White Paper

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Keeping it Legal: Managing FDA Compliance for Consumer-Generated Content

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Social technology platforms allow manufacturers to leverage consumer-generated content about their products ("CGC") more easily than ever before. Such CGC generally takes the form of written testimonials and product reviews from independent, third-party consumers published on discussion forums, blogs, or online message boards. When collecting and utilizing CGC in promotional activities, manufacturers of regulated products should take steps to remain transparent and compliant with regulating authorities.

Regulatory Landscape

The Food and Drug Administration ("FDA") and the Federal Trade Commission ("FTC") share overlapping jurisdiction over the promotion of certain products, including drugs, dietary supplements, food, medical devices, and cosmetics. The two agencies operate pursuant to a 1971 Memorandum of Understanding ("MOU"), under which the FDA exercises primary responsibility for regulating the labeling of these products, as well as the advertising of prescription drugs, while the FTC has primary responsibility for enforcing laws against false or misleading advertising for all non-prescription drug products.[1] Depending on the type of product and where the CGC is published, CGC may become product labeling or advertising and thus be subject to FDA and FTC regulations. This white paper generally describes aspects of the FDA's regulation of CGC, but manufacturers should be aware of this joint jurisdiction and consider the entire regulatory landscape when endeavoring to leverage CGC.[2]

[1] FTC, "Memorandum of Understanding between the Federal Trade Commission and the Food and Drug Administration" (May 1971).

[2] The primary source of rules enforced by the FTC with regard to CGC is the FTC's "Guides Concerning the Use of Endorsements and Testimonials in Advertising" is available at 16 C.F.R. Part 255. Additional rules also governing promotional materials that manufacturers should consider when collecting and utilizing CGC include, for example, state consumer protection and misrepresentation laws, Section 43 of the Lanham Act (Pub.L. 79-489, 60 Stat. 427, codified at 15 U.S.C. §1051 *et seq.*), pre-clearance of television ads by networks and broadcast authorities, etc.

FDA Regulation of Labeling and CGC

Pursuant to federal law and the MOU described above, the FDA exercises regulatory jurisdiction over the labeling of several product categories, including prescription and over-the-counter drugs, food, dietary supplements, and cosmetics. Federal law defines "labeling" to include "all labels and other written, printed, or graphic matter (1) *upon* any article or any of its containers or wrappers, or (2) *accompanying* such article."[3] The FDA has issued a regulation defining labeling materials to include: "[b]rochures, booklets, mailing pieces, detailing pieces . . . calendars, price lists, catalogs . . . letters, motion picture films . . . sound recordings, exhibits, literature and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug . . . *which are disseminated by or on behalf of its manufacturer, packer, or distributor*."[4] Thus, labeling includes a broad spectrum of written materials which are designed for use in the distribution and sale of a product and which are distributed by or on behalf of that product's manufacturer. Generally, manufacturers are responsible for all content that appears on their products' labeling. This can be problematic if, for example, such content includes unsubstantiated health and safety claims or advocates for off-label uses.

Though not expressly confirmed in statute or regulation, the FDA considers a manufacturer's product websites to be extensions of its product's labeling.[5] Generally, a manufacturer is responsible for promotional communications on sites it owns, controls, creates, or influences, or that are operated by the manufacturer or on its behalf. However, the FDA has indicated that a manufacturer is not responsible for "truly independent" CGC contained on such websites.[6] According to the FDA, CGC will be deemed independent if it is not produced by, on behalf of, or prompted by the manufacturer, regardless of whether the manufacturer owns or operates the platforms on which the content is published. However, CGC may be attributed to the manufacturer if the manufacturer actively influences the content in some way, such as by liking, endorsing, soliciting, incentivizing, editing or highlighting it. This could include, for example, rearranging the order of CGC on a message board so as to move positive content to the top; indicating that CGC is particularly helpful or accurate; or suggesting that consumers use certain terms or phrases in CGC.

A manufacturer may seek to remedy misinformation contained in CGC published on its websites by (1) correcting misinformation directly on the websites (either by providing appropriate truthful and non-misleading corrective information or providing a reputable source from which to obtain the correct information, such as the manufacturer's contact information), (2) providing corrective information to the independent author for incorporation, or (3) removing the misinformation. While there is no requirement that manufacturers correct misinformation, the FDA advises that any correction of misinformation be:

- Relevant and responsive, and limited and tailored, to the misinformation;
- Non-promotional in nature, tone, and presentation;
- Consistent with FDA-required labeling;

[3] 21 U.S.C. § 321(m) (emphasis added).

[4] 21 C.F.R. § 202.1(l)(2) (emphasis added).

[5] FDA, Letter to Washington Legal Foundation (November 1, 2001). *See also Lanovaz v. Twinings N. Am., Inc*., 2014 U.S. Dist. LEXIS 1639, 18, (N.D. Cal. Jan. 6, 2014) (in which the parties, including the FDA, "do not seem to dispute that FDA labeling rules should apply to the content on Twinings' website...").

[6] FDA, "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" (January 2014). This is consistent with Section 230 of the Communications Decency Act, which states that "no provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider." 47 U.S.C. § 230(c)(1).

- Posted in proximity to the misinformation; and
- Accompanied by a disclosure that the author is affiliated with the manufacturer.[7]

For example, consider the scenario in which an independent third party writes an online post stating that one reason he likes taking a prescription drug is that it has no food restrictions, which is inconsistent with information from the required labeling. According to the FDA's guidance, one approach to correcting this misinformation would be for a representative of the manufacturer to identify herself as being affiliated with the manufacturer and post the corrective information from the required labeling in accordance with the aforementioned standards.

FDA Regulation of Advertising and CGC

Federal law does not define what constitutes "advertising," but FDA regulations provide several examples, including "advertisements in published journals, magazines, other periodicals, and newspapers broadcast throughout media such as radio, television, and telephone communication systems."[8] The FDA's approach toward regulating the use of CGC in advertising is consistent with its approach toward the use of CGC in labeling. Distinguishing between advertising and labeling is important, however, as the FDA only regulates the advertising of prescription drugs while the FTC enforces its unique regulatory regime on the advertising of other product categories, including food, over-the-counter drugs, dietary supplements, and cosmetics.

Use of Incentives to Collect CGC

Manufacturers often provide incentives to consumers in order to obtain CGC. Unlike the FTC, which has provided considerable guidance on how it will regulate incentivized CGC used in the advertising that falls within its jurisdiction, the FDA has not specifically addressed the use of incentivized CGC. That said, the FDA would likely consider incentivized CGC to be not "truly independent" of the manufacturers. As a result, manufacturers would be responsible for the contents of any incentivized CGC appearing on any websites they own, control, create, influence, or operate. While the FDA has not offered examples of what it may mean to "incentivize," it is reasonable to assume that any of the following items could be considered an incentive:

- Direct compensation;
- Provision of free products, discounts, or sweepstakes entries;
- Promises to appear on labeling or in advertisements; or
- Employment.

[7] FDA, "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices" (June 2014). Once misinformation is corrected, manufacturers are not required to continuously monitor for subsequent posts or comments. *Id.*

[8] 21 C.F.R. § 202.1(l)(1).

Best Practices

The first step for manufacturers seeking to collect and use CGC is to consider whether only the FDA rules (*e.g.*, prescription drugs), only the FTC rules (*e.g*., a sofa), or both (*e.g.*, over-the-counter drugs) apply. If the FDA rules apply, consider the following best practices to help remain compliant:

- Establish an FDA compliance program that includes policies with regard to the use of CGC and incentives.
- When actively soliciting, highlighting, or incentivizing CGC that you intend to host or distribute, ensure you have consistent moderation guidelines and procedures in place to exclude any off-label uses or unsubstantiated health and safety claims.
- Only host or distribute incentivized CGC that you could lawfully state yourself.
- Follow FDA guidance if you seek to correct misinformation contained in CGC.
- Do not use CGC that was incentivized or influenced in order to substantiate claims about a product, as the CGC will lack the requisite credibility.

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