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FDA/CDRH Webinar

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General Wellness Guidance: Policy for Low Risk Devices

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Center for Devices and Radiological Health

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Agenda



- Overview of General Wellness Guidance
- Q& A

Background

- Draft Guidance on General Wellness
published January 20, 2015
- We received 12 comments
- Basic tenets of guidance remain unchanged
- Final guidance published on July 29, 2016



Overview – Big Picture

- The FDA encourages the development of general wellness products such as fitness trackers, which can empower individuals to take a more active role in managing their health.
- The FDA's Final Guidance on General Wellness takes a hands-off approach to the regulation of low risk general wellness products that only promote a healthy lifestyle or that promote a well-known association between a healthy lifestyle and a certain disease or condition.
- The FDA will continue to focus its oversight on products that are invasive, implanted or pose greater risks to patients, even if they are intended for general wellness purposes.

Overview-Key Principle

CDRH does not intend to examine low risk general wellness products to determine whether they are devices 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 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 requirements (21 CFR Part 803).

Definition

General wellness products are defined as products that meet the following two criteria:

1. Are intended for only general wellness use

AND

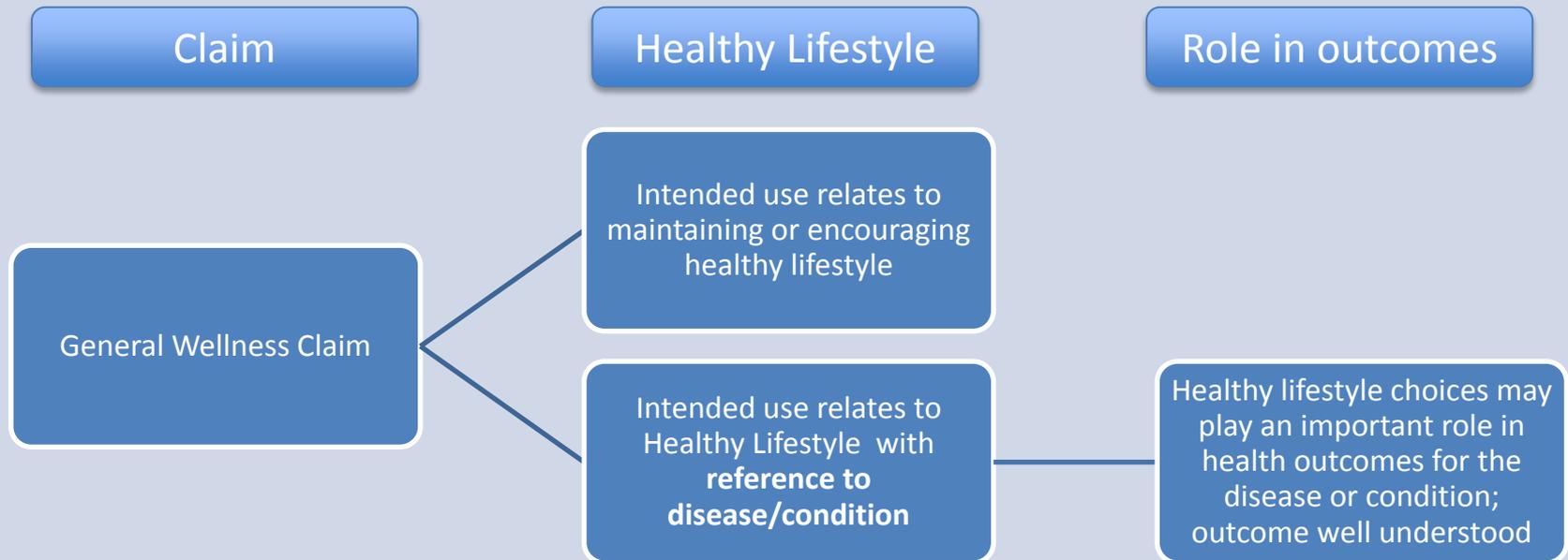
2. Present a low risk to safety of users and other persons.

Low Risk General Wellness Product



Low risk

- 1 Product is not invasive &
- 2 Product is not implanted &
- 3 Product does not pose risk (involve intervention or technology that may pose a risk to safety of users and other persons if regulatory controls were not applied)



General Wellness Intended Use

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.

First Category of Intended Use



- Relates to maintaining or encouraging a general state of health or a healthy activity
- Does NOT make any reference to diseases or conditions.

Examples include:

Claims to promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals;

Claims to promote relaxation or manage stress;

(See section III for additional examples)

Examples of First Category of Intended Use



No mention of disease or condition

- Claims to promote relaxation or manage stress
- Claims to improve mental acuity, instruction following, concentration, problem-solving, multitasking
- Claims to enhance learning capacity



Examples of First Category of Intended Use

- Claims to promote physical fitness, such as to help log, track, or trend exercise activity
- Claims to promote sleep management, such as to track sleep trends
- Claims to promote self-esteem

Second Category of Intended Use

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.

- **Makes reference to diseases or conditions**
- **Two subcategories:**
 1. 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
 2. Promote, track, and/or encourage choice(s) which, as part of a healthy lifestyle, **may help living well with** certain chronic diseases or conditions

Examples of Second Category of Intended Use

- Product promotes physical activity, which, as part of a healthy lifestyle, **may help reduce the risk of** high blood pressure.
- Software product 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 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.

(Section III page 4-5)



Does Product Present Low Risk to Safety of Users and Other Persons?

If the answer to any of the following questions is “YES,” the product is NOT a low risk general wellness product and is not covered by this guidance.

1. Is the product invasive?
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 regulatory controls are not applied, such as risks from lasers or radiation exposure?

(Section IV pg. 5)

Example of Products that Present Risk to User's Safety and Would Not be "Low Risk"

- 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.

(Section IV pg. 6)



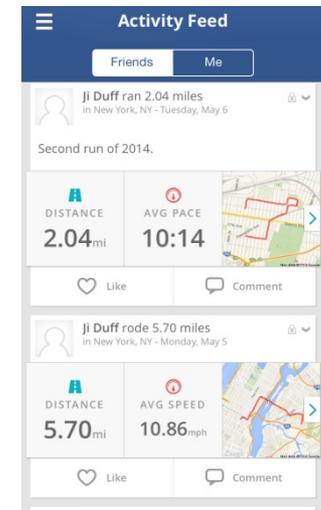
Example of Products that Present Risk to User's Safety and Would Not be "Low Risk"

- Implants promoted for enhanced sexual function.
- Implants pose risks to users such as rupture or adverse reaction to implant materials and risks associated with the implantation procedure.

Examples of Low Risk General Wellness Products

- 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.”

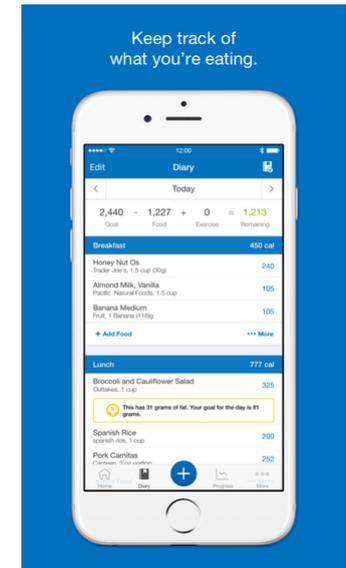
This claim relates to a specific organ only in the context of general health and does not refer to a disease or medical condition. Although the monitoring or recording of exercise activities present risks (such as inaccuracy), when made in the absence of disease or medical condition claims, the technology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



Examples of Low Risk General Wellness Products

- A mobile application that monitors and records food consumption to “manage dietary activity for weight management and alert the user, health care provider, or family member of unhealthy dietary activity.”

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



(Section IV pg. 6)

Examples of Low Risk General Wellness Products

- A portable product that is intended 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 pulse rate 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.

(Section V pg. 7)

Question and Answer Session

Questions?

If you have questions related to specific products or claims,
please contact:

digitalhealth@fda.hhs.gov

Any other questions, please contact:

Division of Industry and Consumer Education at

DICE@fda.hhs.gov

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Under Heading: Specialty Technical Topics; Sub-heading:
Device-Specific Topics