Correcting Online Misinformation About FDA-Approved or Cleared Medical Products

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The FDA released a draft guidance earlier this year titled, *Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers* (the "**Guidance**"), to announce an updated policy of enforcement discretion available to drug and device companies seeking to respond to misinformation related to their FDA-approved or -cleared medical products disseminated online by third parties. This Guidance revises and replaces the Agency's similarly titled draft guidance on this topic, issued almost exactly 10 years prior. In the new Guidance, FDA clarifies the two different approaches firms may utilize to address online misinformation: (1) general medical product communications and (2) "tailored responsive communications." While the former refers to existing avenues of communicating to the public (e.g., sales aids, TV and radio advertisements, and help-seeking and institutional communications), which remain subject to all applicable FDA regulations, the Guidance outlines an enforcement discretion policy for the latter. In particular, FDA does not intend to enforce its regulations governing promotional communications about medical products (e.g., requirements for prescription drug or medical device labeling, advertising, and/or postmarket submissions, as applicable) when a firm uses tailored responsive communication to address misinformation. This summary focuses specifically on tailored responsive communications and the criteria that must be met for FDA's enforcement discretion to apply.

Read the full article here.