Well, Well, Well – What Do We Have Here: FDA Eases Up On Regulating General Wellness Products

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The Food and Drug Administration ("FDA") has issued guidance on general wellness products, which are low risk products it will not regulate as "medical devices." A draft of the guidance was issued in January 2015, and the final guidance, "General Wellness: Policy for Low Risk Devices," was issued in July 2016.[1] This Bulletin summarizes the guidance and offers our own observations.

What is a General Wellness Product?

A general wellness product has the following characteristics:

1. an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or
2. an intended use that 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.[2]

In addition, the products present a low risk to the safety of users.

General wellness claims, as defined in the guidance, relate to sustaining or offering general improvement to functions related to a general state of health, e.g., weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function. These products do not refer to any diseases or medical conditions. FDA gives several examples of claims that fit into this first category of general wellness products, as well as those that do and do not reference specific diseases or conditions:

Acceptable general wellness claims

- Claims to promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals;
- Claims to promote relaxation or manage stress;
- Claims to increase, improve, or enhance the flow of qi "energy;"
- Claims to improve mental acuity, instruction following, concentration, problem solving, multitasking, resource management, decision-making, logic, pattern recognition or eye-hand coordination;
- Claims to enhance learning capacity;
- Claims to promote physical fitness, such as to help log, track, or trend exercise activity, measure aerobic fitness, improve physical fitness, develop or improve endurance, strength or coordination, or improve energy;
- Claims to promote sleep management, such as to track sleep trends;
- Claims to promote self-esteem, such as to boost self-esteem;

1 A copy of our Bulletin on that draft can be accessed at http://www.agg.com/files/Publication/88512980-c48b-4d4c-98b6-2be017fc3714/Presentation/PublicationAttachment/9595cd53-9e07-4ef2-88b0-068b095b02d3/No%20Sweat-FDA-Doesnt-Intend-to-Regulate-Low-Risk-General-Wellness-Products.pdf (last accessed Aug. 16, 2016).

2 Guidance available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf (last accessed Aug. 16, 2016).

- Claims that address a specific body structure or function, such as to increase or improve muscle size or body tone, tone or firm the body or muscle, or enhance or improve sexual performance;
- Claims to improve general mobility or to assist individuals who are mobility impaired in a recreational activity (e.g., sport wheelchairs, beach access wheelchairs);
- Claims to enhance an individual's 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.

Not acceptable general wellness claims

- A claim that a product will treat or diagnose obesity;
- A claim that a product will treat an eating disorder, such as anorexia;
- A claim that a product helps treat an anxiety disorder;
- A claim that a computer game will diagnose or treat autism;
- A claim that a product will treat muscle atrophy or erectile dysfunction;
- A claim to restore a structure or function impaired due to a disease or condition, e.g., a claim that a prosthetic device enables amputees to walk.

Another Category of General Wellness Products

A product may still be a general wellness product even if the claims reference specific diseases or conditions if the claims promote, track, or encourage choices which, as part of a healthy lifestyle, may help to reduce the risk of or may help living well with certain chronic diseases or conditions. FDA emphasizes this specific language in its examples:

- Software Product U coaches breathing techniques and relaxation skills, which, as part of a healthy lifestyle, may help living well with migraine headaches;
- Software Product V tracks and records your sleep, work and exercise routine which, as part of a healthy lifestyle, may help living well with anxiety;
- Product W promotes making 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;
- Product X promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure.

FDA notes that these claims can only be based on "generally accepted" links between healthy lifestyle choices and the disease or condition; this link may be established in peer-reviewed scientific publications or in official statements made by healthcare professional organizations, such as the American Medical Association. The agency lists heart disease, high blood pressure, and Type 2 diabetes as examples of diseases with a well-understood link to lifestyle choices.

Is the Product Low Risk?

As previously noted, FDA's position that it will not regulate wellness products as devices also requires that the product be low risk. Therefore, beyond product claims, FDA will evaluate what the product actually does to evaluate potential risk. If the answer to any of the following three questions is "yes," the product is not low risk and not covered by the guidance (and thus, regulated as a medical device):

1. Is the product invasive (i.e., does it penetrate/pierce the skin or mucous membranes)?
2. Is the product implanted?
3. Does the product involve an intervention or technology that may pose a safety risk to the user or others if specific

regulatory controls are not applied, such as lasers or radiation exposure?

FDA recommends that companies look at whether the agency is currently regulating similar products. The agency provides examples of products that are not low risk, noting that an invasive product cannot avoid FDA regulation simply by making general wellness claims.

- A laser product that claims to improve confidence in the user's appearance by rejuvenating the skin is not a low risk product. Although the claims of rejuvenating the skin and improving confidence in user's appearance are general wellness claims, laser technology presents risks of skin and eye burns.
- A product making claims to enhance a user's athletic performance by providing suggestions based on the results of relative lactic acid testing is not low risk if the product uses venipuncture to obtain the blood samples. The product is invasive (because it pierces the skin) and may pose a risk to the user if specific regulatory controls are not applied (for example, a risk of infection transmission).
- Implants promoted for improved self-image or enhanced sexual function are not low risk, as they pose risk to users, such as rupture or adverse reaction to materials.

In short, FDA summarizes the framework of its general wellness guidance with a series of questions in a flowchart form:

1. Does the product only involve claims about general health? If so, is the product low risk? If the answer to both questions is "yes," the product is likely a general wellness product.
2. If the product is intended to sustain or improve general health, while nevertheless referencing a specific disease or condition, do the claims specifically state that the product "may help reduce the risk of," or "may help living well with" the disease or condition? If the claims do not, the product is not a low risk general wellness product.

AGG Observations

- Overall, the final guidance is similar to FDA's 2015 draft guidance, but the agency made some slight changes. The draft definition of "low risk" excluded products that raised novel questions of usability or raised questions of biocompatibility. Here, FDA has modified the non-low risk criteria to the three discussed above (invasive, implanted, or involving a risky intervention or technology). In addition, this final guidance lists migraine headaches and anxiety as examples of conditions for which a product may make disease-related wellness claims. This guidance provides additional examples of the range of products FDA will not regulate as devices.
- In addition to FDA's guidance on mobile medical applications,[3] the guidance represents the agency's effort to define and categorize emerging technology. For manufacturers developing or marketing general wellness products, we recommend careful evaluation of the claims made about a product and any associated safety risks. FDA has defined parameters for the types of products that can be considered low risk, but even a low risk product may be subject to regulation as a medical device if marketed beyond general wellness claims.

3 Available at http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf (last accessed Aug. 16, 2016).

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