King & Spalding

Client Alert

FDA and Life Sciences

JULY 12, 2024

For more information, contact:

Lisa M. Dwyer
+1 202 626 2393
ldwyer@kslaw.com

Gary C. Messplay
+1 202 626 9224
gmessplay@kslaw.com

Nikki Reeves
+1 202 661 7850
nreeves@kslaw.com

Jessica Ringel
+1 202 626 9259
jringel@kslaw.com

Jeffrey K. Shapiro
+1 202 626 2927
jshapiro@kslaw.com

Elaine H. Tseng
+1 415 318 1240
etseng@kslaw.com

Heather Banuelos
+1 202 626 2923
hbanuelos@kslaw.com

Gillian M. Russell
+1 202 661 7978
grussell@kslaw.com

McKenzie Cato
+1 202 626 9270
mcato@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Suite 900
Washington, D.C. 20006
Tel. +1 202 737 0500

FDA Issues Updated Draft Guidance on Addressing Misinformation About Medical Devices and Prescription Drugs

On July 8, 2024, the U.S. Food and Drug Administration ("FDA") issued a new draft guidance for industry titled, *Addressing Misinformation About Medical Devices and Prescription Drugs – Questions and Answers* (hereafter, "Addressing Misinformation Guidance").[1] The Addressing Misinformation Guidance revises and replaces the draft guidance on misinformation issued in June 2014, *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices* (hereafter, "2014 Draft Guidance"). See our prior Client Alert summarizing the 2014 Draft Guidance.

The Addressing Misinformation Guidance sets forth an enforcement policy applicable to the internet-based communications of entities legally responsible for approved/cleared medical product labeling ("firms").[2] The Addressing Misinformation Guidance provides recommendations for firms that wish to address internet-based misinformation about or relating to their medical products, including medical devices, prescription drugs, and prescription animal drugs. In essence, the Addressing Misinformation Guidance provides a compliance "safe harbor" allowing firms to correct misinformation that third parties may put online without the corrective communication itself triggering the usual legal requirements that apply to a firm's labeling and advertising. FDA's stated intent is to expand the communication options available to firms.

BACKGROUND

The Addressing Misinformation Guidance incorporates feedback from interested third parties since the release of the 2014 Draft Guidance, which had remained in its draft form for a decade and was never finalized.[3] FDA indicates that the intent of the replacement Addressing Misinformation Guidance is to better "empower industry seeking to

voluntarily address misinformation related to their approved/cleared medical products" and to "ensure industry has clarity and additional flexibility to promptly and proactively issue responsive communications to address misinformation they are seeing."[4]

The Addressing Misinformation Guidance emphasizes the importance FDA places on facilitating public access to accurate, up-to-date, science-based information about health and medical products. It observes that both patients and providers often seek information on the internet, and that for patients in particular, the internet has become the leading source of information about health. FDA views the Addressing Misinformation Guidance as helping to combat internet misinformation and it seeks the cooperation of drug and device manufacturers to achieve this goal.[5]

The Addressing Misinformation Guidance sets out guidelines for when and how firms can address false or misleading information posted on the internet by independent third parties about their FDA-approved medical products. If a firm voluntarily corrects internet-based misinformation created or disseminated by independent third parties in the manner described in the Addressing Misinformation Guidance, FDA will not enforce the usual requirements related to promotional labeling and advertising,[6] and, for drugs and biologics, post-marketing submission of promotional communications.[7] Similarly, FDA states that, if a firm voluntarily corrects misinformation suggesting that the firm's approved/cleared product should be used for an unapproved use, FDA will not use the correction communication standing alone as evidence of a new intended use,[8] if the correction is done in the manner described in the guidance.

SCOPE OF THE ADDRESSING MISINFORMATION GUIDANCE

The Addressing Misinformation Guidance applies only to a firm's voluntary responses to internet-based misinformation created or disseminated by independent third parties about or related to the firm's approved/cleared medical products. The Addressing Misinformation Guidance defines "misinformation" as "implicit or explicit false, inaccurate, or misleading representations of fact about or related to the firm's approved/cleared medical product."[9]

In comparison, the 2014 Draft Guidance defined "misinformation" as "positive or negative incorrect representations or implications about a firm's product created or disseminated by independent third parties."[10] Where the 2014 Draft Guidance used the term "incorrect" in the definition, the Addressing Misinformation Guidance now uses the terms "false, inaccurate, or misleading," more closely mirroring the language in the Federal Food, Drug, and Cosmetic Act defining drugs and devices as misbranded if the labeling is "false or misleading in any particular."[11]

As described in the Addressing Misinformation Guidance, misrepresentation includes false, inaccurate, or misleading representations about or related to:

- Unapproved uses of the firm's approved/cleared medical product;
- Instructions or directions for use from the FDA-required labeling of the firm's approved/cleared medical product;
- Attributes of the firm's approved/cleared medical product independent of any particular use (such as statements about where a medical product is made or statements about its components);
- Scientific information about or related to the firm's approved/cleared medical product; and
- Representations that omit a fact or facts that are material in light of the representations made related to the firm's approved/cleared medical product.[12]

"Misinformation" is not limited to communications that explicitly name a firm's product or products. Misinformation may include false or misleading representations about an entire class of drugs or category of products. If a firm's

FDA-cleared or FDA-approved product is included in the referenced class, a response to that misinformation would be covered by the enforcement policy outlined in the Addressing Misinformation Guidance.[13]

The Addressing Misinformation Guidance applies only to misleading communications created by "independent third parties." An "independent third party" is defined as "a person or entity that, in communicating about a firm's approved/cleared medical product, is not acting on behalf of that firm."[14] Communications created by a firm or those acting on behalf of the firm are not within the scope of the guidance.

TV and radio advertisements do not qualify for the enforcement discretion provided by the Addressing Misinformation Guidance, even when distributed via the internet. The Addressing Misinformation Guidance clarifies that such ads would be considered general medical product communications subject to all applicable FDA authorities and any other applicable enforcement policies, even if they are issued to correct third party communications.

TAILORED RESPONSIVE COMMUNICATIONS

When a firm identifies internet-based misinformation from an independent third party about its approved/cleared medical products, the firm may respond with a so-called tailored responsive communication. When a firm issues such communication in the manner described in the Addressing Misinformation Guidance, FDA has indicated that it will not enforce applicable requirements related to promotional communications or use the response, standing alone, as evidence of a new intended use.

Content of Tailored Responsive Communications

A tailored responsive communication should clearly identify both the specific misinformation that the firm is addressing and the specific internet-based, independent third-party communication in which that misinformation appears.

Firms may meet this requirement in several ways. A firm's tailored responsive communication can be shared in conjunction with the third-party misinformation. Alternatively, a firm can capture and embed the internet-based communication containing the misinformation in its tailored responsive communication. Even when addressing widespread misinformation, the firm should, at a minimum, clearly identify at least one internet-based communication from an independent third party with the applicable misinformation.

A tailored responsive communication should clearly identify what specific misinformation within the third-party communication the response is addressing. If a firm indicates that it is responding to a specific portion of a communication, it should address each piece of misinformation in that portion of the communication.

The information within a tailored responsive communication must be:

- Truthful and accurate;
- Scientifically sound – at a minimum, any study or analysis informing the response should meet generally accepted design and other methodological standards for the particular type of study or analysis at issue;
- Directly relevant and responsive to the identified misinformation; and
- Limited to the information necessary to address the identified misinformation as well as any recommended disclosures.

Recommended Disclosures for Tailored Responsive Communications

FDA recommends that firms include certain disclosures in their tailored responsive communications. First, because the firm's tailored responsive communication might not otherwise contain risk information, FDA recommends including a mechanism for obtaining a copy of the current FDA-required labeling, including FDA-approved patient labeling, if any. FDA makes this recommendation for all medical products, even though medical device labeling is not typically as readily available online as FDA-approved labeling for drugs and biologics. Next, FDA recommends that the communication include the date that the response was posted if one is not automatically generated by the platform on which the communication is shared. Finally, FDA recommends a disclosure that the information is being provided by or on behalf of the medical product firm.

There are additional recommendations regarding tailored responsive communications that address unapproved uses. Importantly, FDA recommends a statement identifying the unapproved use and noting that such use has not been approved by the FDA and the safety and efficacy of the product for that use has not been established.

All recommended disclosures should be presented "clearly and prominently."[15] Relevant factors include type, size, style of font, layout, contrast, graphic design, headlines, spacing, volume, articulation, pace, and other techniques to achieve emphasis or notice. For tailored responsive communications that have both audio and video elements, FDA recommends that the disclosures be presented in both audio and text at the same time using the same words.

Location and Form of Tailored Responsive Communications

Tailored responsive communications need not appear in the same setting as the misinformation-containing communication being addressed. Setting is defined as "the location where content appears" including websites, internet-connected applications, platforms, or other internet-based media.[16] Firms may choose to share their tailored responsive communications in different or additional internet-based settings so long as the specific misinformation-containing communication being responded to is clearly identified.

GENERAL MEDICAL PRODUCT COMMUNICATIONS

The Addressing Misinformation Guidance clarifies that firms may also use existing, non-internet-based methods to address misinformation, defined as "general medical product communications."[17] This includes firm-sponsored sales aids, TV and radio advertisements, help-seeking and institutional communications, and any other communication that does not meet the requirements for an internet-based tailored responsive communication.

The Addressing Misinformation Guidance does not make any changes to FDA's existing approach to general medical product communications. It states that if such communications happen to include content aimed at addressing misinformation – whether implicitly or explicitly – the usual rules and FDA enforcement policies would apply.

HOW DOES THE ADDRESSING MISINFORMATION GUIDANCE DIFFER FROM THE 2014 DRAFT GUIDANCE?

The enforcement policy outlined in the Addressing Misinformation Guidance differs from the 2014 Guidance in scope, procedure, and emphasis.

The Addressing Misinformation Guidance is more expansive as to the types of misinformation within the scope of the enforcement policy. Whereas, under the 2014 Draft Guidance, the policy applied only to communications about a firm's own product, the Addressing Misinformation Guidance permits responses to misinformation concerning entire classes of drugs or categories of products.

The procedures for correcting misinformation under the Addressing Misinformation Guidance are also more flexible. Under the 2014 Draft Guidance, firms responding to misinformation had to clearly define the portion of a forum being corrected and correct all the misinformation in that section of the forum. Under the Addressing Misinformation Guidance, responses should clearly identify the misinformation being addressed and at least one specific internet-based communication created or disseminated by an independent third party in which that misinformation appears.

Similarly, the Addressing Misinformation Guidance permits more flexibility in the form and location of responses to misinformation. The 2014 Draft Guidance permitted only a few specific methods of responding to misinformation, namely posting the correction where the misinformation appeared, posting a link to a reputable source containing the correct information, or requesting the removal of the misinformation. In contrast, the Addressing Misinformation Guidance notes that tailored responsive communications do not need to appear in the same setting or medium as the misinformation being corrected.

Finally, the Addressing Misinformation Guidance places particular emphasis on misinformation suggesting unapproved uses of FDA-approved or cleared products. The Addressing Misinformation Guidance outlines specific rules for responses to this type of misinformation, including an additional disclosure regarding safety and efficacy for unapproved uses. As noted, the Addressing Misinformation Guidance clarifies that if these requirements are followed, the responses standing alone will not be treated as evidence of a new intended use.

CONCLUSION

The enforcement policy outlined in the Addressing Misinformation Guidance clarifies how drug and device manufacturers can address online misinformation about or related to their products and allows firms to issue tailored responsive communications without meeting the usual requirements for promotional labeling and advertising. The Addressing Misinformation Guidance appears to have broadened the scope of the policy first outlined in the 2014 Draft Guidance, providing more flexibility in identifying and responding to misinformation.

Comments on the Addressing Misinformation Guidance are due by September 9, 2024.[18]

[1] Food & Drug Admin., *Guidance for Industry: Addressing Misinformation About Medical Devices and Prescription Drugs - Questions and Answers*, (July 8, 2024), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/addressing-misinformation-about-medical-devices-and-prescription-drugs-questions-and-answers (hereafter, "Addressing Misinformation Guidance").
[2] The Addressing Misinformation Guidance defines "firms" as "persons or entities legally responsible for the labeling of approved/cleared medical products, which includes applicants, sponsors, manufacturers, packers, distributors, and any person communicating on behalf of these entities." Addressing Misinformation Guidance at 5.
[3] FDA, Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request, 89 Fed. Reg. 56,387, 56,388 (July 9, 2024).
[4] FDA, Press Release, *FDA Updates Guidance to Further Empower Companies to Address the Spread of Misinformation* (July 8, 2024), https://www.fda.gov/news-events/press-announcements/fda-updates-guidance-further-empower-companies-address-spread-misinformation.
[5] *See id.*
[6] *See, e.g.*, 21 U.S.C. §§ 321(n), 352(a), 352(n) 352(q)-(r); 21 C.F.R. §§ 1.21(a), 202.1(e).
[7] *See, e.g.*, 21 C.F.R. §§ 314.81(b)(3)(i) and 601.12(f)(4) (regarding post-marketing submissions of promotional communications for drugs and biologics for human use using Form FDA 2253); 21 U.S.C. § 356(c)(2)(A)(ii) and 21 C.F.R. §§ 314.550 and 601.45 (regarding submissions of promotional communications for accelerated approval products).
[8] The Addressing Misinformation Guidance provides a description of the concept of "intended use" on page 3, n.11.
[9] Addressing Misinformation Guidance at 4.
[10] 2014 Draft Guidance at 2.
[11] 21 U.S.C. § 352(a)(1).
[12] Addressing Misinformation Guidance at 4-5.
[13] *Id.* at 9.
[14] *Id.* at 6.
[15] *Id.* at 16.
[16] *Id.* at 6.
[17] *Id.* at 19.
[18] Comments may be submitted electronically at https://www.regulations.gov/document/FDA-2014-D-0447-0020 or by mail to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 identified with Docket Number FDA-2014-D-0447.