Refresh on General Wellness: Policy for Low Risk Devices
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Moderator: CAPT Kim Piermatteo
Presenters: Henry Roberts and Aneesh Deoras

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CAPT Kim Piermatteo: Hello and welcome to this CDRH Town Hall. This is CAPT Kim Piermatteo of the United States Public Health Service and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within FDA's Center for Devices and Radiological Health. I'll be the moderator for today.

For today's town hall, we will provide an overview of the General Wellness: Policy for Low Risk Devices, Final Guidance, that reissued on January 6, 2026, and address some previously emailed questions about this topic.

Our presenters are Henry Roberts, Digital Health Specialist in the Division of Digital Health Technology Assessment in CDRH's Office of Strategic Partnerships and Technology Innovation, and Aneesh Deoras, Assistant Director for the Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices within the Office of Cardiovascular Devices in CDRH's Office of Product Evaluation and Quality.

Before I turn it over to Henry to get us started, I'd like to provide one reminder, and that is, the intended audience for this event is industry. National media and press members are encouraged to submit their questions through the FDA Newsroom at www.fda.gov/news-events/fda-newsroom.

Thank you all for joining us. I'll now turn it over to Henry.

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Henry Roberts: Thank you, Kim.

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Henry Roberts: In general, the basic tenets of the General Wellness: Policy for Low Risk Devices guidance remain unchanged. Additional clarity has been added to the guidance on products that perform non-invasive sensing of physiologic parameters.

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Henry Roberts: Before we dive into the specifics, let's take a quick look at our learning objectives for this session. The goals of this presentation are to first, define what constitutes a general wellness product under FDA guidelines. Second, we will reiterate the FDA's current policy regarding low risk general wellness products, and finally, we'll clarify how emerging technologies specifically products that perform non-invasive sensing, like many modern wearables, fit into this regulatory framework.

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Henry Roberts: This slide provides a background on the evolution of our guidance for general wellness products. It outlines how we've refined our policy over the last decade to support low risk innovation. We began with a draft in 2015, which we finalized in 2016, establishing the core principles of enforcement discretion for products that are low risk and solely intended for general wellness uses.

A significant update came in September 2019, following the Cures Act. This was crucial as the Cures Act statutorily excluded certain software functions intended for maintaining or encouraging a healthy lifestyle from the definition of a medical device altogether.

Most recently, in January 2026, we provided further clarity on non-invasive sensing technology, common in modern wearables, explaining how these can remain categorized as general wellness products.

The key takeaway here is our consistent approach to reducing regulatory burdens on low risk technologies. As we gain additional experience with a product type, we can apply learnings to how we regulate devices.

Next, we will move on to a slide that outlines the factors that FDA intends to consider in determining whether a product may be a low risk general wellness product.

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Henry Roberts: CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the Food, Drug, and Cosmetic Act, or if they are devices, whether they comply with the premarket review and postmarket regulatory requirements. Some of those requirements are registration and listing, premarket notification, labeling requirements, good manufacturing practice requirements as well as MDRs, also known as medical device reporting requirements.

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Henry Roberts: In the guidance, we define general wellness products as products that meet two criteria. They are only intended for general wellness use and present a low risk to safety of users and other persons. Your product should have only a general wellness intended use and it should be low risk as described in the guidance to be considered a low risk general wellness product.

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Henry Roberts: The guidance describes two categories of general wellness product intended uses. The first category is an intended use that relates to maintaining or encouraging a general state of health or healthy activity and does not make reference to a disease or a condition.

The second category is an intended use that relates the role of a healthy lifestyle to helping to reduce the risk or impact of a disease or a condition. The role that the healthy lifestyle may play in the health outcome for the disease or condition should be well understood and accepted.

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Henry Roberts: More specifically, the guidance explains that the first category of general wellness intended uses involves claims about sustaining or offering general improvement to functions associated with a general state of health but does not make any reference to diseases or conditions.

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Henry Roberts: Some examples of such general wellness intended uses can include a claim to promote or maintain a healthy weight, encourage healthy eating or assist with weight loss goals, claims to promote relaxation or manage stress, or claims to promote physical fitness.

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Henry Roberts: The guidance explains that the second category of general wellness intended uses 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.

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Henry Roberts: In this second category of general wellness intended uses, there are two subcategories. This includes claims to promote, track and/or encourage choices, which, as part of a healthy lifestyle, may help to reduce the risk of a certain chronic disease or condition, or claims that your product promotes, tracks, and encourages choices, which, as part of the healthy lifestyle, may help to living well with certain chronic disease or conditions.

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Henry Roberts: Some examples of these kinds of general wellness intended uses include a product that promotes physical activity, which, as part of a healthy lifestyle, may help to reduce the risk of high blood pressure. Another example is software that tracks your calories and helps you manage a healthy eating plan to maintain a healthy weight and balanced diet, which may help living well with high blood pressure and type II diabetes. Another example of such general wellness intended uses includes a product that tracks your sleep patterns and promotes healthy sleep habits which may help reduce the risk of developing type II diabetes.

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Henry Roberts: And now we will shift to evaluating whether the product is considered low risk. As described in this guidance, you should answer no to these three questions for the product to be considered low risk. Those questions include, is the product invasive? Is the product implanted? And does the product involve an intervention or technology that poses a risk to the safety of users if regulatory controls are not applied?

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Henry Roberts: Let’s discuss some examples of products that present risk to the user's safety, which then are not considered low risk and therefore not a low risk general wellness product, even if it could have a general wellness intended use.

A laser product that claims to improve a user's appearance by rejuvenating the skin would not be considered low risk. Although the claims of rejuvenating the skin and improving confidence in the user's appearance are general wellness claims, the technology itself poses a risk of skin and eye burns.

A neurostimulation product that claims to improve memory would not be considered low risk. Although the claims to improve memory are general wellness claims, the technology itself poses a risk to the user’s safety from electrical stimulation.

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 intended use 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 intended use 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.

Alright, now I'll hand it over to Aneesh to dive into the latest updates to the guidance.

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Aneesh Deoras: Thank you Henry. Next, we will discuss the clarifying updates to the General Wellness guidance from January 6, 2026. These updates reflect current Agency policy toward low risk general wellness products. Two updates involve clarifications about what products are considered low risk general wellness products, including those that use non-invasive sensing and provide certain user notifications. Also, three examples were added to illustrate these clarifications.

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Aneesh Deoras: The first clarification relates to products that use non-invasive sensing for general wellness purposes. Products that use non-invasive sensing, such as optical sensing, to estimate, infer, or output physiologic parameters may be considered general wellness products when the outputs are intended solely for wellness uses, and the products align with the considerations outlined in the guidance and shared on this slide.

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Aneesh Deoras: Low risk general wellness products within this category can display values, ranges, trends, baselines, or longitudinal summaries, contextualized in relation to sleep, activity, stress, recovery, or similar wellness domains.

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Aneesh Deoras: To be considered a low risk general wellness product within this category, the product should not be intended to measure, estimate, or report physiological values with medical or clinical purposes, including screening, diagnosis, monitoring, alerting, or management of a disease or condition.

Further, the labeling, advertising, user interface, and functionality for the product should not include specific references to specific diseases, clinical conditions or diagnostic thresholds; alerts, alarms, or prompts that recommend or require specific clinical action or medical management; treatment guidance intended to inform or direct medical management; claims of clinical equivalence, clinical accuracy, medical or clinical grade, or substitution for an authorized device; or intended use statements that explicitly target diagnosis, screening, monitoring, or management of a disease or condition.

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Aneesh Deoras: The second clarification relates to products that provide user notifications. These products may include, but are not limited to, those that use non-invasive sensing to output physiologic parameters. Products that provide notifications to a user that evaluation by a healthcare professional may be helpful when outputs fall outside ranges appropriate for general wellness use may be considered general wellness products. These notifications should not identify or name a specific disease or medical condition; should not characterize the output as abnormal, pathologic, or diagnostic; should not include clinical thresholds, diagnoses, or treatment recommendations; and should not provide ongoing alerts or monitoring intended to manage a disease or condition.

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Aneesh Deoras: To support the two clarifications, we have added three illustrative examples to the guidance. The first new example, Example 7, is for a non-invasive wrist-worn wearable product that outputs multiple biomarkers, including hours slept, sleep quality, pulse rate, and blood pressure. These biomarkers are based on non-invasive sensing, such as an accelerometer and a photoplethysmogram, a form of optical sensing. Provided the physiologic parameters are validated, this is a low risk general wellness product. However, if the claims made about the product's functionality implied use in a medical or clinical context, the product would not be a low risk general wellness product.

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Aneesh Deoras: The second new example, Example 8, is for a wearable product that provides estimations of blood glucose for monitoring nutritional impacts and has a general wellness intended use. This example is not a low risk general wellness product because it is invasive.

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Aneesh Deoras: The third new example, Example 9, is for a non-invasive wearable product that outputs physiologic parameters including electrolyte balance, lactate, and hemoglobin. Because it has a general wellness intended use and does not pose a risk to the safety of users, and provided the values are validated, it is a low risk general wellness product.

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Aneesh Deoras: Today we discussed the FDA guidance, General Wellness: Policy for Low Risk Devices, including clarifications to the guidance issued on January 6, 2026. These clarifications were focused on products that use non-invasive sensing and provide user notifications. Examples were discussed to illustrate the policy clarifications.

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CAPT Kim Piermatteo: Thank you Aneesh and Henry for your presentations.

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CAPT Kim Piermatteo: As I mentioned earlier for this town hall we will be addressing some previously emailed questions about today's topic. I will read a question and then Aneesh will provide a response.

Aneesh, our first question is, should manufacturers and developers reach out to FDA for updated feedback?

Aneesh Deoras: Thanks Kim. If you have any questions about how the updated version of the General Wellness Guidance may impact your product, we recommend that you submit a Pre-Submission to the review division that may be responsible for your product or a product that provides similar physiologic parameters or values. Office of Product Evaluation and Quality, or OPEQ, review teams will be working closely with the Digital Health Center of Excellence, or DHCoE, to provide clear direction and consistency with the updated guidance.

CAPT Kim Piermatteo: Thanks Aneesh. The next question is, the guidance states that non-invasive sensing products may not be general wellness products if they include values that mimic those used clinically, unless validated to reflect those values. What does it mean for a physiologic parameter or value to be validated? Does information supporting validation need to be made public?

Aneesh Deoras: A physiologic parameter or value can be validated through a variety of means, including testing conducted by the manufacturer and publication of validation results in a peer-reviewed journal. FDA encourages making validation results public. If information supporting the validation of a physiologic parameter or value are not made public, FDA may request a summary of the information supporting validation. Under this policy there are no specific requirements for validation, but manufacturers are encouraged to consider whether there exist relevant FDA guidance documents or performance standards, FDA-recognized voluntary consensus standards, requirements promulgated by professional societies, and other criteria.

CAPT Kim Piermatteo: Thanks again Aneesh. This next question consists of a few questions, so here they are, what does it mean for a product to use non-invasive sensing? Does that include inflatable cuffs? Are microneedle-based technologies, such as some continuous glucose meters, within scope of this policy? Are other products, such as urinalysis test strips, included?

Aneesh Deoras: Products that are non-invasive, not implanted, and 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 generally are considered low risk. Such products may include those that use optical sensing, such as photoplethysmography, accelerometer data, and environmental data. Depending on the specific context of use, this may include products that use an inflatable cuff.

Products that use a microneedle, such as continuous glucose monitors, are invasive and not considered low risk, and therefore are not considered low risk general wellness products. However, if the product was non-invasive and had solely a general wellness intended use, then it may be a low risk general wellness product. This could include certain wearable software products that provide health or wellness recommendations based on glucose measurements made by a separate medical device, when those recommendations have a general wellness intended use.

Urinalysis test strips can be considered general wellness products, provided the products have a general wellness intended use and are low risk. However, the design and labeling of urinalysis test strips available today suggest intended uses that would not be a general wellness intended use, such as for the identification of a urinary tract infection or ketoacidosis.

CAPT Kim Piermatteo: Thanks for addressing all the parts of that question Aneesh. Alright, the next question is, the guidance says that a product may still be a low risk general wellness product if it provides notifications informing a user that evaluation by a healthcare provider may be helpful when values exceed ranges for general wellness use. What might these notifications look like, and on what thresholds?

Aneesh Deoras: A product may still be a low risk general wellness product if it provides notifications when outputs fall outside ranges appropriate for general wellness use. These notifications should not name a specific medical disease or condition. However, ranges appropriate for general wellness use may fall within the clinical thresholds defined for specific medical diseases or conditions, such as 100 beats per minute for resting heart rate being an accepted clinical threshold for tachycardia. In this case, low risk

general wellness products may provide notifications that align with clinical thresholds but should not include the numeric value of the threshold or name the specific medical disease or condition.

Low risk general wellness products can also indicate that a physiologic parameter is higher or lower than a threshold; for example, “Your resting heart rate was high over the past few days. You should check with your doctor if this is an unexpected result.”

In addition, such notifications should not include other features, such as colors or sounds, that characterize the output as abnormal, pathological, or diagnostic. These limitations do not preclude notifications that are triggered by or include numeric values for thresholds defined by the user, user community, or those that are based on typical values for the user or user community, which may not be those typically used by the medical community.

CAPT Kim Piermatteo: Thanks Aneesh. The next question is, are there low risk general wellness products that make reference to specific diseases or conditions?

Aneesh Deoras: The General Wellness guidance includes a category of general wellness products that have intended uses that make reference to diseases or conditions and relate to sustaining or offering general improvement to functions associated with a general state of health. These products may help users live well with or may help reduce the risk of certain chronic diseases or conditions. As discussed in the guidance, these products do not perform non-invasive sensing of physiologic parameters.

CAPT Kim Piermatteo: Thanks Aneesh. Alright, for our next question, that is, do the clarified policies on non-invasive sensing and user notifications apply to both adults and children?

Aneesh Deoras: Low risk general wellness products may be intended for use by both adults and children, provided the products are consistent with the policy that the product has a general wellness intended use and is low risk. Manufacturers should consider the characteristics of an intended use population in determining whether a product has a general wellness intended use.

For example, measurement of blood oxygen in an infant population may not relate to maintaining or encouraging a general state of health or a healthy activity. We recommend reaching out to the review division responsible for your product or product that provides similar physiologic parameters or values for additional feedback on products intended for general wellness use by specific populations.

CAPT Kim Piermatteo: Thanks again Aneesh. The next question is, are there any cybersecurity requirements or limitations on data sharing?

Aneesh Deoras: As described in the General Wellness guidance, and which remains unchanged in this update, FDA does not intend to examine compliance with device requirements, including cybersecurity requirements, in the Federal Food, Drug, and Cosmetic Act, and its implementing regulations for low risk general wellness products. Data communication and privacy requirements administered by other agencies may apply. Patients may choose to share such data output from low risk general wellness products with their healthcare provider.

CAPT Kim Piermatteo: Thanks again Aneesh. One last question for today, and that is, are any previously authorized devices no longer being regulated? Also, how should one differentiate between an FDA-authorized device and a low risk general wellness product?

Aneesh Deoras: As stated in the Guidance, a wellness product is solely for wellness uses and not intended to substitute for an FDA-authorized device. FDA does not intend to change the classification of any previously authorized devices based on the recommendations in this guidance.

The policy provides that a product within the scope of this policy should have only a general wellness intended use, as described in the guidance, and be low risk. FDA continues to actively regulate devices

that non-invasively measure blood pressure when they are not intended solely for a general wellness intended use. Manufacturers of products that may be low risk general wellness products should review the guidance and learn more about what FDA considers to be appropriate general wellness intended uses. For general wellness products, labeling should not include statements regarding being medical or clinical grade.

CAPT Kim Piermatteo: Thanks Aneesh. That wraps up our questions and answers for this town hall. I appreciate Aneesh and the Center for providing responses to those questions.

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CAPT Kim Piermatteo: I'll now turn it back over to you, Aneesh, for some closing remarks regarding today's topic.

Aneesh Deoras: Thank you Kim. Today we discuss clarifications to the FDA guidance on General Wellness: Policy for Low Risk Devices shared on January 6, 2026. The clarifications address general wellness products that output physiologic parameters or values and user notifications. If you have any questions, we recommend leveraging our Q-Submission program to obtain additional feedback.

Thank you all for your time today.

CAPT Kim Piermatteo: Thanks again Aneesh and again thank you Henry. And thank you to all of our viewers for attending the town hall today.

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CAPT Kim Piermatteo: Before we conclude, I want to remind everyone a recording of today's event, and the slides and a transcript will be posted as soon as possible to the event page, as well as to CDRH Learn under the section titled "Specialty Technical Topics," and the sub-section "Device-Specific Topics." A screen shot of where you will be able to find these materials on CDRH Learn has been provided on this slide.

If you have any additional questions regarding today's town hall, feel free to reach out to DICE at DICE@fda.hhs.gov.

And lastly, I encourage you to monitor our CDRH Events webpage at www.fda.gov/CDRHevents, for a listing of upcoming CDRH Events.

Thank you all again for joining. This concludes our CDRH Town Hall.

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