a
93 device safety communication, a communication regarding an emerging signal may lack certainty
94 about the significance of the information, including whether it represents a new, potentially
95 causal association, or a new aspect of a known association (e.g., increased rate or severity of
96 event), between a medical device and one or more adverse events or outcomes.

97
98 Timely communication about emerging signals is intended to provide health care providers,
99 patients, and consumers with access to the most current information concerning the potential
100 benefits and risks of marketed medical devices so that they can make informed treatment choices
101 based on all available information. Such communication may also reduce or limit the number of
102 patients exposed to the potential risk while the issue is being further evaluated. In addition,
103 communicating emerging signals may also promote enhanced vigilance on the part of clinicians,
104 risk managers, patients and consumers, who may respond by increasing their reporting to FDA.
105 This may in turn assist the Agency in further understanding the emerging signal.

106
107 FDA's guidance documents, including this draft guidance, do not establish legally enforceable
108 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should
109 be viewed only as recommendations, unless specific regulatory or statutory requirements are
110 cited. The use of the word *should* in Agency guidances means that something is suggested or
111 recommended, but not required.

112 **II. Background**

113 All medical devices have benefits and risks. Health care providers, patients, and consumers must
114 weigh these benefits and risks when making health care decisions. FDA weighs probable benefit
115 to health from the use of the device against any probable risk of injury or illness from such use in
116 determining the safety and effectiveness of a device.¹ However, not all information regarding
117 benefits and risks for a given device may be fully known or characterized prior to the device
118 reaching the market. New information about the safety and/or effectiveness of the device often

¹ See 21 U.S.C. 360c(a)(2) and 21 C.F.R. 860.7.

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119 becomes available once the device is more widely distributed and used under real-world
120 conditions of actual clinical practice.

121
122 The FDA strives to provide current information concerning the potential benefits and risks of
123 marketed medical devices to health care providers, patients, and consumers so that they can
124 make informed treatment choices based on all available information.² We also recognize the
125 potential unintended consequences of public communication about emerging signals, prior to
126 confirmation and full evaluation of the data, including the possibility that a beneficial device's
127 use may be avoided or inappropriately stopped because of uncertain or unproven risks or
128 uncertainty around the benefits. This latter concern is particularly relevant when the Agency has
129 not yet developed specific recommendations. However, FDA believes that when an emerging
130 signal meets the criteria described in Section III, including that it is based on reliable data, the
131 benefits of providing early information to the public outweigh these risks if communicated
132 carefully and thoughtfully.

133
134 Emerging signals may include, but are not limited to, a newly recognized type of adverse event
135 associated with a medical device, an increase in the severity or frequency of reporting of a
136 known event, new product-product interactions, device malfunctions or patient injuries
137 potentially related to improper device use or design, or a reduction in benefit to the patient. A
138 medical device emerging signal may be associated with one product from one manufacturer, one
139 type of product or similar products from multiple manufacturers, or multiple different product
140 types from multiple different manufacturers (e.g., materials issues).

141
142 The gathering and interpretation of the additional data needed to fully characterize an emerging
143 signal can be complex, and it may take weeks or months to conduct the analyses to understand
144 the implications of the signal for device performance and for its clinical significance. In addition,
145 in certain circumstances, the FDA may collaborate with other federal and state public health
146 agencies, or elect to seek recommendations from one of its Advisory Committees to assist in
147 evaluating available information pertaining to a signal. These factors contribute to variability in
148 the amount of time needed to sufficiently evaluate an emerging signal and to determine whether
149 public communication of specific recommendations and/or regulatory action are warranted.

III. Considerations for Determining When FDA Will Issue a Public Notification About an Emerging Signal

150
151
152 FDA considers many factors in the course of evaluating and communicating about medical
153 device emerging signals. These factors may include, but are not limited to, the following:

- 154
155
- 156 • Seriousness of the adverse event(s) (e.g., severity and reversibility) relative to the known benefits of the device;

² FDA discloses such information pursuant to all applicable laws, regulations, and policies, including sections 301(j) and 520(c) of the Federal Food, Drug, and Cosmetic Act, the Trade Secrets Act, the Privacy Act, and FDA disclosure regulations.

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- 157 • Magnitude of the risk (e.g., likelihood of occurrence);
- 158 • Magnitude of the benefit;
- 159 • Strength of the evidence of a causal relationship between the use of a device and the
- 160 adverse event;
- 161 • Extent of patient exposure (e.g., how broadly is the device used, is the device still
- 162 actively manufactured and distributed);
- 163 • Whether there is a disproportionate impact on vulnerable patient populations (e.g.,
- 164 children, pregnant women, elderly, cancer patients, chronically ill, at-
- 165 home/unmonitored);
- 166 • Potential for preventing, identifying, monitoring or mitigating the risk;
- 167 • Availability of alternative therapies;
- 168 • Implications for similar or related devices (e.g., multiple models from multiple
- 169 manufacturers);
- 170 • Anticipated time for completion of initial FDA assessment and development of
- 171 recommendations;
- 172 • Accuracy and availability of information already in the public domain.

173

174 At times, the decision to communicate about a medical device emerging signal may be affected
175 by information the public has received from sources other than FDA, such as in the mainstream
176 or social media. In some cases, the safety of a particular medical device or type of device may be
177 publicly questioned based on incorrect, incomplete, or misleading information. In such cases,
178 FDA may issue a statement or engage in other methods of communication to clarify or correct
179 information and respond to public interest.

180

181 The decision to provide public information about a medical device emerging signal is intended to
182 give health care providers, patients and consumers access to the most current information about
183 an emerging signal. It does not mean that FDA has concluded that there is a causal relationship
184 between the medical device and the emerging signal. Nor does communicating about the
185 emerging signal mean that FDA is advising health care providers, patients, or consumers to limit
186 their use of the device.

187

188 Whenever FDA discusses medical device safety, it should exercise judgment in determining
189 whether and when to communicate and what to say. FDA staff should strongly consider public
190 communication about an emerging signal when all of the following statements apply:

191

- 192 1. the information represents a new, potentially causal association, or a new aspect of a
- 193 known association (e.g., increased rate or severity of event or reduced benefit), between a
- 194 medical device and one or more adverse events or clinical outcomes;
- 195 2. the available information is reliable and supported by sufficient strength of evidence; and
- 196 3. the information could have important clinical implications for patient management
- 197 decisions and/or could it significantly alter the known benefit-risk profile of the device.

198

199 FDA staff should conduct an initial assessment of the need to communicate about an emerging
200 signal within 30 days of receiving the information.

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201
202 If during the evaluation of a signal, a decision is made to NOT communicate, FDA staff should
203 conduct an internal reassessment of the decision within 30 days of receiving new information,
204 using the considerations described above.

205 **IV. Content of Communication and Follow-up**

206 FDA strives to keep all communications clear and understandable. We consider elements of
207 human behavior in our decision to communicate and in the content of our communication. We
208 realize that risk information provided without context may alarm patients, causing them to
209 discontinue therapy with a beneficial device or to avoid a potentially beneficial therapy. In our
210 communications on medical device emerging signals, whenever possible and appropriate, we will
211 include specific information on the known benefits and risks of the device and its use, as well as
212 information on the emerging signal.

213
214 To provide consistency, FDA proposes to communicate medical device emerging signals using
215 the format and content described in Appendix A of this guidance. Once a medical device
216 emerging signal is communicated, the Agency may provide updates that:

- 217
- 218 • Provide new information related to the emerging signal collected since the initial public
219 notification;
 - 220 • Update the public that no additional substantive information is available and/or that no
221 known change in the benefit-risk profile of the device has occurred since the last posting;
 - 222 • Notify the public of additional actions being taken or completed by FDA and/or the
223 manufacturer(s).
- 224

225 Updates to the communication should be posted to the FDA website at least twice per year, or
226 more often as necessary and appropriate, until either the Agency issues a more formal “Safety
227 Communication” containing specific recommendations for patients, health care providers, and/or
228 health care facilities, or until the signal evaluation is otherwise completed and the public is
229 notified of the Agency’s conclusions.

230

231 **Appendix A: Format of Public Notification about a Medical**
232 **Device Emerging Signal**
233

234 **Early Communication: FDA Evaluating [summary of issue]**

235
236 This communication reflects FDA’s current assessment of available information about [issue]. It
237 is intended to highlight this information at an early stage in the FDA’s review, before the FDA
238 has completed a full investigation or determined whether this information warrants regulatory
239 action. Posting this information does not mean that FDA has concluded there is a causal
240 relationship between the medical device and the emerging signal. Nor does it mean that the FDA
241 is advising patients or health care professionals to discontinue or modify use of these products.
242 The FDA will update this document when additional information or analyses become available.

243
244 **Date:**

245 **Device (including known benefits and risks):**

246 **Summary of Emerging Signal:**

247 **Additional Information for Patients and Health Care Professionals (if any):**

248 **Ongoing FDA Actions:**

249 **How to Report Problems to the FDA:**
250

