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FDA Finalizes Guidance on Communication of Unapproved Uses of Approved or Cleared Medical Products

January 17, 2025

Reading Time : **2 min**

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On January 6, 2025, the FDA released final guidance for industry entitled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers." The guidance outlines FDA's enforcement policy concerning certain firm-initiated communications of scientific information on unapproved uses (SIUU) of the firm's approved or cleared medical products to health care providers involved in prescribing or administering those products to individual patients. It finalizes the October 2023 draft guidance, which itself revised draft guidance from 2014 and 2009. The latest guidance is not for current implementation and is pending the Office of Management and Budget's (OMB) approval of the guidance's information collection provisions.

Although a firm's SIUU communication may indicate the product's intended use and could suggest the firm's noncompliance with premarket authorization requirements or the product's misbranding or adulteration, the FDA recognizes that health care providers may seek SIUU to inform clinical practice decisions for individual patients. Through this long-awaited final guidance, the FDA is providing an assurance to firms that SIUU communications made in accordance with these recommendations will not, on their own, be treated as evidence of a new intended use. The FDA's recommendations aim to ensure that SIUU communications are truthful, non-misleading and provide sufficient information to help health care providers assess the strengths, weaknesses, validity and clinical utility of the scientific information. The guidance includes specific recommendations for the sharing of certain resources in a SIUU, such as source publications (reprints, clinical practice guidelines, reference texts and digital

clinical practice resources) and firm-generated presentations. In particular, the final guidance makes several clarifications or changes that will largely be welcomed by firms marketing drugs and devices, including:

- Opening the door to SIUUs relying on early-stage data, if such data are scientifically sound.
- Clarifying that presentational elements may be used to illustrate or explain scientific content, which was not clear from the draft guidance.
- Confirming that communications do not have to be based on reprints of journal articles to fall within the policy, and may also be based on other types of publications such as clinical practice guidelines.
- Abandoning the proposed clinical relevance standard in favor of a standard of scientific soundness.
- Clarifying that there is no expectation to submit SIUU communications to the FDA in advance of dissemination or use.

Comments on the collection of information will be received until February 21, 2025.

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