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General Wellness: Policy for Low Risk Devices

Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the Digital Health Center of Excellence by e-mail at digitalhealth@fda.hhs.gov.



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

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Identify all comments with the docket number FDA-2014-N-1039. Comments may not be acted upon by the Agency until the document is next revised or updated.

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General Wellness: Policy for Low Risk Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

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]

Section 3060(a) of the 21st Century Cures Act (Cures Act) amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on December 13, 2016, removing certain software functions, including those intended for maintaining or encouraging a healthy lifestyle that are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, from the definition of device in section 201(h) of the FD&C Act. Section 520(o)(1)(B) of the FD&C Act, states that software that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition" is not a device under section 201(h) of the FD&C Act.

[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 combination products, contact the Office of Combination Products at combination@fda.gov. See 21 CFR 3.2(e) for the definition of a combination product.

This guidance clarifies FDA's interpretation of this provision and its application to general wellness products.

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 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 21 CFR Part 820 (referred to as the Quality System regulation prior to February 2, 2026 and the Quality Management System Regulation starting February 2, 2026); 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 low risk to the safety of users and other persons. 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. Additionally, section 520(o)(1)(B) of the FD&C Act excludes software functions that are intended for maintaining or encouraging a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition from the definition of

[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..." and "does not include software functions excluded pursuant to section 520(o) of the FD&C Act."

[4] For more discussion regarding FDA's regulatory approach towards certain device software functions and mobile medical applications, see the FDA Guidance: Policy for Device Software Functions and Mobile Medical Applications, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.

device in section 201(h) of the FD&C Act.[5] We have included examples of products below that meet the definition of general wellness products to help illustrate the concepts in the guidance.

A product's inclusion under the general wellness policy in this guidance does not establish that it has been shown to be safe and/or effective for its intended use.

III. General Wellness Products

A **general wellness product**, for the purposes of this guidance, 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 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.

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 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;
- 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;

[5] "Nothing in this subsection shall be construed as limiting the authority of the [FDA] to— (A) exercise enforcement discretion as to any device subject to regulation under this Act . . ." (section 520(o)(4) of the FD&C Act).

- 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 (e.g., "fitness" or "activity" trackers);
- 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, 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); 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 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; and
- 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.[6]

The second category of general wellness intended uses relate to sustaining or offering general improvement to functions associated with a general state of health while **making reference to diseases or conditions.** For the purposes of this guidance, this second category of general wellness claims 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 be based on references where it is well understood that healthy lifestyle choices may reduce the risk or

[6] Products intended to restore a structure or function impaired due to a disease might be regulated by FDA as devices. For example, an artificial limb prosthesis intended to provide disabled persons the ability to walk might be regulated under 21 CFR 890.3420 or 21 CFR 890.3500.

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 described in peer-reviewed scientific publications or official statements made by healthcare professional organizations.[7] 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:

- 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.
- 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.

FDA may consider certain products that use non-invasive sensing (e.g. optical sensing) to estimate, infer, or output physiologic parameters (e.g. blood pressure, oxygen saturation, blood glucose, heart rate variability) to be general wellness products when such outputs are intended solely for wellness uses, and provided they:

- are non-invasive and not-implanted;
- do not involve an intervention or technology that may pose a risk to the safety of users or other persons if specific regulatory controls are not applied;
- are not intended for the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;
- are not intended to substitute for an FDA-authorized, cleared, or approved device;
- do not include claims, functionality, or outputs that prompt or guide specific clinical action or medical management; and
- do not include values that mimic those used clinically unless validated (e.g. manufacturer testing, peer-reviewed clinical literature) to reflect those values.

[7] By organizations we mean associations and colleges such as American Medical Association (AMA), American Heart Association (AHA), American Association of Clinical Endocrinologists (AACE), American College of Rheumatology, etc.

Products that meet the aforementioned criteria may display values, ranges, trends, baselines, or longitudinal summaries, and may contextualize these outputs in relation to sleep, activity, stress, recovery, or similar wellness domains.

Products are not general wellness products when they are intended to measure, estimate, or report physiologic values for medical or clinical purposes, including screening, diagnosis, monitoring, alerting, or management of a disease or condition.

Examples of such products include but are not limited to: blood pressure monitors or sphygmomanometers, blood glucose measuring devices such as fingerstick blood glucose meters and continuous glucose monitoring systems, electrocardiogram recording and analysis devices, and any product that is intended to provide outputs used to make treatment decisions (e.g., medication dosing).

Products are not general wellness products if their labeling, advertising, user interface, or functionality includes any of the following: 1. references to specific diseases, clinical conditions, or diagnostic thresholds; 2. alerts, alarms, or prompts that recommend or require specific clinical action or medical management; 3. treatment guidance intended to inform or direct medical management; 4. claims of clinical equivalence, clinical accuracy, medical or clinical grade, or substitution for an FDA-authorized, cleared, or approved medical device; or 5. intended-use statements that explicitly target diagnosis, screening, monitoring, or management of a disease or condition.

For purposes of this guidance, a product may be considered a general wellness product even if it includes a notification informing a user that evaluation by a healthcare professional may be helpful when outputs fall outside ranges appropriate for general wellness use, provided that such notifications:

- do not identify or name a specific disease or medical condition;
- do not characterize the output as abnormal, pathological, or diagnostic;
- do not include clinical thresholds, diagnoses, or treatment recommendations; and
- do not provide ongoing alerts or monitoring intended to manage a disease or condition.

FDA expects that a product intended for general wellness use will have labeling (including instructions for use, user-facing claims, promotional materials, and marketing communications) that is consistent with, and does not exceed, the product's stated intended use.

IV. Determining Risk for General Wellness Products

CDRH's general wellness policy applies only to general wellness products that are low risk.[8] If the answer to any of the following questions is YES, the product is not low risk and is not covered by this guidance.

1) Is the product invasive[9]?

[8] Whether a device is classified as class I under section 513(a)(1) of the FD&C Act does not necessarily mean that it is "low risk" for purposes of this guidance.

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

2) Is the product implanted?
3) Does the product involve 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?

In assessing whether a product 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 actively 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.[10] Therefore, these types of devices would not be considered low risk general wellness products.

The following are examples of products that 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.[11]
- Implants promoted for improved self-image or enhanced sexual function. Implants pose 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.
- A neurostimulation product that claims to improve memory, due to the risks to a user's safety from electrical stimulation.
- 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. Such a product is not low risk because it is invasive (e.g., obtains blood samples by piercing the skin) and also because the product involves an intervention that may pose a risk to the safety of the user and other persons if specific regulatory controls are not applied (e.g., venipuncture may pose a risk of infection transmission).

[10] See the FDA Guidance: Class II Special Controls Guidance Document: External Penile Rigidity Devices, issued on December 28, 2004, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/class-ii-special-controls-guidance-document-external-penile-rigidity-devices-guidance-industry-and

[11] See Final Order reclassifying UV lamps intended to tan the skin from class I exempt from premarket notification to class II (special controls): General and Plastic Surgery Devices: Reclassification of Ultraviolet Lamps for Tanning, Henceforth To Be Known as Sunlamp Products and Ultraviolet Lamps Intended for Use in Sunlamp Products, available at https://www.federalregister.gov/articles/2014/06/02/2014-12546/general-and-plastic-surgery-devices-reclassification-of-ultraviolet-lamps-for-tanning-henceforth-to

V. Examples of General Wellness Products that Are Not Medical Devices and Examples of General Wellness Products that Are Medical Devices for which FDA Does Not Intend to Enforce Requirements

Illustrative Example 1: A software function plays music to "soothe and relax" an individual and to "manage stress." Such a software function is not a device function.

> This software function has claims that 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 pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 2: A software function 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." Such a software function is not a device function.

> This software function has a claim that relates to a specific organ only in the context of general health and does not refer to a disease or medical condition. In addition, although the monitoring or recording of exercise activities present risks (such as inaccuracy), when made in the absence of disease or medical condition claims, the technology does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 3: A software function 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." Such a software function is not a device function.

> This software function has a claim that relates to dietary choices and weight management, and thus is a general wellness claim. In addition, the technology for monitoring or recording food consumption does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 4: A software function 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.

> This claim relates to tracking preventive measures which, as part of a healthy lifestyle, may help reduce the risk of a medical condition. The claim is for a healthy lifestyle choice and it is generally accepted that the choice may play an important role

in health outcomes. Thus, it is a general wellness claim. In addition, the technology reminding users to keep exposed skin out of direct sunlight does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 5: A portable product that is intended to monitor the pulse rate and/or oxygen saturation 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 pulse rate and/or oxygen saturation does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 6: A product is intended to mechanically exfoliate the face, hands and feet to make the skin smoother and softer. The product cannot be used in a manner that penetrates or pierces the skin.

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 product is noninvasive as it does not penetrate the stratum corneum and the technology for exfoliating the face does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Note: However, if the product is intended to exfoliate the skin in order to enhance the delivery of a topically applied product containing one or more active pharmaceutical ingredients through the stratum corneum, the product would be invasive. Therefore, the product would not be a low risk general wellness product.

Illustrative Example 7: A wrist-worn wearable product intended to assess activity and recovery that outputs multiple biomarkers, among which are hours slept, sleep quality, pulse rate, and blood pressure. Sleep is measured via an accelerometer, while pulse rate and blood pressure are measured via a photoplethysmogram.

The claim relates to general wellness and does not refer to a specific disease or medical condition, and thus is a general wellness claim. In addition, the technology for monitoring these biomarkers does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product, provided the product has validated values for blood pressure.

Note: However, if the claims made about any of the product's functionality implied the product's use in a medical or clinical context, the product would not be a low risk general wellness product.

Illustrative Example 8: A wearable product that is intended to provide estimations of blood glucose for monitoring nutritional impacts. The blood glucose measurement is made via

minimally invasive microneedle technology, is explicitly contraindicated for use with diabetics and pre-diabetics, and is marketed to users as a means of better understanding their insulin response to certain foods.

This claim relates to a general understanding of a user's health and is specifically contraindicated for use with a specific disease or conditions. Thus, it is a general wellness claim provided the product has validated values for blood glucose. However, the product penetrates the stratum corneum and is therefore not a low risk general wellness product.

Illustrative Example 9: A non-invasive wearable product advertised toward elite athletes and intended for monitoring of several parameters, among which are electrolyte balance, lactate, and hemoglobin. The product is labeled as for use in an exercise/fitness context only, displays values from cleared devices or ranges from the wearable's optical sensor, and is disclaimed for use diagnosing any condition or disorder.

This claim relates to exercise and fitness and does not refer to a disease or medical condition. Thus, it is a general wellness claim. In addition, the technology for measuring these physiologic parameters does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied, provided it has validated values for these parameters. Therefore, this product meets both factors for a low risk general wellness product.

VI. Determining whether General Wellness Products are within Scope of the Guidance

The following questions reflect the framework described in this guidance to determine whether general wellness products are within the scope of the guidance. Please note that these questions are intended to be addressed in the context of the full text of the guidance.

A1. Does the product have an intended use that relates to maintaining or encouraging a general state of health or a healthy activity?

Does the product only involve claims about sustaining or offering general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions? Claims in this category include: weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function.

YES ➔	**Go to A3.**
NO ➔	**Go to A2.**

A2. Does the product have an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions? *(In answering this question, the following two questions must be considered together.)*

a) Does the product have an intended use that relates to sustaining or offering general improvement to functions associated with a general state of health while making reference to 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?

AND

b) Is the relation between healthy lifestyle and disease specifically expressed as "**may help to reduce the risk of**," or "**may help living well with**," a chronic disease or condition?

YES ➔	**Go to A3.** *Both questions A2(a) and A2(b) must be answered "Yes" in order to proceed to question A3.*
NO ➔	Product is **NOT** a low risk general wellness product, and is **outside the scope of this guidance**.

A3. Is the product low risk?

Is the product not invasive, and not implanted, and does not involve a technology that may pose a risk to the safety of users or other persons if specific regulatory controls are not applied, such as risks from lasers or radiation exposure? *In answering this question, consider whether CDRH actively regulates products of the same type as the product in question.*

YES ➔	**The product is likely a general wellness product within the scope of this guidance, but the factors and examples in the guidance should be reviewed to confirm the status of the product.**
NO ➔	Product is **NOT** a low risk general wellness product, and is **outside the scope of this guidance**.