Addressing Misinformation About Medical Devices and Prescription Drugs Questions and Answers Guidance for Industry

DRAFT GUIDANCE

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Questions and Answers
Guidance for Industry

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Addressing Misinformation About Medical Devices and Prescription Drugs Questions and Answers Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. INTRODUCTION

This guidance responds to common questions **firms**[2] may have when voluntarily addressing **misinformation** about or related to their **approved/cleared medical products**. In addition to describing already existing avenues for communications by firms, this guidance sets out an enforcement policy for certain kinds of **internet-based** communications that firms might choose to use to address internet-based misinformation about or related to the firm's approved/cleared medical product when that misinformation is created or disseminated by an **independent third party**.[3] The recommendations and illustrative examples in this guidance are intended to help support firms that choose to address misinformation about or related to their approved/cleared medical products.[4]

For the purposes of this guidance and as further described in section II, the term misinformation refers to implicit or explicit false, inaccurate, or misleading representations of fact about or related to a firm's approved/cleared medical product. Misinformation about or related to a firm's

[1] This guidance has been prepared by the Office of Prescription Drug Promotion in the Office of Medical Policy in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, and the Office of the Commissioner at the Food and Drug Administration.

[2] Terms that appear in **bold** at first mention are further explained in section II.

[3] This guidance is not intended to address a firm's correction of its own false or misleading representations about its medical products.

[4] This revised draft guidance does not apply to communications by firms that address misinformation about or related to an emergency use authorized for the firm's medical product under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-3), whether the use that is subject to emergency use authorization is an "unapproved use of an approved product" or is a use of an "unapproved product" as those terms are used in section 564(a). See sections 564(a)(2) and (a)(4) of the FD&C Act.

approved/cleared medical product can cause harm to both individuals and the public health in general. Basing medical decisions on misinformation can lead patients and health care providers (HCPs) to choose treatments that are not safe and effective, or to forgo treatments that are, which can have adverse consequences. While misinformation can appear in many forms of communication and be shared in many different ways, internet-based forms of communication have enabled misinformation to travel quickly and reach more people who otherwise might not be exposed to that misinformation. The spread of misinformation on the internet can be particularly rapid and harmful when the misinformation is shared by an internet user who has a large follower base or holds a position of trust, since those users may have a wider range or higher degree of influence. Additionally, misinformation about or related to medical products that treat or prevent serious or life-threatening diseases is especially concerning and represents a significant public health concern.

This guidance, when finalized, is intended to advance FDA's mission to help members of the public get the accurate, up-to-date, science-based information they need to inform their decisions about medical products to maintain and improve their health.

This guidance revises and replaces the draft guidance for industry *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices* issued in June 2014 (2014 draft guidance).[5] This guidance reflects the Agency's consideration of feedback from interested parties, including comments received on the 2014 draft guidance.

This guidance includes two subsections within section IV. Subsection IV.A sets out recommendations for certain kinds of internet-based communications (*tailored responsive communications*) that firms might choose to use to address internet-based misinformation. Subsection IV.B describes already existing avenues for communications by firms under the FDA Authorities[6] (*general medical product communications*) that firms might also choose to use to address misinformation. More specifically, these subsections describe the following:

- Subsection A. Tailored Responsive Communications: Subsection IV.A outlines recommendations for firms' tailored responsive communications. A tailored responsive communication is a firm's voluntary, internet-based communication that identifies and addresses internet-based misinformation about or related to the firm's approved/cleared medical product when that misinformation is created or disseminated by an independent third party.[7]

  This guidance outlines an enforcement policy for tailored responsive communications, based on recommendations in subsection IV.A. For the purposes of this guidance, we

[5] We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[6] In this guidance, the FD&C Act, the Public Health Service Act, and their implementing regulations are collectively referred to as the *FDA Authorities*.

[7] This type of misinformation is further described in Q1.

refer to this policy for firms' tailored responsive communications as "the enforcement policy outlined in this guidance"[8]:

First, if a firm chooses to share a tailored responsive communication to address misinformation consistent with the recommendations in subsection IV.A, Q1 and Q3 through Q5, FDA does not intend to enforce (with respect to that tailored responsive communication):

1. Applicable requirements, if any, related to promotional labeling and advertising[9] (collectively, promotional communications)

2. Applicable requirements, if any, related to postmarketing submission of promotional communications[10]

Second, where the tailored responsive communication addresses misinformation that suggests that the firm's approved/cleared medical product should be used for an **unapproved use** and the tailored responsive communication is consistent with the recommendations in subsection IV.A, Q1 and Q3 through Q5, FDA does not intend to use such communication standing alone as evidence of a new intended use.[11]

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[8] Note that the enforcement policy outlined in this guidance for firms' tailored responsive communications does not include television (TV) and radio advertisements, even when disseminated by firms via the internet (such as during streamed TV shows). However, although TV and radio advertisements disseminated by firms are not within the scope of the enforcement policy outlined in this guidance for firms' tailored responsive communications, firms can share general medical product communications, including TV and radio advertisements, to support diverse strategies for addressing misinformation. Firms can also consider using general medical product communications in a variety of settings, internet-based or not, to address misinformation that is disseminated in a non-internet-based communication (see Q8).

[9] See, e.g., sections 201(n) and 502(a) and (n) of the FD&C Act (21 U.S.C. 321(n) and 352(a) and (n)); 21 CFR 1.21(a) and 202.1(e); and sections 502(q) and (r) of the FD&C Act (21 U.S.C. 352(q) and (r)). For example, if a tailored responsive communication does not contain a comprehensive presentation of a prescription drug's side effects and contraindications, FDA does not intend to take enforcement action so long as the tailored responsive communication discloses any risks that are material to its specific content (see Q4) and otherwise follows the recommendations of this guidance.

[10] See, e.g., 21 CFR 314.81(b)(3)(i) and 601.12(f)(4) (regarding postmarketing submissions of promotional communications for drugs and biologics for human use using Form FDA 2253); section 506(c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 356(c)(2)(A)(ii)); 21 CFR 314.550 and 21 CFR 601.45 (regarding submissions of promotional communications for accelerated approval products); section 506(h)(3)(B) of the FD&C Act (21 U.S.C. 356(h)(3)(B)) (regarding submissions of promotional communications for Limited Population Antibacterial and Antifungal Drugs); 21 CFR 314.640 (subpart I) and 601.94 (subpart H) (regarding submission of promotional communications for products where human efficacy studies are not ethical or feasible); and 21 CFR 514.80(b)(5)(ii) (regarding submission of promotional communications for animal drugs).

[11] The concept of intended use is fundamental to the regulatory approach for medical products embodied in the FDA Authorities. Intended use is an element in the definitions of *drug* and *device*, helping to define the scope of FDA's authority over medical products and subjecting the medical products to the drug or device provisions of the FDA Authorities, as applicable. In addition, intended use may affect the appropriate premarket review pathway for a medical product and is a separate element in establishing certain violations under the FDA Authorities. See, generally, the notice of proposed rulemaking "Regulations Regarding 'Intended Uses'" (85 FR 59718 at 59724,

- Subsection B. General Medical Product Communications: Subsection IV.B describes many existing avenues available to firms for communicating information about or related to their approved/cleared medical products (e.g., sales aids, TV and radio advertisements, help-seeking and institutional communications). For the purposes of this guidance, communications through existing avenues are collectively referred to as *general medical product communications*. Unlike the tailored responsive communications described in subsection IV.A, general medical product communications are not necessarily internet-based or prompted by or tailored to address specific identified internet-based misinformation. General medical product communications can include, among other things, content and messaging that address misinformation about a firm's approved/cleared medical product. Inclusion in a general medical product communication of content that addresses misinformation creates no special considerations regarding the application of the FDA Authorities or other FDA enforcement policies. General medical product communications are expected to comply with all applicable requirements of the FDA Authorities, unless the communication is the subject of another enforcement policy. For further description of other enforcement policies and general medical product communications, see Q8.

This guidance includes examples intended to illustrate some of the recommendations and general considerations outlined in the guidance. The examples in this guidance contain hypothetical scenarios for illustrative purposes only.

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

II. SCOPE

For the purposes of this guidance, the scope of the terms in **bold** is further explained as follows:

- **Misinformation** refers to implicit or explicit false, inaccurate, or misleading representations of fact about or related to the firm's approved/cleared medical product. This includes false, inaccurate, or misleading:

  – Representations of fact about or related to approved or unapproved uses of the firm's approved/cleared medical product

September 23, 2020) and the final rule "Regulations Regarding 'Intended Uses'" (86 FR 41383 at 41385, August 2, 2021). FDA acknowledges that a tailored responsive communication addressing misinformation about or related to an unapproved use might not always be persuasive evidence of a new intended use, but this guidance nevertheless offers the assurance that FDA does not intend to rely on a tailored responsive communication that follows the recommendations of this guidance, standing alone, as evidence of a new intended use.

  - Representations of fact about or related to instructions/directions for use from the FDA-required labeling of the firm's approved/cleared medical product

  - Representations of fact about or related to an attribute of the firm's approved/cleared medical product that is independent of any particular use (e.g., statements about where the medical product is made or about the components of the medical product)

  - Representations of scientific information about or related to the firm's approved/cleared medical product (e.g., scientific information about a medical product's risk, effectiveness, or mechanism of action; representations about the type, characteristics, or extent of scientific information about the approved/cleared medical product)

  - Representations that omit a fact or facts that are material in light of the representations made or implied about or related to the firm's approved/cleared medical product

- **Firms** refers to the persons or entities legally responsible for the labeling of approved/cleared medical products, which includes applicants, sponsors, manufacturers, packers, distributors, and any persons communicating on behalf of these entities.

- **Medical product** refers to a medical device for human use (including one that is a biological product), a prescription human drug (including one that is a biological product), or a prescription animal drug.

- **Approved/cleared medical product** refers to medical products (as that term is defined in this guidance) that may be introduced into interstate commerce for at least one use under the FDA Authorities as a result of having satisfied applicable premarket requirements. For ease of reference, when *approval* and *clearance* (and similar terms) are used in discussing devices, the terms refer to FDA permitting the marketing of a device via the premarket approval (PMA), premarket notification under section 510(k) of the FD&C Act (510(k)), De Novo classification, or Humanitarian Device Exemption (HDE) pathways and to devices that are exempt from premarket notification.

- **FDA-required labeling** refers to the labeling reviewed and approved by FDA as part of the medical product premarket review process.[12] For medical devices for human use, this includes the labeling approved during the review of a PMA application, HDE application, or De Novo classification request. For medical devices for human use not subject to PMA but instead subject to 510(k) requirements or exempt from premarket review, the term FDA-required labeling includes the labeling that provides indications for use and

[12] Such labeling may include, for example, the FDA-approved Prescribing Information for a human drug (including a drug that is licensed as a biological product), carton labeling, container labels, and FDA-approved patient labeling, if any, that, under 21 CFR 201.100(d), must accompany any labeling distributed by or on behalf of the manufacturer, packer, or distributor of the drug; the FDA-approved Prescribing Information for a prescription animal drug; or the labeling approved during the premarket approval process for a device.

adequate directions for use and other information required to appear on the label or in labeling.

- **Approved use**[13] refers to a use that is lawfully included as an indication or use in the FDA-required labeling of an approved/cleared medical product (as the terms FDA-required labeling and approved/cleared medical product are defined in this guidance).

- **Unapproved use** refers to a use that is not lawfully included as an indication or use in the FDA-required labeling of an approved/cleared medical product (as the terms FDA-required labeling and approved/cleared medical product are defined in this guidance).

- **Internet-based** refers to information available through the internet (regardless of whether the information originated on the internet). This includes, for example, information available via social media, podcasts, email (e.g., listserv), group messaging, and discussion forums.

- **Setting** refers to the location where content appears. Internet-based settings include websites, internet-connected applications, platforms, or other internet-based media.

- **Independent third party** refers to a person or entity that, in communicating about a firm's approved/cleared medical product, is not acting on behalf of that firm.

III. BACKGROUND

Misinformation in the health information environment is a longstanding and increasingly widespread public health concern. FDA has long been involved in addressing the public health concerns stemming from misinformation. For example, in the 1980s during the early years of the AIDS crisis, when researchers were struggling to identify the virus that was causing the rapidly expanding epidemic, audiences were inundated with false, misleading, and inaccurate information about the causes of and treatments for the disease. During this period, FDA took action against numerous fraudulent cures that claimed therapeutic benefits in treating or preventing HIV/AIDS.[14]

In the modern American health care system, many individuals want to take an active role in their health care decision-making, and they often seek out relevant information to inform their choices. The internet is now the leading source used by consumers to obtain health

[13] The term *approved use* is chosen for ease of reference within this guidance. We note that for certain categories of medical products, the FDA Authorities use terms other than *approved* to describe satisfaction of applicable premarket requirements.

[14] Office of the Commissioner. (2019). The History of FDA's Role in Preventing the Spread of HIV/AIDS. U.S. Food and Drug Administration. https://www.fda.gov/about-fda/fda-history-exhibits/history-fdas-role-preventing-spread-hivaids.

information,[15] and HCPs also frequently seek the latest medical information on the internet.[16,17] However, not all information about medical products found on the internet is reliable; there are many false, inaccurate, or misleading statements shared on the internet. The structure and popularity of social media platforms have meant that false, inaccurate, and misleading information about medical products can spread rapidly to a broad audience.[18]

FDA continues to proactively engage in addressing misinformation through a number of efforts. FDA has enhanced and expanded its social media presence and communications on the internet to inform public understanding and help improve understanding of the uses, benefits, and risks of FDA-regulated medical products as well as to foster better understanding of the role FDA plays in the regulation of medical products.[19] FDA has also used speaking engagements to draw attention to the dangers of misinformation and to provide factual and accurate information about FDA-regulated medical products and public health issues.[20] In August 2022, FDA launched the

[15] See, e.g., Aikin KJ, Sullivan HW, Berktold J, Stein KL, and Hoverman VJ. (2021). Consumers' Experience With and Attitudes Toward Direct-to-Consumer Prescription Drug Promotion: A Nationally Representative Survey. Health Marketing Quarterly, DOI: 10.1080/07359683.2021.1947067.

[16] See, e.g., Van der Keylen P, Tomandl J, Wollmann K, Möhler R, Sofroniou M, Maun A, Voigt-Radloff S, and Frank L. (2020). The Online Health Information Needs of Family Physicians: Systematic Review of Qualitative and Quantitative Studies. J Med Internet Res, 22(12):e18816. https://doi.org/10.2196/18816.

[17] See, e.g., Clarke MA, Belden JL, Koopman RJ, Steege LM, Moore JL, Canfield SM, and Kim MS. (2013). Information Needs and Information-Seeking Behaviour Analysis of Primary Care Physicians and Nurses: A Literature Review. Health Information and Libraries Journal, 30(3), 178–190. https://doi.org/10.1111/hir.12036.

[18] See, e.g., Suarez-Lledo V, Alvarez-Galvez J. (2021). Prevalence of Health Misinformation on Social Media: Systematic Review. J Med Internet Res, 23(1):e17187, DOI: 10.2196/17187; Health Misinformation — Current Priorities of the U.S. Surgeon General. (2021). https://www.hhs.gov/surgeongeneral/priorities/health-misinformation/index.html.

[19] See, e.g., Center for Drug Evaluation and Research. (2023). Overview of Our Role Regulating and Approving Drugs | Video series. U.S. Food and Drug Administration. https://www.fda.gov/drugs/information-consumers-and-patients-drugs/overview-our-role-regulating-and-approving-drugs-video-series.

[20] Speeches by FDA Officials, for example: Califf, R. (2023, May 25). Remarks by Dr. Califf to the 2023 FDLI Conference. U.S. Food and Drug Administration. https://www.fda.gov/news-events/speeches-fda-officials/remarks-commissioner-robert-califf-2023-food-and-drug-law-institute-fdli-annual-conference-05172023; Califf, R. (2023a, May 8). Patient Empowerment in the Digital Health Era. U.S. Food and Drug Administration. https://www.fda.gov/news-events/speeches-fda-officials/speech-robert-m-califf-md-national-health-councils-2023-science-patient-engagement-symposium-patient; Califf, R. (2023a, April 28). Food is Medicine National Summit: "Transforming Health Care." U.S. Food and Drug Administration. https://www.fda.gov/news-events/speeches-fda-officials/remarks-commissioner-robert-m-califf-food-medicine-national-summit-transforming-health-care-04262023; Califf, R. (2022, October 1). Remarks by FDA Commissioner Robert Califf to Health Connect South. U.S. Food and Drug Administration. https://www.fda.gov/news-events/speeches-fda-officials/remarks-fda-commissioner-robert-califf-health-connect-south-09222022; Califf, R. (2022a, April 20). Remarks by FDA Commissioner Robert Califf to the 2022 RX and Illicit Drug Summit. U.S. Food and Drug Administration. https://www.fda.gov/news-events/speeches-fda-officials/remarks-fda-commissioner-robert-califf-2022-rx-and-illicit-drug-summit-04202022.

Rumor Control web page,[21] which is focused on public health priorities and describes what information is accurate and what is a rumor and how interested parties can help stop the spread of misinformation. FDA has also undertaken educational efforts[22] and provided "toolkits" to interested parties.[23] These toolkits include materials and messages from FDA about public health issues and FDA-regulated medical products that can empower interested parties by providing them with resources that better enable them to address false, misleading, and inaccurate information with facts. FDA also routinely creates and shares webinars, email alerts, videos, podcasts, and medical product safety communications in order to provide factual and accurate information to the public.[24]

In addition to FDA's actions to support its commitment to addressing misinformation, other interested parties can also help the public get truthful, accurate, and scientifically sound information. We are therefore issuing this revised draft guidance to describe avenues available to firms interested in addressing misinformation and to provide recommendations for firms that choose to voluntarily address internet-based misinformation about or related to their own approved/cleared medical products.

IV. QUESTIONS AND ANSWERS

A. Tailored Responsive Communications

Q1. Within the enforcement policy outlined in this guidance, what types of misinformation might a firm choose to address with a tailored responsive communication?

The enforcement policy outlined in this guidance applies when a firm voluntarily shares an internet-based communication that identifies and addresses misinformation that is:

- about or related to the firm's approved/cleared medical product;
- in an internet-based communication; and

[21] Office of the Commissioner. (2023). Rumor Control. U.S. Food and Drug Administration. https://www.fda.gov/news-events/rumor-control.

[22] As an example, these efforts include a variety of multimedia resources, online outreach, and other educational tools to inform patients and HCPs about the benefits and safety of biosimilars while dispelling misinformation; see https://www.fda.gov/drugs/our-perspective/education-efforts-help-increase-biosimilar-understanding-and-acceptance.

[23] FDA toolkits include, for example: FDA Office of Women's Health. (2023). Mammograms Matter: 5 Things to Know About Mammograms. U.S. Food and Drug Administration. https://www.fda.gov/media/172601/download?attachment.

[24] For information about recent public meetings, workshops, and conferences held by FDA, see https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops. To learn about ways to stay informed and connected with FDA through video, social media, email alerts, and podcasts, see https://www.fda.gov/news-events/interactive-and-social-media.

- created or disseminated by an independent third party.

Firms remain free to use other communications (see subsection IV.B. General Medical Product Communications) to address statements that are not covered by the enforcement policy outlined in this guidance.

Note that the enforcement policy outlined in this guidance is not limited to situations in which the firm's approved/cleared medical product is explicitly named in the identified misinformation. For example, the identified misinformation may include false information about an entire class of drugs or category of devices that includes a firm's approved/cleared medical product (e.g., "statins cause earlobe enlargement"). In that case, a firm could choose to use a tailored responsive communication if one of the firm's approved/cleared medical products is included in the referenced class of medical products.

We note there are some important limitations on the enforcement policy outlined in this guidance. Because, under this policy, FDA does not intend to enforce certain requirements that help ensure that the information firms disseminate about their medical products is truthful, non-misleading, and consistent with the FDA-required labeling, it is important that this policy be drawn sufficiently narrowly so that it helps support firms' voluntary efforts to address misinformation but does not undermine the purposes of those requirements. The limitations on the enforcement policy are as follows:

As previously noted in section I, TV and radio advertisements are not within the scope of the enforcement policy outlined in this guidance for firms' tailored responsive communications, even when disseminated by firms via the internet (such as advertisements during streamed TV shows).[25] Additionally, in the case of misinformation about or related to unapproved uses of approved/cleared medical products, the enforcement policy outlined in this guidance is limited to a firm's response to misinformation created or disseminated by an independent third party that suggests that the firm's approved/cleared medical product should be used for an unapproved use. Further, the enforcement policy outlined in this guidance does not extend to a firm's responses to statements describing opinions or value statements about a firm's approved/cleared medical product. It also does not extend to a firm's responses to representations about an individual patient's experience using a firm's approved/cleared medical product (whether made by that patient or others). Notwithstanding these limits, the enforcement policy outlined in this guidance provides an additional communication avenue for firms beyond preexisting channels for communication and thus expands, rather than restricts, firms' options for communications. Firms also remain free to use general medical product communications (see subsection IV.B) to address communications about or related to their medical products, including independent third-party communications that fall outside the enforcement policy for tailored responsive communications outlined in this guidance.

[25] See footnote 8.

The following examples[26] illustrate communications that include opinions, value statements, or representations about an individual patient's experience such that the firm's responses to them would not fall within the enforcement policy outlined in this guidance (but these communications could be addressed with general medical product communications):

> ***Example 1***: An influencer, who is an independent third party, posts a video on his social media account telling his followers that he does not like Drug X, a prescription drug indicated to treat acne vulgaris, because it didn't work for his acne vulgaris. He recommends his followers consider a different treatment.
>
> The influencer's statements describe his own experience, opinion, and value judgments.
>
> ***Example 2***: A celebrity, who is an independent third party, posts on their social media account regarding their cousin's reported negative personal experience after using Drug X, a prescription drug approved for chronic weight management in patients with obesity. The celebrity opines that they believe Drug X made their cousin gain weight rather than lose weight.
>
> The celebrity's statements describe an individual's experience and opinion.
>
> ***Example 3***: A celebrity and well-known animal lover, who is an independent third party, makes a statement on her social media accounts saying that she has stopped giving her dogs Drug A, an animal drug indicated for the treatment and prevention of flea infestation in dogs, and switched to Drug B, another animal drug indicated for the treatment and prevention of flea infestation in dogs. She states that Drug B is working much better for her dogs.
>
> The celebrity's statement describes her personal experience.

However, in cases where an opinion, value statement, or representation about an individual patient's experience references, either implicitly or explicitly, a basis that falls within the definition of misinformation in section II, a firm's use of a tailored responsive communication to address the underlying misinformation would be consistent with the enforcement policy outlined in this guidance if the tailored responsive communication follows other recommendations in Q3 through Q5. This distinction is illustrated in some of the examples provided in Q2.

[26] Each of the examples in this guidance is intended to stand on its own, and the use of "Drug X" or similar terms represents a different fictitious medical product in each example.

Q2. Within the enforcement policy outlined in this guidance, what are some examples of internet-based, independent third-party communications that include misinformation that a firm might choose to address with a tailored responsive communication?

The following are examples of some general scenarios involving internet-based, independent third-party communications that include misinformation that a firm might choose to address with a tailored responsive communication within the enforcement policy outlined in this guidance.

Example 4: An HCP, who is an independent third party, posts on her own social media account a statement that Drug Class A (a class of drugs approved to lower low-density lipoprotein (LDL) cholesterol, as an adjunct to diet, in certain patients) has been shown to cause Alzheimer's disease and therefore should not be used by patients to lower LDL.

There is no evidence that drugs in Drug Class A cause Alzheimer's disease. The HCP's statement is false, inaccurate, and/or misleading.

Example 5: A celebrity, who is an independent third party, posts on her social media account that she recommends using Drug X because it works great to prevent pregnancy, and you can even take it after sex to prevent pregnancy.

Drug X is only indicated for the prevention of pregnancy when used prior to sexual intercourse. There is no evidence that Drug X is effective in preventing pregnancy when used after sex, as the celebrity describes. The celebrity's statement that Drug X works great to prevent pregnancy is a statement that reflects an individual patient's opinion, so a firm's response to this part of her communication would not be within the enforcement policy outlined in this guidance. However, the celebrity's statement about when to take Drug X is false, inaccurate, and/or misleading. A firm's response to this statement about when to take Drug X could fall within the enforcement policy outlined in this guidance if the recommendations of the guidance are followed.

Example 6: A sports celebrity, who is an independent third party, posts on his blog about Device Y, a 510(k) cleared water-circulating cold therapy device, intended for the temporary relief of localized pain. He tells his blog readers that Device Y was cleared by FDA for use to accelerate healing and that anyone with an injury should use the device and keep the wrap directly on their skin, rather than putting any towels or barriers between the wrap and their skin. He also advises blog readers to keep the device on and running all the time for the best pain relief and to accelerate healing.

Device Y, the water-circulating cold therapy device referenced by the sports celebrity, includes directions to limit use to a specific number of minutes in each therapy session and to always keep barriers between the wrap and a patient's skin to prevent potentially serious reactions and injuries. The device is intended for pain relief, and there is no evidence that it has an effect on healing time. The sports celebrity's statements about how to use Device Y and about what Device Y is FDA-cleared to treat are false, inaccurate, and/or misleading.

Example 7: A well-known blogger, who is an independent third party, is writing a post on the opioid epidemic. He notes that there is a prescription drug, Drug X, that is a reversal agent that you can use to rescue patients suffering from an overdose. He tells people not to administer Drug X to someone who has overdosed on opioids because you will overdose on opioids yourself by administering Drug X. He tells people to instead dial 9-1-1 and wait for help to arrive.

The Prescribing Information for Drug X includes instructions for how to administer Drug X in a manner that is safe for both the patient and the individual administering Drug X. For Drug X to be effective, it is critical to administer it as soon as possible in a person with a known or suspected opioid overdose. The blogger's statement that administration of the reversal agent will result in overdose for the person administering the drug is false, inaccurate, and/or misleading.

Example 8: A nurse, who is an independent third party, posts on his online blog that a new prescription drug, Drug X, has been approved to treat non-small cell lung cancer.

According to the Prescribing Information for Drug X, it is a second-line treatment approved for certain patients with non-small cell lung cancer who have tried a chemotherapy regimen containing platinum, but that chemotherapy regimen did not work or is no longer working. The nurse's post is false, inaccurate, and/or misleading because the nurse omits material facts regarding the full indication for Drug X.

Example 9: An influencer, who is an independent third party, posts on his social media account that he is supportive of his 25-year-old wife taking Drug X, a medical product approved to treat acne vulgaris, since she is happy with the results and there are no known side effects of the drug.

The Prescribing Information for Drug X includes a boxed warning about embryo-fetal toxicity and a contraindication (Drug X is contraindicated during pregnancy) because there is an extremely high risk of severe birth defects if pregnancy occurs while taking Drug X in any amount, even for short periods of time. The influencer's statement that his wife is happy with the results of Drug X reflects an individual patient's experience and opinion, so a firm's response to this part of his communication would not be within the enforcement policy outlined in this guidance. However, the influencer's statement that he is supportive of his wife taking Drug X because there are no known side effects rests on a basis that falls within the definition of misinformation because the statement that there are no known side effects of the drug is false. Therefore, a firm's response to this statement could fall within the enforcement policy outlined in this guidance if the recommendations of the guidance are followed.

Example 10: A medical doctor with a large social media following, who is an independent third party, posts a statement that published studies show that Device Y increases the risk of severe, life-threatening vascular injuries tenfold over other comparable devices.

There are no published studies that support the assertion that Device Y increases the risk of severe, life-threatening vascular injuries, and Device Y's prescribing information also does not include any warnings about vascular injuries. The statement by the medical doctor is false, inaccurate, and/or misleading.

Example 11: A content creator on a social media platform, who is an independent third party, posts a video on the social media platform where they make claims that a study has just been found that shows that a prescription drug manufacturer has known for years that its medical product, Drug X, is lethal to humans. The content creator includes a link in their video to a published study that was conducted prior to the drug's approval.

The study described in the publication that is the basis for the content creator's claims was a safety pharmacology study designed specifically to assess the effects of Drug X on the central nervous system in rats at a range of doses, some that were 40 to 50 times the maximum recommended dose for humans. Central nervous system toxicity leading to mortality was only seen in rats given greater than 40 times the maximum dose recommended for humans in the Prescribing Information for Drug X. The study and the findings do not support the content creator's statement that the drug is lethal to humans. The content creator's statements are false, inaccurate, and/or misleading.

Example 12: A veterinary technician and well-known podcaster, who is an independent third party, uploads a new episode of her podcast to the host platform she uses for her podcast series on animal health issues. In the new episode, the veterinary technician discusses the use of animal Drug X, a newly approved drug for the control of pruritus associated with allergic dermatitis in dogs. The veterinary technician discusses how hard it is for pets to struggle with allergies and states that animal Drug X is an option for all pet owners who have pets with any kind of allergy, since studies have shown it works for every kind of allergic reaction.

Animal Drug X is only indicated for use in dogs and only for the control of pruritus (severe skin itching) associated with allergic dermatitis, and there are no studies that have shown it works for every kind of allergic reaction. The veterinary technician's statements that indicate that studies support the conclusion that animal Drug X is an option for all pets and works for every kind of allergic reaction are false, inaccurate, and/or misleading.

Example 13: An individual, who is an independent third party, posts on his social media account that his dad is taking a new prescription drug, Drug X, in the form of an injection to treat his lung cancer. The individual states that Drug X is a terrible choice for his dad because it is made using tissue from cadavers.

While the individual's statement that Drug X is a terrible choice is a value statement, that statement rests on a basis that falls within the definition of misinformation because the statement that Drug X is made using tissue from cadavers is false. Therefore, a firm's response to this statement could fall within the enforcement policy outlined in this guidance if the recommendations of the guidance are followed.

Q3. For the purposes of the enforcement policy outlined in this guidance, should a tailored responsive communication identify a specific communication being addressed, as well as the specific misinformation in that communication? If so, how?

Yes, a firm's tailored responsive communication should clearly identify both the specific misinformation that the firm is addressing and a specific internet-based, independent third-party communication in which that misinformation appears.[27]

There are a number of mechanisms through which firms might identify a specific internet-based, independent third-party communication. For example, a firm might share a tailored responsive communication in conjunction with a specific internet-based, independent third-party communication or capture and embed an internet-based, independent third-party communication (or a portion of it) in a tailored responsive communication. When a firm identifies misinformation that is widespread, the firm should, at a minimum, clearly identify at least one internet-based, independent third-party communication that contains the misinformation the firm is addressing. A firm might do this by, for example, noting the date and specific location within the internet-based setting where the independent third-party communication was posted. A firm can also note that the identified misinformation appears on other social media platforms.

In addition to identifying a specific internet-based, independent third-party communication, a firm's tailored responsive communication should clearly identify what specific misinformation within an internet-based, independent third-party communication the firm is addressing. Note, if a firm indicates that their tailored responsive communication is, for example, addressing just one sentence of content posted by an independent third party in a specific location within an internet-based setting, the firm should address each piece of misinformation in that sentence.

> ***Example 14***: A firm decides to voluntarily address misinformation about its approved/cleared medical product that appeared in an internet-based short form video posted by an independent third party on a social media platform. The firm posts a tailored responsive communication in the form of a short-form video on their medical product's page, on the same social media platform. To identify the specific misinformation the firm is addressing, the firm incorporates a segment of the original video containing the misinformation into its response video, and the firm's communication clearly identifies the specific false, inaccurate, or misleading content it is addressing within the video segment. The firm also describes the specific location within the internet-based setting as well as the date of the independent third party's social media post that contained the misinformation.

[27] Because addressing misinformation is voluntary, firms are under no obligation to continue to monitor or address responses to the firm's tailored responsive communication.

Q4. For the purposes of the enforcement policy outlined in this guidance, what should a firm consider when determining what information to include in their tailored responsive communication?

For the purposes of the enforcement policy outlined in this guidance, a firm should ensure that the information in their tailored responsive communication is:

- Truthful and accurate.

- 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 (e.g., provide a clear description of the hypothesis stated and tested, acknowledge and account for potential bias, and otherwise meet generally accepted scientific standards for the type of study or analysis performed), taking into account established scientific principles. Statistical rigor and validity are generally necessary, but not sufficient, for a study or analysis to be scientifically sound.

- Directly relevant and responsive to the identified misinformation.

- Limited to the information necessary to address the identified misinformation as well as any recommended disclosures (see Q5).[28] Note, this does not mean a firm can omit information that is material to the specific content of the tailored responsive communication.

  Example 15: A firm identifies an internet-based, independent third-party communication that includes a false statement alleging that the firm is aware of and has failed to disclose that there have been multiple fatalities associated with a specific adverse reaction for the firm's prescription human drug, Drug X. The firm has received no reports of fatalities associated with the specific adverse event for Drug X.[29] However, the Prescribing Information for Drug X includes a warning for the adverse reaction. If the firm chooses to address the false statement and notes that no reports have been made to the firm regarding patient fatalities due to this adverse reaction, the warning from the Prescribing Information about the adverse reaction is material to the information in the firm's response.

[28] If a firm chooses to also include a statement in its tailored responsive communication to contact the firm's medical or scientific affairs staff for more information, that also would be consistent with the recommendations in this guidance.

[29] If the firm obtained or received adverse drug experience information, that information would be subject to the reporting requirements under 21 CFR 314.80 and 314.98.

Q5. For the purposes of the enforcement policy outlined in this guidance, what additional disclosures should a firm include in a tailored responsive communication?

FDA recommends that firms include certain disclosures in their tailored responsive communication to help ensure that audiences have the appropriate context to understand the communication, as follows:

- A mechanism for obtaining a copy of the current FDA-required labeling (including FDA-approved patient labeling, if any). This is particularly important because under the enforcement policy outlined in this guidance, depending on the nature of the identified misinformation, risk information and other key information about the approved/cleared medical product (e.g., the medical product's full indication) might not be included in the firm's tailored responsive communication if that information is not directly relevant and responsive to the identified misinformation or material to the information in the tailored responsive communication (see Q4).

- The date the firm's tailored responsive communication is posted (if a date is not automatically generated).

- A disclosure that the tailored responsive communication is being shared by the medical product firm or that the person addressing the misinformation is providing information about the medical product on behalf of the firm. For example:

  – "This information is being shared by [Firm X], the maker of [Medical Product Y]."

  – "This information is being shared on behalf of [Firm X], the maker of [Medical Product Y]."

Additionally, if a firm wishes to use a tailored responsive communication to address misinformation that suggests that the firm's approved/cleared medical product should be used for an unapproved use, FDA recommends that it include:

- A statement identifying the unapproved use or uses and noting that the unapproved use or uses of the medical product have not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use or uses has not been established. For example, the following statement would be consistent with this recommendation:

  – "[Medical Product X] has not been approved by FDA for use in [Condition Y], and the safety and effectiveness of [Medical Product X] for [Condition Y] has not been established."

Tailored responsive communications should clearly and prominently present all recommended disclosures. Factors to be considered when determining whether information is clearly and prominently presented include, but are not limited to, type size, style of font, layout, contrast,

graphic design, headlines, spacing, volume, articulation, pace, and any other techniques to achieve emphasis or notice.[30] For tailored responsive communications that have both audio and visual components, FDA recommends that disclosures be presented in both the audio and in the text at the same time using the same words (key terms and phrases or a full transcript).

Q6. Is the enforcement policy outlined in this guidance limited to tailored responsive communications that are shared by firms only in the same internet-based setting or settings where the identified misinformation appears or appeared?

No. The enforcement policy outlined in this guidance is not limited to cases in which firms share their tailored responsive communication in the same internet-based setting or settings where the identified misinformation appears or appeared. If firms choose to share their tailored responsive communication in different or additional internet-based settings, that tailored responsive communication would still fall within the enforcement policy outlined in this guidance.

> ***Example 16***: A firm decides to voluntarily address misinformation about its approved/cleared medical product that was shared through an internet-based blog by an independent third party. The firm posts a tailored responsive communication to address this specific misinformation on several social media platforms where the firm has accounts for its medical product. In the firm's social media post, the firm clearly identifies the specific misinformation to which it is responding and also includes a description of the specific location within the internet-based setting as well as the date of the independent third party's blog post that contained the misinformation.

Q7. Are there other operational and presentational considerations that FDA recommends a firm take into account when addressing misinformation with a tailored responsive communication?

Yes, there are a number of operational and presentational considerations that FDA recommends a firm take into account, as follows:

- FDA recommends that when firms choose to voluntarily address misinformation, they prioritize (1) misinformation that has current relevance (e.g., misinformation that is trending or actively spreading on internet-based platforms) and (2) misinformation that is being spread by independent third parties that have large follower bases or hold positions of trust because those users may have a wider range or a higher degree of influence. For example, a post by a social media personality with a large follower count will generally reach a broader group of users compared to a user with a small follower count.

- If the setting where a firm chooses to post its tailored responsive communication has functionality that allows communications to be shared to other settings by a user who is an independent third party, the firm should consider whether the shared version of its tailored responsive communication would include the entirety of the original post. Some settings may not allow the entirety of the tailored responsive communication, including

[30] Disclosure clarity and prominence are assessed case by case.

all disclosures recommended in this guidance, to be transferred when a firm has enabled sharing of its post to other settings.

Example 17: A firm posts a tailored responsive communication on platform A and includes the recommended disclosures in a caption within the firm's post. The firm specifically enables sharing of its post to platform B because the post will display on that platform in its entirety when shared. The firm does not enable sharing to platform C because the caption containing the disclosures will not be displayed in that platform.

- Firms should consider the layout and format of platform controls (e.g., engagement buttons) to help ensure that the firm's tailored responsive communication, including all disclosures recommended in this guidance, are not obscured in the setting where the tailored responsive communication is being posted. A firm should also consider how the location of platform controls in other settings would impact how its tailored responsive communication would appear in that setting if the firm enabled sharing of its response to that setting.

- When firms enable sharing to other settings, firms should consider how the limitations of these other settings may impact their tailored responsive communication. For example, the inclusion of platform-specific branding or watermarks applied from the use of a specific platform's built-in video creation tool can limit the distribution of the tailored responsive communication to other settings.

The following example includes layout, format, and portability considerations for a firm's tailored responsive communication.

Example 18: A firm decides to voluntarily address misinformation about its approved/cleared medical product on a social media platform and posts a response video on the firm's own social media account within the same social media platform where the misinformation was identified. The firm enables sharing of its post. The firm clearly identifies an internet-based, independent third-party communication and the specific misinformation within that communication that it is addressing. The firm includes the disclosures recommended in Q5 of this guidance in the audio as well as in on-screen text within the video component of the post instead of captions below the video because captions may not transfer with the post if the post is shared to other settings. Additionally, the firm ensures that no platform controls (e.g., engagement buttons) obscure the disclosures in the tailored responsive communication by including the on-screen text for those disclosures in the middle third of the video and considers how its post will display if shared by users to other settings.

B. General Medical Product Communications

Q8. Can a firm address misinformation about or related to its approved/cleared medical product through existing avenues other than tailored responsive communications?

Yes, a firm can use many existing avenues for communicating information about or related to its approved/cleared medical product or products, including information that addresses misinformation. For the purposes of this guidance, communications through existing avenues are collectively referred to as *general medical product communications*. With the exception of communications that fall within the enforcement policy outlined in this guidance, the inclusion of content aimed at addressing misinformation—whether implicitly or explicitly—creates no special considerations regarding the application of the FDA Authorities or other FDA enforcement policies.

Promotional communications are one type of general medical product communication that often provide information about an approved/cleared medical product's safety and effectiveness.[31] Using such promotional communications that comply with the FDA Authorities to provide truthful and non-misleading information about the approved uses of a firm's medical product is one avenue for addressing misinformation. In promotional communications, a firm can choose to address misinformation implicitly, without repeating or redirecting attention to that misinformation, or if preferred, the firm can call out the misinformation expressly, with the degree of specificity that it chooses.[32] In promotional communications, a firm can also provide a broad scope of information about its medical product, rather than retaining a narrow focus on communicating the information that is directly relevant and responsive to specific misinformation.

A firm can also design its promotional communications to be shared in a variety of settings, internet-based or not, which could support diverse strategies for addressing misinformation. For example, if a firm wants to address a misinformation concept about or related to its medical product that has become widespread in both internet-based and non-internet-based settings, choosing communications that comply with applicable FDA labeling/advertising requirements would generally give the firm flexibility to decide how to craft and direct its communications to reach as many people who may have encountered the misinformation as possible. That might include, for example, enlisting the help of HCPs through promotional communications directed to that audience; reaching the general public through a TV advertising campaign; enlisting an influencer to convey the firm's message in internet-based settings; or any combination of these techniques. If the resulting promotional communication is consistent with applicable FDA labeling/advertising requirements, there are no special considerations created by the fact that the promotional communication addresses misinformation.

FDA has issued a number of guidance documents with recommendations for firms relevant to the sharing of promotional communications about their approved/cleared medical products. The recommendations in these guidances can also be used by firms that intend to use promotional

[31] Certain exceptions exist, for example, regarding reminder labeling for prescription devices and prescription drugs and reminder advertisements for prescription drugs. See, e.g., 21 CFR 801.109(d) for prescription devices and 21 CFR 201.100(f), 201.105(d), and 202.1(e)(2)(i) for prescription drugs.

[32] While the enforcement policy outlined in this guidance includes recommendations for identifying the specific misinformation that a firm's tailored responsive communication addresses, those recommendations do not restrict a firm from identifying misinformation with specificity in other types of communications that fall outside the scope of the enforcement policy outlined in this guidance.

communications to address misinformation about or related to the approved uses of their medical products. For example, the guidance for industry *Medical Product Communications That Are Consistent With the FDA-Required Labeling: Questions and Answers* (June 2018) (CFL guidance) provides firms with specific recommendations for communicating data and information in promotional communications that are not contained within the FDA-required labeling but are consistent with the FDA-required labeling for a medical product. The CFL guidance also provides general recommendations for conveying information in a truthful and non-misleading way, with illustrative examples, to aid firms in complying with the FDA Authorities.

Additionally, the guidance for industry *Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements* (December 2023) (Quant Info guidance) outlines FDA's recommendations for how firms that include quantitative efficacy or risk information in direct-to-consumer promotional communications for their drugs can make the language and presentation more consumer friendly. The Quant Info guidance covers the following topics: (1) providing quantitative efficacy or risk information for the control group, when applicable; (2) presenting probability information in terms of absolute frequencies, percentages, and relative frequencies; (3) formatting quantitative efficacy or risk information; and (4) using visual aids to illustrate quantitative efficacy or risk information. The recommendations in the Quant Info guidance are aimed at helping firms convey information about a drug's efficacy and risks so the audience understands the information. Communications that facilitate comprehension of the information they contain can be effective tools in addressing misinformation.

In addition to the enforcement policy outlined in this guidance as it relates to addressing misinformation about or related to unapproved uses of approved/cleared medical products, FDA has issued other documents that describe other circumstances when a firm's dissemination of information regarding an unapproved use of its approved/cleared medical product, standing alone, would not be determinative of intended use.[33,34] The applicability of these documents is not changed when such a dissemination of information helps address misinformation.

FDA has also issued the draft guidance for industry *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers* (October 2023) (SIUU guidance)[35] that provides answers to common questions regarding certain communications of scientific information on unapproved use(s) of approved/cleared medical products, which may be helpful in addressing misinformation. The recommendations in the SIUU guidance are not changed when the SIUU communication helps address misinformation that may be spreading among the HCP audience.

[33] See footnote 11.

[34] See the FDA Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products (January 2017, pages 20–21) (available at https://www.regulations.gov/document?D=FDA-2016-N-1149-0040).

[35] When final, this guidance will represent FDA's current thinking on this topic.

FDA has also issued guidance that provides recommendations for firms that are interested in communicating unapproved use information with payors and similar entities[36] and has provided guidance with recommendations for industry support of scientific or educational activities (such as Continuing Medical Education programs), which can be an important source of information on medical products for HCPs.[37] In addition, it has long been FDA policy not to consider a firm's presentation of truthful and non-misleading scientific information about unapproved uses at the planned sessions and presentations at medical or scientific conferences to be evidence of intended use when the presentation is made in non-promotional settings and is not accompanied by promotional communications.[38] All of the communication types discussed in these guidances could be used by firms to address misinformation.

Finally, communications sometimes characterized as *help-seeking* or *institutional* represent another option firms have to address misinformation. These are communications that (1) do not name any specific medical product or make representations or suggestions that are associated with a specific medical product and (2) are separate and distinct from promotional communications about any specific approved/cleared medical product. Such communications are often used to provide information to raise awareness about diseases or general classes of available treatments. This information may be helpful in addressing false, inaccurate, or misleading information on these topics.[39]

[36] See the guidance for industry and review staff *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities: Questions and Answers* (June 2018). See also section 502(gg) of the FD&C Act enacted in December 2022 as part of the Consolidated Appropriations Act, 2023 (Public Law 117-328).

[37] See the guidance for industry *Industry-Supported Scientific and Educational Activities* (December 1997).

[38] See footnote 34.

[39] These help-seeking or institutional communications are generally not subject to the FDA Authorities.