



No Sweat: FDA Doesn't Intend to Regulate Low-Risk General Wellness Products

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The Food and Drug Administration (FDA) has issued a draft guidance entitled, “General Wellness: Policy for Low Risk Devices.”¹ The agency describes its enforcement policy as it relates to low-risk medical devices that “promote a healthy lifestyle,” which FDA refers to as “general wellness products.” The bottom line is that the agency does not intend to evaluate whether these types of products are “medical devices,” subject to its regulation, or, if they qualify as devices, whether they comply with those requirements applicable to medical devices, such as marketing authorization, establishment registration and listing, labeling, Quality System Regulations, and Medical Device Reporting.

The agency has solicited comments to the draft guidance.

Highlights of the Draft Guidance Policy

- The draft guidance only applies to medical devices.
- FDA defines “general wellness products” as those that meet two criteria: (1) intended for only general wellness use (to be defined below); and (2) present a very low risk to users’ safety.
 - A “general wellness product,” is one that has: (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use claim that associates 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.
 - “Low risk” would not include a device that:
 - is invasive;
 - involve 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;
 - raise novel questions or usability;
 - raise questions of biocompatibility.
 - FDA recommends looking at whether FDA’s Center for Devices and Radiological Health actively “regulates products of the same type as the product in question” to assess risk.

Categories of Wellness Products

- Examples of general wellness products include, but are not limited to, exercise equipment, audio recordings, and video games.
- FDA makes clear that general wellness products should not make reference to diseases or conditions; otherwise, the draft guidance does not apply, i.e., FDA will regulate the product.
- Okay → acceptable general wellness claims relating to maintaining or encouraging a general state of health or healthy activity include: weight management, physical fitness (including products for recreational use), relaxation or stress management, mental activity,

¹ See <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf>.

- self-esteem, sleep management, or sexual function.
- Not Okay→ claims relating to obesity, eating disorders (e.g., anorexia), anxiety, autism, muscle atrophy, erectile dysfunction, or restoring a structure or function impaired due to a disease.
- A general wellness product may also be one that associates the role of a healthy lifestyle with helping to reduce the risk of certain chronic diseases or diseases or with helping live well with such conditions.
 - Examples include heart disease, high blood pressure, and type 2 diabetes.
- The following are examples of acceptable disease-related general wellness claims:
 - Product X promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure.
 - Software product Y tracks one's caloric intake and helps 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.
 - Product Z 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.
- The following are examples of low-risk general wellness products:
 - A mobile application plays music to "soothe and relax" an individual and to "manage stress."
 - A mobile application that solely monitors and records daily energy expenditure and cardiovascular workout activities to "allow awareness of one's exercise activities to improve or maintain good cardiovascular health."
 - A mobile application monitors and records food consumption to "manage dietary activity for weight management and alert the user, healthcare provider, or family member of unhealthy dietary activity."
 - A portable product that claims to monitor the pulse rate of users during exercise and hiking.
 - A product intended to mechanically exfoliate the face, hands, and feet to make the skin smoother and softer.
- At the end of the draft guidance, FDA offers a useful "decision algorithm" for evaluating whether the product makes only general wellness claims and whether the device is low risk.

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