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FDA's Final Guidance on Firm Communication to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products

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The U.S. Food and Drug Administration (FDA) recently finalized its 2023 draft guidance to industry on certain firm-initiated communications of scientific information on unapproved use(s) (SIUU) of medical products to health care providers (HCPs). The guidance is titled, "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers."[1] Importantly, this guidance applies only to communications about an "unapproved use of an approved product." It does not cover statements about products that have not been approved. In common terms, "pre-approval promotion."

A key tenet underlying the enforcement policy is to promote public health. Thus, any individual firm-initiated communication of SIUU should be truthful and non-misleading and provide all information necessary for HCPs to understand and evaluate the strengths, weaknesses, and clinical utility of the SIUU. The final guidance provides recommendations consistent with those principles. Implementation is pending Office of Management and Budget (OMB) approval of information collection.

This guidance is important because it helps life sciences companies navigate issues concerning scientific advancements that occur after their products launch. In 2021, the FDA revised its Intended Use Regulation (2021 Final Rule),[2] saying it would consider a wide variety of firm activity as evidence of a firm's intent to promote a new, unapproved use. This intent could become important if there were later allegations of misbranding. Nevertheless, firms often need to share this information because HCPs find it valuable when making clinical decisions about their patients. The January guidance aims to reassure firms that if their communications align with FDA recommendations, FDA will not consider those communications alone as evidence of a new intended use. Additionally, firms will not be required to submit such communications to FDA at the time they share them with HCPs.

Key Recommendations

- Guidance concerning source publications:
    - Source publications should describe studies and analyses that are scientifically sound.
    - Firms should take into account existing scientific knowledge to determine whether a source publication is appropriate to include, both when initially preparing the communication and at the time of each subsequent dissemination.
    - 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.

- SIUU communications should state:
    - The use(s) has not been approved by FDA and the safety and effectiveness of the medical product for the unapproved use(s) has not been established.
    - The FDA-approved use(s) of the medical product, including any limitations of use specified in the FDA-required labeling.
    - Any limitations, restrictions, cautions, warnings, or precautions described in the FDA-required labeling about the unapproved use(s).
    - Any contraindication(s) in the FDA-required labeling for the medical product.
    - Any serious, life-threatening, or fatal risks posed by the medical product that are in the FDA-required labeling for the medical product or known by the firm and that are relevant to the unapproved use(s).

- Firms should also:
    - Identify 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.
    - Include a copy of the most recent prescribing information (or provide a mechanism for obtaining it, e.g., a QR code or link).

- When presenting SIUU, firms should:
    - Clearly and prominently present the recommended disclosures.
    - Separate SIUU from promotional communications.
    - Share SIUU through only media and via platforms that enable firms to implement the FDA's recommendations.

- When disseminating reprints firms should clearly disclose the article:
    - Is published in a journal managed by an independent organization that has an editorial board composed of persons 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.

- Is peer-reviewed by experts in the subject of the article, as established by education or experience.
- 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.

- Guidance regarding clinical references:

  - The SIUU communication should include all information from the clinical reference resource necessary for HCPs to interpret the strengths and weaknesses, validity, and clinical utility of the scientific information on unapproved use(s) that the clinical reference resource presents. This may involve the sharing of multiple sections of the clinical reference resource that contain related or linked information. Any sections shared must remain unaltered, unabridged, and directly extracted from the original clinical reference resource.

[1] Food and Drug Admin., *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers* (Jan. 2025), https://www.fda.gov/media/184871/download.
[2] 86 Fed. Reg. 41383 (Aug. 2, 2021).

