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CLIENT ALERT

FDA Proposes Clarifying Amendments to Its Medical Product "Intended Use" Regulations

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On September 23, 2020, the Food and Drug Administration (FDA or the Agency) published proposed rules to amend its medical product "intended use" regulations.[1] FDA will accept written and electronic comments on the proposal until October 23, 2020.

FDA's action is intended to provide direction and clarity to regulated industry and other stakeholders and further repeals and replaces portions of the final rule issued on January 9, 2017, that never became effective. The proposed regulations provide for and describe the types of evidence relevant to determining a product's intended uses under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act (PHS Act), and FDA's implementing regulations, including but not limited to whether a product meets the definition of a drug or device, whether an approved or cleared medical product is intended for a new use, whether a manufacturer must add information to the label regarding awareness of unapproved uses for the product, and further guidance on the regulation of tobacco intended for human consumption.

See Regulations Regarding "Intended Uses," *available at* https://www.fda.gov/news-events/press-announcements/fda-clarifies-types-evidence-relevant-determining-intended-use-fda-regulated-products?utm_medium=email&utm_source=govdelivery.

First, FDA's proposed action seeks to better reflect the Agency's current practice in evaluating whether a product is intended for use as a drug or device, including whether an approved or cleared medical product is intended for a new use. In particular, FDA seeks to address industry concern that the last sentence of section 201.128 could be read to mean that a firm's[2] mere knowledge of an unapproved use of its approved drug product automatically triggers requirements for new labeling that, in turn, renders distribution of that approved product unlawful without approval of a supplemental application.

For example, health care providers commonly prescribe or use approved or cleared medical products for unapproved, so-called "off-label," uses when they judge that the unapproved use is medically appropriate for their patient. In this instance, the Agency would not regard a firm as intending an unapproved use based solely on the firm's knowledge that such product was being prescribed or used by health care providers off-label. To remedy this, FDA's proposal deletes the contested sentence and inserts a new clause to clarify that a firm's knowledge (potentially derived from sales and orders, among other sources) that health care providers are prescribing or using

its approved or cleared medical product for an unapproved use would not, *by itself*, automatically trigger obligations for the firm to provide labeling for that unapproved use.

FDA also notes that knowledge of a physician's off-label prescription of a medical product in combination with conduct that falls within an acknowledged safe harbor would not be sufficient to establish a new intended use. Indeed, there may be limited instances where a firm disseminates safety information about an unapproved use to minimize risk to patients. Such action does not trigger the prohibitions on distributing a product for an unapproved use or misbranding a product and, similarly, is not itself evidence of a new intended use and, therefore, does not automatically trigger the obligation to seek modifications to the label. FDA further notes that this inquiry is heavily fact-bound, and under other circumstances or in other contexts, similar material may be evaluated differently by the Agency.

Second, FDA proposes amending the text of section 201.128 and section 801.4 to provide clarification regarding the types of evidence that are relevant to determining a product's intended uses. FDA is reaffirming its longstanding position that "in evaluating a product's intended use, any relevant source of evidence may be considered." FDA notes that this understanding is, first, unchanged, and likewise supported by case law. Indeed, evidence of intended use may include the product's labeling, promotional claims, and advertising, among other sources. Further, any claim or statement made by or on behalf of a firm that explicitly or implicitly promotes a product for a particular use may be taken into account.

A firm's subjective claims of intent are not necessarily exclusively determinative of an intended use; however, objective evidence of the firm's intent (evidenced by a variety of direct and circumstantial evidence) *is* relevant—particularly when it contradicts the firm's claims. Further, FDA believes that the public's health could be put at risk from the Agency endorsing a narrow view of identifying an intended use, compiled solely from firms' claims, because the approach could create a loophole for evading FDA oversight and could open the door to the marketing of products that are unapproved for any medical use. In any event, consistent with FDA practice and relevant case law, courts have rejected the narrow proposition that evidence of intended use is limited solely to the manufacturer's labeling or its other claims concerning a drug or device. Instead, intended use is determined by looking to **all** relevant evidence, including:

- express claims and representations;
- implied claims;
- product characteristics, including known physiological effects, and design; and
- circumstances of the sale or distribution.

Third, FDA is also proposing to insert into section 201.128 and section 801.4 a reference to language already present in section 1100.5 (21 C.F.R. § 1100.5) that describes when a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or combination product. Through this language, FDA hopes to clarify the interplay between the drug and device intended use regulations and FDA's separate regulations governing products that are made or derived from tobacco and intended for human consumption.

We note that government orders on the local, state, and federal levels are changing every day, and the information contained herein is accurate only as of the date set forth above.

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For further information or questions on FDA's rulemaking or to submit a comment with Winston & Strawn, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher Parker, or your Winston relationship attorney.

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[1] Sections 201.128 and 801.4 (21 C.F.R. §§ 201.128 and 801.4).

[2] “Firm” refers to manufacturers, packers, and distributors of FDA-regulated products and all their representatives, including both individuals and corporate entities.

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