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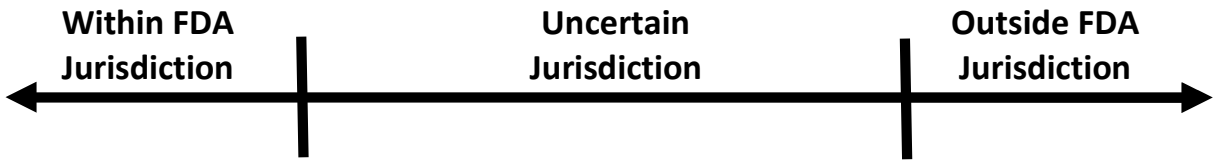
FDA Regulation of mHealth Wellness Claims

We need your help. The mHealth Regulatory Coalition is currently in the process of developing a guidance document to propose to FDA that clarifies what types of mHealth technologies FDA will regulate. FDA jurisdiction over a product is determined by its intended use. So the first step in this process is to identify types of intended use claims that mHealth manufacturers might wish to make. We have created a chart that breaks these intended use claims into four different types using the following continuum.



Bucket 1	Bucket 2A	Bucket 2B	Bucket 3
Those disease related claims that ***clearly do*** constitute medical device claims	Those wellness related claims that ***technically*** constitute medical device claims, but should ***not*** be regulated to encourage such claims.	Those disease/wellness related claims that ***might*** constitute medical device claims, but it is ***unclear***.	Those wellness related claims that ***clearly do not*** constitute medical device claims.

While we developed the chart by focusing on the specific claim language, we are not trying to gather each and every specific claim that might be made. Instead, we just want to make sure that we have representative examples. We will use these examples to test the guidance document we are writing.

Of course the context around the specific claim language impacts its meaning and, therefore, could affect the bucket into which the product falls. Although intended use is determined by looking at all of the evidence of the manufacturer's intent (e.g., explicit statements, design characteristics, target markets, etc.), in this chart we assume that all of the other evidence of intended use is consistent with the statements in the chart.

Please let us know if you are aware of other useful examples we should include. If you have questions about the role of the intended use, please read the coalition's paper on "A Call for Clarity: Open Questions on the Scope of FDA Regulation of mHealth."

March 1, 2011

Intervention Area/ Product Type	Intended Use Claims			
	Bucket 1 **Clearly Within FDA Jurisdiction**	**Bucket 2A** **Should Not Fall Within FDA Jurisdiction for Public Policy Reasons**	**Bucket 2B** **May Not Fall Within FDA Jurisdiction due to Ambiguous Language**	**Bucket 3** **Clearly Outside of FDA Jurisdiction**
Sleep	• To diagnose or treat cardiac disease associated with sleep disorders through system-interpreted data. • To diagnose or treat sleep disordered breathing and other sleep dysfunctions. • To alert an HCP of sleep dysfunction determined based on system-interpreted data. • To improve sleep function based on system-interpreted data.	• To alert an HCP of sleep dysfunction based on an HCP-recommended threshold. • To reduce the risk of sleep dysfunction and associated cardiac disease.	• To allow an HCP to monitor your sleep activity. • To incorporate your sleep activity (uninterpreted) into an EMR.	• To improve the quality of your sleep via uninterpreted data. • To reduce tiredness and improve overall awareness while awake via physical or brain exercises. • To allow you to monitor your sleep activity.
Exercise	• To improve heart health and/or lung function specific to a diagnosed disease state based on system-interpreted data. • To alert an HCP of deficiencies in exercise activity necessary for prescribed disease treatment based on system-interpreted data. • To diagnose or treat heart disease, stroke, obesity, diabetes, or peripheral artery disease based on system-interpretted data • To improve heart health and/or lung function specific to a diagnosed disease state without system-interpreted data.	• To reduce the risk of heart disease, stroke, obesity, diabetes, or peripheral artery disease. • To reduce the risk of disease through improvement of immunological response/tolerance. • To build muscle function or restore joint motion.	• To allow an HCP to monitor daily exercise activity.	• To improve overall health and physical conditioning. • To allow you to monitor and record daily energy expenditure. • To report and display daily exercise activity in relation to other health parameters. • To improve heart health and/or lung function not specific to a diagnosed disease state.

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Diet	• To diagnose or treat obesity, diabetes, or eating disorders (e.g., anorexia and belemia). • To improve fetal health through system-interpreted data.	• To reduce the risk of heart disease, stroke, obesity, diabetes, or peripheral artery disease. • To reduce the risk of disease through improvement of immunological response/tolerance. • To reduce the risk of pregnancy-related disorders.	• To alert an HCP and/or family member of unhealthy dietary activity.	• To monitor and record food consumption. • To improve overall health and physical conditioning. • To improve fetal health. • To monitor weight gain/loss.
Stress Management	• To improve fetal health through system-interpreted data.	• To reduce the risk of disease through improvement of immunological response/tolerance. • To reduce the risk of depression, sleep dysfunction, or heart disease. • To reduce the risk of pregnancy-related disorders.	• To reduce the risk of hair-loss. • To alert an HCP and/or family member of elevated stress levels or stressful activities.	• To reduce stress or improve relaxation. • To improve fetal health.
Weight Management	• To diagnose or treat congestive heart failure, obesity, diabetes, or eating disorders (e.g., anorexia and belemia). • To improve fetal health through system-interpreted data.	• To improve heart health associated with a diagnosed condition based on recommended thresholds. • To reduce the risk of pregnancy-related disorders. • To improve or restore joint function.	• To improve heart health not associated with a diagnosed condition. • To reduce pain (e.g., back or joint).	• To improve overall health and physical conditioning. • To monitor weight gain/loss.

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Allergies	• To detect or prevent a high-risk allergic reaction based on system-interpreted data. • To monitor and manage allergic reactions based on system-interpreted data. • To alert an HCP or emergency medical service of a high-risk allergic reaction.	• To reduce the risk of disease through improvement of immunological response/tolerance. • To alert an HCP of a low-risk allergic reaction. • To detect or prevent a low risk allergic reaction.	• To alert a family member of an alergic reaction.	• To identify generally-known allergens.
Smoking Cessation	• To diagnose or treat smoking addiction based on system-interpreted data.	• To reduce the risk of lung disease (e.g., COPD or cancer). • To reduce the risk of heart disease, stroke, or peripheral artery disease.	• To improve heart health by tracking tobacco use and/or smoking cessation progress.	• To assist in the effort to quit smoking. • To detect the presence of second-hand smoke.
Software	• To collect data directly from a medical device. • To store, retrieve, and display individual patient data that is collected by means other than manual entry. • To assist in the remote administration of medication. • To analyze laboratory results and other data for diagnosis or treatment purposes. • To view and analyze images for diagnosis, prognosis, or treatment purposes. • To alert an HCP or emergency medical service of a high-risk adverse medical event.	• To alert an HCP or emergency medical service of a low-risk adverse medical event. • To aggregate patient information and medical device data into a single report.	• To allow a patient to monitor their medical device data for personal use. • To remind a patient of the need to take medication or to complete some aspect of treatment (e.g., attend an HCP appointment) • To transfer patient information to an EMR. • To display patient information for review by an HCP.	• To allow an HCP or a patient to enter patient information into an EMR. • To store, retrieve, and display individual patient data collected by manual entry. • To display patient information for personal use.

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Communications Technologies/ Network Infrastructure	• To facilitate the connection between various medical devices. • To transfer medical device data to an EMR.		• To facilitate the display of patient information for review by an HCP. • To transfer patient information to an EMR. • To allow the exchange of information and communication between medical devices.	• To facilitate the exchange of patient information among HCPs and the patient.
General Mobile Technologies	• To connect to peripheral medical devices regardless of class. • To control delivery of medication or other therapy. • To alert an HCP of the delivery of medication or other therapy. • To provide real-time diagnosis or treatment of disease. • To analyze patient data for medical diagnosis or treatment. • To enable healthcare providers to diagnose or treat patients during a "face-to-face" HD video consultation. • To evaluate patient cognitive/audio/visual/motor/ sensory function for diagnosis or treatment purposes. • To evaluate effective patient therapy based on activity tracking of patients.	• To run medical/healthcare-related software apps. • To enable easy self-monitoring of your health or vital statistics. • To provide real-time reporting of patient health information to an HCP. • To prevent the onset of disease. • To enable healthcare providers to perform "face-to-face" HD video consultations. • To monitor elderly individuals for purpose of alerting an HCP or emergency medical service of a low-risk adverse medical event. • To manually collect and store patient information for medical diagnosis or treatment.	• To help manage your health. • To ensure compatability with medical device interoperability standards. • To provide quality and reliability in the delivery of healthcare. • To reduce the frequency of hospitalization. • To provide real-time reporting of patient health information to the patient or family member. • To automatically deliver prescription refill requests directly to your pharmacy. • To provide non-diagnostic-quality electrophysiological signals or medical images. • To allow patients to perform congnitive/audio/visual/motor/ sensory challenges/games.	• To serve basic communication needs. • To improve your quality of life. • To ease the stress of managing your health. • To ease the stress of your family members regarding your health. • To manage diet and exercise. • To keep track of your medical records and personal health information. • To deliver health and wellness services (e.g., diet and exercies advice, motivational advice, etc.) directly to your mobile device. • To collect and store health information/data for personal use.

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General Mobile Technologies (cont'd)	• To diagnose and treat patients based on activity analysis. • To determine treatment parameters based on patient location. • To monitor elderly individuals for purpose of alerting an HCP or emergency medical service of a high-risk adverse medical event.		• To monitor elderly individuals for purpose of alerting family members in the event of an emergency.	• To analyze health data for personal use. • To report health data to a non-medical advisor. • To enable patients, family members, and HCPs to stay connected. • To improve personal productivity, both for the patient and the HCP. • To allow "face-to-face" HD video conversations. • To allow individuals to play "mind challenging" games. • To access educational health and medical information. • To access patient medical records. • To monitor and record human activities and location. • To connect you directly to an HCP. • To connect your HCP directly to you.
Therapy Compliance	• To alert an HCP of the delivery of medication or other therapy. • To assist in the remote administration of medication.		• To remind a patient of the need to take medication or to complete some aspect of treatment (e.g., attend an HCP appointment)	

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Senior/Elderly Monitoring	• To diagnose and treat patients based on activity analysis. • To evaluate effective patient therapy based on activity tracking of patients. • To evaluate patient cognitive/audio/visual/motor/ sensory function for diagnosis or treatment purposes. • To alert an HCP or emergency medical service of a high-risk adverse medical event. • To assist in the remote administration of medication. • To alert an HCP of the delivery of medication or other therapy.	• To alert an HCP or emergency medical service of a low-risk adverse medical event. • To detect falls for the purpose of alerting an HCP or emergency medical service.	• To allow patients to perform congnitive/audio/visual/motor/ sensory challenges/games. • To monitor elderly individuals for purpose of alerting family members in the event of an emergency. • To remind a patient of the need to take medication or to complete some aspect of treatment (e.g., attend an HCP appointment)	• To allow individuals to play "mind challenging" games. • To monitor and record human activities and location. • To detect falls for the purpose of alerting a family member.
Emergency Response Devices	• To alert an HCP or emergency medical service of a high-risk adverse medical event.	• To alert an HCP or emergency medical service of a low-risk adverse medical event. • To detect falls for the purpose of alerting an HCP or emergency medical service.	• To monitor elderly individuals for purpose of alerting family members in the event of an emergency.	• To monitor and record human activities and location. • To detect falls for the purpose of alerting a family member.
Electronic Medical Records	• To transfer medical device data to an EMR.	• To aggregate patient information and medical device data into a single report	• To incorporate your sleep activity (uninterpreted) into an EMR. • To transfer patient information to an EMR. • To allow a patient to monitor their medical device data for personal use.	• To allow an HCP or a patient to enter patient information into an EMR. • To access patient medical records. • To collect and store health information/data for personal use. • To analyze health data for personal use. • To report health data to a non-medical advisor.