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FDA Publishes Draft Guidance Describing General Wellness Claims

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On January 20, 2015, FDA issued a highly anticipated draft guidance ("Draft Wellness Guidance") that outlines the current thinking of the Center for Devices and Radiological Health (CDRH) regarding its regulation of low-risk general wellness products. The Draft Wellness Guidance sets forth a definition of "general wellness products" and articulates a policy under which these products will not be actively regulated by FDA. However, the agency stops short of clearly drawing the line as to which wellness products meet the definition of a medical device.

The market for wellness products is rapidly developing. Products that (among other things) help consumers track and manage fitness, sleep, weight and nutrition are becoming more sophisticated. For example, these products are automatically uploading information from smart scales, analyzing data from fitness trackers and other sources to provide users with health suggestions and coaching, storing and sharing data and images, and combining multiple features to track a user's total health.

Despite these advances, the line between wellness products and medical devices that are regulated by FDA had not been clearly articulated by the agency. Therefore, there was uncertainty as to whether some wellness products would be actively regulated by FDA as medical devices.

Background

In 2013, FDA provided some initial guidance on when wellness mobile apps would be subject to FDA regulation in the FDA Mobile Apps Guidance (see our previous alert here). Similar to FDA's approach in the Draft Wellness Guidance, FDA stated in the Mobile Apps Guidance that it intended to exercise enforcement discretion toward certain types of wellness apps, without definitively stating whether these apps meet the definition of a device. This enforcement discretion policy means that even if the wellness apps meet the definition of a device, FDA does not intend to impose medical device regulatory requirements on them. However, because FDA did not define general wellness products in the Mobile Apps Guidance or clarify how FDA would treat wellness products that did not fall within the express categories of enforcement discretion, FDA's policy regarding wellness products remained uncertain.

The examples that FDA provided in the Mobile Apps Guidance of general wellness apps subject to enforcement discretion include apps that "log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness," such as those that:

- provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;
- provide dietary logs, calorie counters or make dietary suggestions;
- provide meal planners and recipes;
- track general daily activities or make exercise or posture suggestions;
- track a normal baby's sleeping and feeding habits;
- actively monitor and trend exercise activity;
- help healthy people track the quantity or quality of their normal sleep patterns;
- provide and track scores from mind-challenging games or generic "brain age" tests;
- provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
- use social gaming to encourage healthy lifestyle habits; or
- calculate calories burned in a workout.

In addition, pursuant to Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA), FDA (in consultation with other federal agencies) issued a Health IT Report in 2014 that outlined a proposed strategy and recommendations on a "risk-based regulatory framework pertaining to health information technology, including mobile medical applications." One of these recommendations was for FDA to develop a draft document that provides greater clarity between the distinction between wellness and disease related claims.

The Draft Wellness Guidance

The Draft Wellness Guidance defines "general wellness products" as products that "(1) are intended only for general wellness use, as defined in [the] guidance, and (2) present a very low risk to users' safety." These products may include exercise equipment, audio recordings, software programs (including mobile apps), video games, and other products that are typically available from retail establishments (including online retailers and distributors that offer mobile apps to be directly downloaded). While FDA acknowledges that some general wellness products discussed in the Draft Wellness Guidance may not meet the definition of a medical device, the draft guidance states that "CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the [Federal Food, Drug, and Cosmetic Act (FDCA)]." Instead, if a product qualifies as a low risk general wellness product, the agency does not intend to regulate the product under the FDCA.

The Draft Wellness Guidance separates general wellness products into two categories:

- **Category 1: Products intended to maintain or encourage a general state of health or a healthy activity.** These products do *not* claim or make any reference to diseases or medical conditions, such as obesity, anorexia, anxiety or autism. This category of

general wellness products relate to weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function.[1]

- **Category 2: Products that associate the role of a healthy lifestyle with helping to reduce the risk or impact of chronic diseases or conditions.** An important requirement is that it must be "well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition." Examples provided by FDA of such chronic diseases include heart disease, high blood pressure, and type 2 diabetes. FDA provides two subcategories of claims under Category 2: (1) "may help to reduce the risk of" and (2) "may help living well with." Thus, for example, a product that promotes physical activity as part of a healthy lifestyle "may help reduce the risk of" high blood pressure. A software product that tracks caloric intake can help to maintain a healthy weight and balanced diet, which "may help living well" with high blood pressure and type 2 diabetes.

FDA also makes clear in the Draft Wellness Guidance that the general wellness policy does *not* "extend to devices that present inherent risks to a user's safety." FDA states that the following factors should be used to determine whether or not a product is low risk for purposes of the Draft Wellness Guidance:

- whether a product is "invasive," which is defined in the draft guidance as a product that "penetrates or pierces the skin or mucous membranes of the body;"
- whether a product includes an "intervention or technology that may pose a risk to a user's safety if device controls are not applied, such as risks from lasers, radiation exposure, or implants;"
- whether a product "raises novel questions of usability;" or
- whether a product "raises questions of biocompatibility."

FDA recommends that when assessing whether a product is low risk, a company should consider whether CDRH actively regulates products of the same type in question. However, FDA does not otherwise provide guidance on how a company should apply these factors to determine whether a particular product is low risk. In particular, the General Wellness Guidance is unclear about what constitutes a "novel question of usability."

[1] Many of the examples in the first category of general products are similar to the types of wellness products described in the Mobile Apps Guidance examples.

General Wellness Examples

The following are examples that FDA provides in the Draft Wellness Guidance of general wellness claims.

Category	General Wellness Claims
Weight management	▪ "Promote or maintain a healthy weight" ▪ "Assist with weight loss goals" ▪ "Tracks your caloric intake and helps you manage a healthy eating plan to maintain a healthy weight and balanced diet. Healthy weight and balanced diet may help living well with high blood pressure and type 2 diabetes"
Physical fitness, including products intended for recreational use	▪ "Develop or improve endurance, strength or coordination, or improve energy" ▪ "Increase or improve muscle size or body tone" ▪ "Improve general mobility" or "assist individuals who are mobility impaired in a recreational activity" ▪ "Enhance" participation in recreational activities by monitoring the consequences of participating in such activities, such as to "monitor heart rate or monitor frequency or impact of collisions" ▪ "Promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure."
Relaxation or stress management	"Promote relaxation or manage stress"
Mental acuity	"Improve mental acuity, instruction following, concentration, problem-solving, multitasking, resource management, decision-making, logic, pattern recognition or eye-hand coordination"
Self-esteem (including products with a cosmetic function)	▪ "Promote" or "boost self-esteem" ▪ "Mechanically exfoliate the face, hands and feet to make the skin smoother and softer"
Sleep management	▪ Promote sleep management (e.g., "track sleep trends") ▪ "Tracks activity sleep patterns and promotes healthy sleep habits, which, as part of a healthy lifestyle, may help reduce the risk for developing type 2 diabetes"
Sexual function	"Improve sexual performance"

The Draft Wellness Guidance will be open for public comment through April 20, 2015. FDA states in the Federal Register Notice for the guidance that it is specifically interested in comments on "CDRH's proposed list of general wellness intended uses that relate to maintaining or encouraging a general state of health or a healthy activity" that do not make any reference to diseases or conditions. FDA requests comments on the current list as well as suggestions for other intended uses that should be included in the guidance.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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