Use of "FDA Approved"

On occasion, medical device manufacturers receive warnings letters for making claims about the status of a device. In particular, the manufacturer will state that the device is "FDA Approved". The statements may appear on the company's website, in marketing literature, at a tradeshow, *etc*. FDA considers these statements as misbranding.

Misbranded is a technical term from the Food, Drug, and Cosmetics Act, FD&CA, that indicates a particular status for a drug or device. In addition, the contrasting term adulterated may also apply to a drug or a device. These terms, with their complicated definitions, typically for the basis for warning letters and other action that FDA may initiate.

FDA Approved

A warning letter, for this problem will typically cite the regulation, 21 CFR §807.97. The regulation explains that allowing a device into commercial distribution through the 510(k) process, "does not in any way denote official approval of the device". The section goes on to state, "Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding".

On February 25, 2015, FDA sent a warning letter to Tiller Mind Body, Inc., a manufacturer of the LIBBE Colon Hydrotherapy Irrigation System ("LIBBE System"). The warning letter says, "Specifically, your firm's website states that '[i]n the treatment of every disease, the colon must be considered. Cleansing the colon using safe FDA approved Colon Hydrotherapy Devices is the best start'. Your firm's website also states that LIBBE System components, including colonic nozzles, are 'FDA Approved'. The LIBBE System was not approved by the FDA, but was determined to be substantially equivalent …"

On August 17, 2016, FDA sent a warning letter to Simpro, LLC, an initial importer and distributer of non-invasive blood pressure monitors, fingertip pulse oximeters, and portable fetal dopplers. The warning letter says, "Following a review of your firm's website, www.naturespiritproduct.com, we noted that your firm stated the Portable Fetal Doppler with Speaker and Backlit LCD Display is 'FDA approved'. Statements such as 'FDA approved' create an impression of official approval of a device due to clearance of a premarket notification submission and may cause the device to be misbranded … If this device was subject to official FDA approval through the premarket approval application submission process, we request that you provide evidence of this in your response to this letter. However, if this device was determined by FDA to be substantially equivalent … [we recommend] that the statement, 'FDA Approved' be removed from the labeling of the device, to include your firm's website."

FDA Registered

Firms may receive a warning for a similar problem with registration. 21 CFR §807.39 says, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

On December 22, 2010, FDA sent a warning letter to Heritage Labs International LLC, a manufacturer of In-Vitro Diagnostic Devices (IVDs) including the Appraise® Biometric Collection Tests for Hemoglobin Ale, Microalbumin, Prostate Specific Antigen, Thyroid Stimulating Hormone, and Lipids. The warning letter says, "Our inspection also revealed that your devices are misbranded … within the meaning of 21 CFR §807.39. Your website displays a large banner which states 'FDA Registered' which creates an impression of official approval of your establishment or its products."

Recommendations
Train sales and marketing people about the requirement discussed above.

As part of your process to review and approve marketing material, including websites, include a check for phrases such as "FDA Approved" or "FDA Registered". A search with a word processor for the "FDA" will usually reveal any potential problems.

As part of your internal quality audit program, review the marketing material in general for claims. Look for these phrases in particular.