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Correcting Online Misinformation About FDA-Approved or Cleared Medical Products

Authored by: Suzie Trigg, Kayla Cristales, and Carleigh Lenz

The FDA released a draft guidance earlier this year titled, *Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers* (the "**Guidance**"), to announce an updated policy of enforcement discretion available to drug and device companies[1] seeking to respond to misinformation related to their FDA-approved or -cleared medical products[2] disseminated online by third parties. This Guidance revises and replaces the Agency's similarly titled draft guidance on this topic, issued almost exactly 10 years prior.[3] In the new Guidance, FDA clarifies the two different approaches firms may utilize to address online misinformation: (1) general medical product communications and (2) "tailored responsive communications." While the former refers to existing avenues of communicating to the public (e.g., sales aids, TV and radio advertisements, and help-seeking and institutional communications), which remain subject to all applicable FDA regulations, the Guidance outlines an enforcement discretion policy for the latter. In particular, FDA does not intend to enforce its regulations governing promotional communications about medical products (e.g., requirements for prescription drug or medical device labeling, advertising, and/or postmarket submissions, as applicable) when a firm uses tailored responsive communication to address misinformation. This summary focuses specifically on tailored responsive communications and the criteria that must be met for FDA's enforcement discretion to apply.

What type of "misinformation" can be addressed under the Guidance?

A statement will be considered "misinformation" that can be addressed with a tailored response under the Guidance **if**:

1) **It contains a false or misleading statement of fact about the firm's approved or cleared medical product;**
   - Statements of value, opinion, or individual patient experiences do not qualify. However, a firm may utilize the Guidance to address any *underlying* fact(s) that may be reflected in such statements, as misinformation may be express or implied.
   - The false or misleading statement may be about the general class of drugs or devices to which a firm's medical product belongs, even if such product is not specifically identified.
   - The false or misleading factual statement may relate to approved or unapproved uses of the product; instructions or directions for use; an attribute of the product that is independent of any particular use (e.g., statements about where the product is made or its components); or scientific information about the product.
   - A statement may also be false or misleading by omission (e.g., if it fails to disclose one or more facts that are material in light of the representation(s) made or implied about the product).

2) **It is an Internet-based communication; *and***
   - Responses to misinformation stated in television and radio are not within the scope of the Guidance, even if disseminated via Internet (*e.g.*, television commercials on streaming platforms).

[1] The Guidance is intended for those entities legally responsible for complying with FDA's labeling requirements for approved or cleared prescription drugs (for humans or animals) or medical devices. Such entities may be referred to in this summary as drug and/or device "companies" or "firms."

[2] In this summary, any references to "drugs and devices," "medical products," or any similar variations is intended to refer to prescription human drugs, medical devices, and prescription animal drugs that have been approved or cleared for marketing by FDA.

[3] The previous version of this Guidance was titled, *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices* (June 2014).

3) **It is created or disseminated by an independent third party (i.e., "a person or entity not acting on behalf of the firm").**

What does FDA look for in a tailored response?

A tailored response issued under the Guidance should:

1) **Only contain information that is truthful, accurate, and scientifically sound.**

To be scientifically sound, any study or analysis that informs a firm's tailored responsive communication, at a minimum, should meet generally accepted design and other methodological standards for the particular type of study or analysis performed, taking into account established scientific principles.

2) **Identify the specific misinformation you are addressing and do not address anything else.**

The tailored response should clearly identify what specific misleading or false factual statement it seeks to correct. Only a firm's tailored response *to misinformation* falls within the scope of FDA's enforcement discretion. Anything that is not narrowly tailored to directly respond to a false or misleading statement of fact that meets the Guidance's definition of misinformation will be viewed by the Agency as a typical promotional communication and must, accordingly, meet all applicable FDA requirements. This is particularly important when responding to misinformation that is implied or included within or among a statement(s) of opinion or about a patient's experience.

3) **Identify the source of each piece of misinformation.**

A tailored response should identify where the online misinformation it seeks to address was communicated. This may be done in a number of ways, depending on the applicable source for the misinformation at-issue. For example, a firm could share or "re-post" the third-party communication containing the misinformation in conjunction with its tailored responsive communication; include the misinformation as a quote, noting the date and location of publication; or provide an embedded link directly to the communication; among other means. If the misinformation is widespread across multiple online sources, the firm should identify at least one such source and may note in its response that there are others.

4) **Include recommended disclosures.**

The following disclosures should be clearly and prominently included in all tailored responses.

- Indicate where/how a copy of the product's current FDA-required labeling can be accessed.
- Include the date on which you are posting/publishing the response (if not automatically generated).
- Note that the response is being shared by or on behalf of the medical product firm, e.g.:

  "This information is being shared [by / on behalf of] [Firm X], the maker of [medical product Y]."
- If the misinformation being addressed suggests that the product should be used for an unapproved use, include a statement that such use has not been approved by FDA and that the safety and effectiveness of the product for such use has not been established.

What non-substantive considerations may be relevant?

The response does not need to be on the same platform as the misinformation, and firms should consider platform-specific attributes before deciding how to disseminate the response. For example, if users will be able to repost to otherwise share the firm's response, ensure the user-shared version will properly display all necessary information and disclosures included in the original post. Similarly, if the firm's post will be displayed in various formats (e.g., desktop and mobile version, full post and thumbnail, etc.), ensure all versions of the original post will display all necessary information and disclosures.

The comment period for the draft Guidance ended on September 9, 2024. Haynes Boone's FDA Regulatory and Compliance Group is monitoring FDA's actions and will provide an update if/when the Guidance is finalized. For more information, contact Kayla Cristales, Suzie Trigg, or any member of the FDA Group.