

FDA ISSUES FINAL GUIDANCE ON COMMUNICATIONS ABOUT UNAPPROVED USES OF MEDICAL PRODUCTS

Before the U.S. Food and Drug Administration ("FDA" or "Agency") halted communications with the industry after the Presidential Inauguration on January 20, 2025, the Agency issued a final guidance for firms in the medical products industry titled, "[Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers](#)" ("Final Guidance"). The Final Guidance summarizes FDA's enforcement policies related to communications by firms regarding unapproved uses of medical products (referred to as "SIUU communications") and aims to balance the need for health care providers ("HCPs") to access scientific information with FDA's mandate to protect public health and ensure compliance with regulatory standards.

This guidance finalizes FDA's revised draft issued in [October 2023](#), which updated and replaced the [2014](#) and [2009](#) draft guidance documents. That said, the Final Guidance is not for current implementation, pending the Office of Management and Budget's decision on the collection of information.

POLICY

The Final Guidance emphasizes that SIUU communications must be truthful, non-misleading and include all necessary information to help HCPs assess the validity, strengths, weaknesses and clinical utility of the scientific data shared. According to the Final Guidance, if a firm follows FDA's recommendations and shares such information with HCPs, FDA would not consider this communication alone as evidence of the firm's intention to promote the product for an unapproved use, nor does it require the firm to submit the communication to the Agency at the time of dissemination. While FDA seeks to reassure in the Final Guidance, it is important to keep in mind that such communications, combined with other factors, could be used as evidence of the firm's intended use of the product, potentially leading to the product being deemed misbranded or adulterated if it violates premarket requirements.

KEY RECOMMENDATIONS

Selecting Source Publications

When determining whether a source publication is appropriate to be included in an SIUU communication, FDA recommends the following:

1. Source publications included by firms in SIUU communications should describe studies and analyses that are scientifically sound.
2. Firms should take into account existing scientific knowledge to determine whether a source publication is appropriate to include in an SIUU communication, both when initially preparing the communication and at the time of each dissemination of that communication.
3. Any conclusions articulated in a source publication should align with the prespecified hypothesis or research question from the described study or analysis and be supported by the results from that study or analysis.

Content of SIUU Communications

FDA recommends that firms include all of the following information as part of SIUU communications:

1. A statement that the unapproved use(s) of the medical product has not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use(s) has not been established.
2. A statement disclosing FDA-approved use(s) of the medical product, including any limitations of use specified in the FDA-required labeling.
3. A statement disclosing any limitations, restrictions, cautions, warnings or precautions described in the FDA-required labeling about the unapproved use(s).
4. A copy of the most current FDA-required labeling (or a mechanism for obtaining this labeling, as appropriate).
5. A statement describing any contraindication(s) in the FDA-required labeling for the medical product.

6. A statement describing any serious, life-threatening or fatal risks posed by the medical product that is in the FDA-required labeling for the medical product or known by the firm and that is relevant to the unapproved use(s).
7. A statement identifying any authors, editors or other contributors to publication(s) included in the SIUU communication who were employees of or consultants to or who received compensation from the firm at the time of writing, editing or contributing to the publication, to the extent a firm acting reasonably would know of such relationship.
8. In the case of an SIUU communication that includes one or more source publications primarily focused on a particular scientific study or studies for each such study where the following information is not included in the source publication, provide a description of:
 - o All material aspects of study design, methodology and results.
 - o All material limitations related to the study design, methodology and results.
 - o Any conclusions—from other scientifically sound studies that evaluated the same or similar hypotheses or research questions—that are in conflict with the conclusions from the studies or analyses described in the source publication(s). The citations for any such studies should also be included.
9. The publication date of any referenced or included source publication (if not specified in the source publication or citation).

Presentation Considerations

To ensure HCPs understand and evaluate an SIUU communication effectively, FDA recommends that:

1. SIUU communications should clearly and prominently present the disclosures recommended in the Final Guidance.
2. SIUU communications should be separate from promotional communications about approved uses of medical products.
3. SIUU communications should be shared through media and via platforms that enable firms to implement the recommendations in the Final Guidance.

Recommendations for Specific Materials

Reprints

When sharing SIUU communications that include reprints, firms should ensure the articles are unaltered and unabridged to avoid introducing bias or omitting important information. FDA recommends that the articles shared meet certain criteria:

1. The article should be published in a journal managed by an independent organization that has an editorial board composed of individuals who have demonstrated expertise in the subject of the articles under review by the organization (through education or experience) and that has a publicly stated policy regarding the disclosure of conflicts of interest or biases for all authors, contributors and editors.
2. The article is peer-reviewed by experts in the subject of the article, as established by education or experience.
3. The article is generally available (or the journal from which the article is taken is generally available) through independent distribution channels (e.g., internet sources, book retailers, subscriptions, libraries) where periodicals and reprints are sold or are accessible.

Clinical Practice Guidelines ("CPGs")

When firms include CPGs in SIUU communications, FDA recommends that the CPG:

1. Is based on rigorous reviews of the existing evidence conducted according to a clear, established procedure and following a transparent process that minimizes biases and conflicts of interest.
2. Includes ratings of the recommendations to reflect the quality and strength of evidence that supports each recommendation.
3. Is revised when important new evidence warrants modifications of current recommendations.
4. Is generally available through independent distribution channels (e.g., internet sources, book retailers, subscriptions, libraries) where CPGs are sold or are accessible.

To ensure their appropriateness for inclusion in SIUU communications, FDA also recommends that firms consider CPGs that follow the National Academy of Medicine's trustworthiness standards.

Reference Texts and Materials from Digital Clinical Practice Resources

FDA recommends that a reference text or material from a digital clinical practice resource have all of the following characteristics if included in an SIUU communication:

1. It is published by an independent publisher that is in the business of publishing scientific or medical educational content.
2. It is published in a manner consistent with current standards for medical content creation and review that are generally accepted by the medical publishing industry and in accordance with any specific peer-review procedures of the publisher.
3. It is authored, edited and contributed to by experts who have demonstrated expertise in the subject area(s) through education or experience.
4. It is generally available or sold through independent distribution channels (e.g., internet sources, book retailers, subscriptions, libraries) for medical and scientific educational content reference texts or material(s) from digital clinical practice resources that misrepresent or overstate findings from a study or analysis in light of the limitations of such study or analysis would not fall within the enforcement policy outlined in the Final Guidance.

Firm-Generated Presentations

Unlike independent source publications, which are generally available and have an inherent level of independence, firm-generated presentations are crafted by the firms themselves, presenting additional challenges in maintaining scientific integrity. These presentations must focus on truthful, non-misleading information from source publications, clearly disclose their origin and include all relevant study details, including limitations. Importantly, firms should avoid misrepresenting study results or using techniques that might mislead HCPs such as implying greater generalizability of data or making unsupported claims about a product's safety and effectiveness.

Specifically, FDA recommends that firm-generated presentations should:

1. Be limited to the scientific information on unapproved use(s) from one or more source publications, and the source publication(s) should be consistent with the recommendations outlined in the Final Guidance.
2. Be provided with the source publication(s).
3. Include all information material to the representations made in the firm-generated presentation with those representations within the firm-generated presentation.
4. Include the disclosures and also clearly disclose what portions of the SIUU communication are firm-generated.
5. Be consistent with the recommendations in the Final Guidance regarding presentational considerations.

PRACTICAL TAKEAWAYS

1. Firms should ensure that SIUU communications adhere closely to FDA's recommendations in the Final Guidance to avoid inadvertently promoting a product for unapproved uses in a way that could result in an enforcement action. To prevent confusion, SIUU communications about unapproved uses should be distinct from promotional communications regarding approved uses of a medical product. This helps avoid misleading HCPs into thinking that the product is safe and effective for all listed uses, including unapproved ones.
2. Firms should evaluate the platforms and media used to disseminate SIUU communications to ensure they meet FDA's requirements for transparency and full disclosure. As such, it is likely that certain platforms would not be appropriate places to disseminate SIUU communications but could be used to direct HCPs to the information.

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