Contains Nonbinding Recommendations
Draft - Not for Implementation

General Wellness: Policy for Low Risk Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on: January 20, 2015

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact the Office of the Center Director at 301-796-5900.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive copy of the guidance. Please use the document number 1300013 to identify the guidance you are requesting.

Table of Contents

General Wellness: Policy for Low Risk Devices

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) is issuing this guidance document to provide clarity to industry and FDA staff on the Center for Devices and Radiological Health's (CDRH's) compliance policy for low risk products that promote a healthy lifestyle (general wellness products)[1]. This guidance does not apply to products (e.g., drugs, biologics, dietary supplements, foods, or cosmetics) regulated by other FDA Centers or to combination products,[2] including those regulated by CDRH.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory

[1] This guidance does not change or rescind any requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or any applicable regulations. This guidance also does not preclude FDA from consulting with the Consumer Product Safety Commission (CPSC) as to whether a general wellness product is a consumer product under CPSC's authority or a device. FDA may coordinate with other agencies and authorities, such as the CPSC, to determine jurisdiction over products. If a product is a device under section 201(h) of the FD&C Act, it is generally excluded from CPSC's authority over "consumer products" under the Consumer Product Safety Act (15 U.S.C. § 2052(a)(5)(ii)(H)). However, CPSC and FDA may both have jurisdiction over certain medical devices under other statutory authorities the CPSC administers.

[2] For determinations on whether a combination product meets the statutory definition of a medical device, contact the Office of Combination Products at combination@fda.gov.

requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Policy on Low Risk General Wellness Products

CDRH does not intend to examine low risk general wellness products to determine whether they are devices[3] within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations, including, but not limited to: registration and listing and premarket notification requirements (21 CFR Part 807); labeling requirements (21 CFR Part 801 and 21 CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21 CFR Part 820); and Medical Device Reporting (MDR) requirements (21 CFR Part 803).

For purposes of this guidance, CDRH defines **general wellness products** as products that meet the following two factors: (1) are intended for only general wellness use, as defined in this guidance, and (2) present a very low risk to users' safety. General wellness products may include exercise equipment, audio recordings, video games, software programs[4] 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), when consistent with the two factors above.

CDRH regularly receives inquiries about whether particular products are devices as defined by the FD&C Act. There are instances where certain general wellness products, as discussed in this guidance, do not meet the definition of a device under section 201(h) of the FD&C Act and therefore are not subject to the FD&C Act's regulatory requirements for devices. We have included examples of these kinds of products to illustrate the scope of this guidance, rather than to suggest they meet the device definition.

A product's inclusion under this guidance does not establish that it has been shown to be safe, effective, and not misbranded for its intended use.

[3] The term "device" is defined in 201(h) of the FD&C Act to include an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is …intended for use in 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..."

[4] For more discussion regarding FDA's regulatory approach towards certain mobile medical applications, see the FDA Guidance: Mobile Medical Applications, issued on September 25, 2013, available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.

III. General Wellness Products

A **general wellness product**, for the purposes of this guidance, has (1) an intended use that relates to a 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).

If the product's intended uses are not limited to the above general wellness intended uses, this guidance does not apply.

The first category of general wellness intended uses involve claims about sustaining or offering general improvement to conditions and functions associated with a general state of health that **do not make any reference to diseases or conditions**. For the purposes of this guidance, this first category of general wellness claims relate to:

- weight management,
- physical fitness, including products intended for recreational use,
- relaxation or stress management,
- mental acuity,
- self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem),
- sleep management, or
- sexual function.

The following are examples of this category of 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 when there is no reference to anxiety disorders or other reference to a disease or condition;
- Claims to increase, improve, or enhance the flow of qi;
- Claims to improve mental acuity, instruction following, concentration, problem-solving, multitasking, resource management, decision-making, logic, pattern recognition or eye-hand coordination;
- 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;

- 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, enhance cardiac function, or enhance or improve sexual performance;
- Claims to improve general mobility or to assist individuals who are mobility impaired or who have limited mobility in a recreational activity; and
- 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.

The following are examples of claims that do not fall into this category of 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 anxiety;
- 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, e.g., a claim that a prosthetic device enables amputees to play basketball.[5]

The second category of general wellness intended uses is comprised of two subcategories:

1) intended uses 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; and
2) intended uses to promote, track, and/or encourage choice(s) which, as part of a healthy lifestyle, **may help living well with** certain chronic diseases or conditions.

Both subcategories of disease-related general wellness claims should only contain references where it is well understood that healthy lifestyle choices may reduce the risk or impact of a chronic disease or medical condition. That is, the claim that the healthy lifestyle choice(s) may play an important role in health outcomes should be generally accepted; such associations are typically described in peer-reviewed scientific publications. Examples of chronic diseases for which a healthy lifestyle is associated with risk reduction or help in living well with that disease include heart disease, high blood pressure, and type 2 diabetes.

The following are examples of this category of disease-related general wellness claims:

[5] Devices intended to restore a structure or function impaired due to a disease may be regulated by FDA as individually classified recreational use devices or products classified in a general classification. For example, an artificial limb prosthesis intended to provide disabled persons the ability to run may be regulated under 21 CFR 890.3420 or 21 CFR 890.3500.

- 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 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.
- 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.

IV. Low Risk

CDRH's general wellness policy does not extend to devices that present inherent risks to a user's safety.

Whether a device is low risk for purposes of this guidance is determined by whether or not the product:

1) is invasive[6];
2) involves 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;
3) raises novel questions of usability; or
4) raises questions of biocompatibility.

If the answer to any of these questions is yes, the device is not a low risk general wellness product and is not covered by this guidance.

The following are examples of products that present inherent risks to a user's safety and would not be considered "low risk" as described in this guidance:

- Sunlamp products promoted for tanning purposes, due to risks to a user's safety from the ultraviolet radiation, including, without limitation, an increased risk of skin cancer.
- Implants promoted for improved self-image or enhanced sexual function, due to risks to users such as rupture or adverse reaction to implant materials, and risks associated with the implantation procedure.
- A laser product that claims to improve confidence in user's appearance by rejuvenating the skin. 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 and presents usability considerations that may be addressed with labeling and other device controls.

6 For purposes of this guidance, "invasive" means penetrates or pierces the skin or mucous membranes of the body.

In assessing whether a device is low risk for purposes of this guidance, FDA recommends that you also consider whether CDRH actively regulates products of the same type as the product in question. For example, CDRH currently regulates external penile rigidity devices, which are devices intended to create or maintain sufficient penile rigidity for sexual intercourse, under 21 CFR 876.5020 as class II devices exempt from premarket notification with special controls. The special controls for these devices address risks to health that are associated with the use of these devices, including, without limitation, tissue injury, trauma or infection.[7] Therefore, these types of devices would not be considered low risk general wellness products.

V. Examples of Low Risk General Wellness Products

Illustrative Example 1: A mobile application plays music to "soothe and relax" an individual and to "manage stress."

> These claims relate only to relaxation or stress management, not to any disease or medical condition, and thus are general wellness claims. In addition, the technology to play music does not present inherent risks to a user's safety. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 2: 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."

> This claim relates to a specific organ only in the context of general health and does not refer to a disease or medical condition. In addition, to the extent the monitoring or recording exercise activities present risks (such as inaccuracy), when made in the absence of disease or medical condition claims, the risks to the user's safety are low. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 3: 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".

> This claim relates to dietary choices and weight management, and thus is a general wellness claim. In addition, the technology for monitoring or recording food consumption poses a low risk to the user's safety. Therefore, this product meets both factors for a low risk general wellness product.

[7] See the FDA Guidance: Class II Special Controls Guidance Document: External Penile Rigidity Devices, issued on December 28, 2004, available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm072098.htm.

Illustrative Example 4: A portable product that claims to monitor the pulse rate of users during exercise and hiking.

> This claim relates only to exercise and hiking and does not refer to a disease or medical condition. Thus, it is a general wellness claim. In addition, the technology for monitoring poses a low risk to the user's safety. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 5: A product is intended to mechanically exfoliate the face, hands and feet to make the skin smoother and softer.

> This claim relates to self-esteem and does not refer to a specific disease or medical condition, and thus is a general wellness claim. In addition, the technology for exfoliating the face poses a low risk to the user's safety as it does not penetrate the stratum corneum. Therefore, this product meets both factors for a low risk general wellness product.
>
> Note: However, if the product exfoliates the skin to enhance the delivery of a topically applied product containing one or more active pharmaceutical ingredients through the stratum corneum, the product would present inherent risks to the user's safety because of its invasive nature. Therefore, then, the product would not be a low risk general wellness product.

Decision Algorithm for General Wellness Products

1. Does the product make only general wellness claims?

a. Does the product's intended use and claims refer to sustaining or offering general improvement to conditions and functions associated with a general state of health: weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, including personal appearance, sleep management, or sexual function?

Yes → Go to b.
No → Not general wellness, outside the scope of this guidance.

b. Does the product's intended use include a claim relating to a disease or medical condition?

Yes → Go to c.
No → Go to 2.

c. Is the disease or medical condition a chronic one for which it is well understood that healthy lifestyle choices may play a part in helping to reduce its risk or impact, as discussed in this guidance?

Yes → Go to d.
No → Not general wellness, outside the scope of this guidance.

d. Does the claim use language that the product may help to reduce the risk of, or may help living well with, a chronic disease or condition, as discussed in this guidance?

Yes → Go to 2.
No → Not general wellness, outside the scope of this guidance.

2. **Does the product present inherent risks to a user's safety (i.e., is the device low risk)?**

Is the product invasive, involve an intervention or technology that would pose a risk to the user's safety if device controls are not applied, such as risks from lasers, radiation exposure, implantation procedures, raise novel questions of usability, or raise questions of biocompatibility? In answering this question, consider whether CDRH actively regulates products of the same type as the product in question.

Yes → Not general wellness, outside the scope of this guidance.
No → General wellness product.