KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

August 12, 2016

FDA Finalizes Wellness Product Guidance

The Food and Drug Administration Safety Innovation Act of 2012 ("FDASIA") required a collaborative effort by the Food and Drug Administration ("FDA"), Federal Communications Commission and Office of the National Coordinator for Health Information Technology to provide a proposed strategy and recommendations for an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications and other software products, that promotes innovation, protects patient safety, and avoids regulatory duplication. In response to the FDASIA, the three agencies issued the FDASIA Health IT Report ("Health IT Report") on April 3, 2014. As part of the Health IT Report, FDA indicated it would provide clarification regarding the distinction between wellness and disease-related medical device claims. FDA's clarification on this point came in January 2015, when the draft guidance on "General Wellness: Policy for Low-Risk Devices" (the "Draft Guidance") was issued, describing wellness devices for which the agency would not enforce oversight due to sufficiently low risk. This guidance was recently finalized on July 29, 2016 (the "Final Guidance"). FDA has also attempted to clarify its digital health policies through other guidance on mobile medical applications, medical device data systems, and medical device accessories, and further guidance is expected on clinical decision support tools in connection with the same. This client alert ("Alert"): (1) summarizes the Final Guidance, (2) highlights the differences between the Final and Draft Guidance, which provide additional insight to FDA's thinking in this area, and (3) discusses implications of the guidance for industry.

1. FINAL GUIDANCE SUMMARY

Manufacturers of products intended for general health and wellness have historically struggled with determining whether they are subject to FDA regulation. The ambiguity is typically caused by the definition of "device" in section 201(h) of the Food, Drug & Cosmetic Act triggering FDA oversight, which includes products intended to be used for "the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man … or intended to affect the structure or any function of the body of man...."

For more information, contact:

Lisa M. Dwyer
+1 202 626 2393
ldwyer@kslaw.com

Elaine H. Tseng
+1 415 318 1240
etseng@kslaw.com

Lara D. Compton
+1 213 443 4369
lcompton@kslaw.com

King & Spalding
San Francisco
101 Second Street
Suite 2300
San Francisco, CA 94105
Tel: +1 415 318 1200
Fax: +1 415 318 1300

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

www.kslaw.com

Even though the products that meet the definition of "general wellness products" in the Final Guidance may also fall within the definition of "device", FDA's Final Guidance effectively provides a regulatory safe harbor, reassuring manufacturers of these products that they need not comply with FDA's device regulations because FDA is exercising enforcement discretion (i.e., withholding active regulation).

For purposes of qualifying for FDA enforcement discretion under the Final Guidance, general wellness products are ones that:

- Are intended for only general wellness use (as described in the guidance and summarized below); and
- Present a low risk to the safety of users and other persons.

The Final Guidance permits two categories of general wellness uses, namely products that have an intended use that:

- Relates to maintaining or encouraging a general state of health or a healthy activity (referenced in this Alert as "General Products"); or
- Relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition (referenced in this Alert as "Healthy Lifestyle Products").

Claims for General Products must not make any reference to diseases or conditions, and the product must relate to:

- Weight management;
- Physical fitness;
- Mental acuity;
- Self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem);
- Sleep management; or
- Sexual function.

For example, products that "promote relaxation or manage stress" would qualify as General Products, but products that "help manage anxiety disorder" would not.

Healthy Lifestyle Products, provided the link to health outcome is "well understood," include products intended to:

- Promote, track and/or encourage choice(s), which, as part of a healthy lifestyle, may help to reduce the risk of certain chronic diseases or conditions; or
- Promote, track and/or encourage choice(s) which, as part of a healthy lifestyle, may help living well with certain chronic diseases or conditions.

Healthy Lifestyle Product claims associating healthy lifestyle choice(s) with health outcomes are "well understood" if described in peer-reviewed scientific publications or official statements made by healthcare professional organizations, such as the American Medical Association or the American Association of Clinical Endocrinologists. Examples provided by FDA where the association of healthy lifestyle choices and health outcome are "well understood" include heart disease, high blood pressure, and type 2 diabetes.

In addition to intended use requirements, general wellness products must be "low risk". Under the Final Guidance, a product exceeds the "low risk" threshold if it is invasive (e.g., penetrates or pierces the skin or mucous membranes of

the body), implanted, or involves an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied (such as risks from lasers or radiation exposure). Examples of risks that are not considered "low" include:

- Skin and eye burns;
- Tissue damage and/or disease risk from ultra-violet radiation, electrical stimulation, and venipuncture;
- Risk of infection transmission;
- Implant rupture;
- Adverse reaction to implants and other implantation procedure risks; and
- Electrical hazards.

2. DIFFERENCES BETWEEN DRAFT AND FINAL GUIDANCE

a. Definition of General Wellness Product Changes

FDA made changes in connection with risk, but on balance it is unclear whether the change will make a material difference. The Final Guidance relaxes the risk threshold for a general wellness product from "very low risk" to "low risk" but expands safety considerations to include any risks to persons beyond product users.

In addition, FDA provides the same illustrative examples of general wellness products in the Final Guidance as in the Draft Guidance, namely exercise equipment, audio recordings, video games, software programs and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded).

b. General Wellness Product Uses and Examples

The Final Guidance retains the two categories of products described in the Draft Guidance (i.e., General Products and Healthy Lifestyle Products).

The requirements for General Products did not materially change. FDA added products intended to "enhance learning capacity" to its list of examples for this category and deleted products "enhancing cardiac function".

The requirements for Healthy Lifestyle Products have not materially changed. However, the Final Guidance does add some flexibility in establishing when the role of healthy lifestyle is "well understood" as helping to reduce the risk or impact of certain chronic diseases or conditions, by allowing "official statements made by healthcare professional organizations" to show that an association between the two is generally accepted. As in the Draft Guidance, the Final Guidance also provides that the role of a healthy lifestyle in disease prevention and management can be shown to be well understood or generally accepted by reference to discussions in peer-reviewed scientific publications.

The Final Guidance also offers several new examples of products in this general wellness product category, including:

- Software coaching breathing techniques and relaxation skills, which, as part of a healthy lifestyle, may help living well with migraine headaches;
- Software tracking and recording sleep, work and exercise routine which, as part of a healthy lifestyle, may help living well with anxiety;

- Product promoting healthy lifestyle choices such as getting enough sleep, eating a balanced diet and maintaining a healthy weight, which may help living well with type 2 diabetes; and
- Mobile application that reminds users to keep exposed skin out of direct sunlight when the UV index is high, which, as part of a healthy lifestyle, may help reduce the risk of skin cancer.

c. Risk Analysis

The Final Guidance continues to exclude from enforcement discretion products that are invasive or involve an intervention or technology that may pose a risk to the user if regulatory controls are not applied (e.g., tissue injury, trauma or infection). Further, the Final Guidance adds to the scope of products that are non-low risk ones that pose a risk to persons other than the user if regulatory controls are not applied, as well as implanted devices. The Final Guidance may add some flexibility for innovation in that it did not retain the Draft Guidance's specific exclusions from enforcement discretion for products raising novel questions of usability or questions of biocompatibility.

In addition to these changes, FDA added the following examples of products that would not be considered low risk:

- A neuro-stimulation product that claims to improve memory, due to the risks to a user's safety from electrical stimulation; and
- A product that claims to enhance a user's athletic performance by providing suggestions based on the results of relative lactic acid testing, when the product uses venipuncture to obtain the blood samples needed for testing.

3. IMPLICATIONS FOR THE INDUSTRY

The Final Guidance articulates FDA's policy of enforcement discretion regarding products that meet the definition of "general wellness products," namely certain products that help maintain or encourage a healthy activity or a healthy lifestyle and present a low safety risks to users. In addition, the Final Guidance is an example of FDA's broader intent to implement a risk-based framework for health technology and other innovative digital health products. According to Jeffrey Shuren, M.D., Director of FDA's Center for Devices and Radiological Health, the intent of the Health IT Report strategy, as seen with FDA's approach to mobile apps, is to adopt a balanced approach to these products that supports continued innovation while ensuring appropriate patient protections; the focus of regulatory oversight is on products that present a greater risk to patients if they do not work as intended.[1]

Although the Final Guidance provides a number of examples that attempt to define the line between an appropriate general wellness claim and a regulated structure/function or disease claim, which would render the product subject to FDA's active enforcement as a "device," gray area is likely to remain. For example, a number of questions are likely to arise regarding the meaning of "well understood" health outcomes associated with healthy lifestyle product claims (e.g., how to handle areas where peer-reviewed studies and healthcare professional organizations disagree about the role of

[1] *See* News Release, Department of Health and Human Services, Proposed health IT strategy aims to promote innovation, protect patients, and avoid regulatory duplication (April 3, 2014), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm390988.htm; Examining Federal Regulation of Mobile Medical Apps and Other Health Software: Hearing Before the H. Subcomm. on Health of the H. Comm. on Energy and Commerce, 113th Cong. (Nov. 19, 2013) (statement of Jeffrey Shuren, M.D., J.D. Director, Center for Devices and Radiological Health, Food and Drug Administration), http://www.fda.gov/NewsEvents/Testimony/ucm375462.htm.

certain lifestyle choices, how statistically significant a study in a peer-reviewed scientific publication needs to be, or how many studies must establish the claim, in order for a claim to be "well understood").

Based on the definition of "general wellness product" articulated in the final guidance, the analysis of whether a product falls within that definition is necessarily fact specific. Accordingly, in making the determination of whether a certain product falls within the definition of "general wellness product," counsel should be consulted, and the rationale for determining that a product meets that definition should be well-documented.

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In 2015, King & Spalding was named "Law Firm of the Year" for FDA law by U.S. News & World Reports. King & Spalding's FDA & Life Sciences team has more than 30 attorneys and other professionals, who provide practical legal counseling and technical consulting on a full array of issues involving all FDA-regulated products. Among other things, our team is experienced in responding to warning letters and FDA-483 observations, conducting audits of quality systems, representing clients before FDA on enforcement issues, and helping clients submit marketing applications. We also have significant experience shaping policy at FDA and before Congress.

In addition, our team calls upon the expertise of lawyers in several related areas within the firm, including the civil and criminal litigation group, the appellate group, and the government advocacy and public policy group, which have effectively represented clients who are the targets of government initiated lawsuits and investigations. Please let us know if you have any questions.

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