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Client Alert

FDA & Life Sciences Practice Group

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2013 Year in Review: CDRH Promotion and Marketing Enforcement Letters

In 2013, FDA's Center for Devices and Radiological Health (CDRH) made publicly available on its website a total of 22 promotion and marketing-related enforcement letters to device manufacturers. Of the 22 enforcement letters, 21 were Warning Letters. Although FDA stated publicly that it would begin publishing (for the first time) Untitled Letters on its website, FDA made publicly available only one Untitled Letter in 2013.

The vast majority of the 2013 enforcement letters resulted from CDRH review of company or product websites. However, 5 of the 22 letters cited materials reviewed by FDA during a manufacturing facility inspection. All five of those inspection-based letters were issued to foreign manufacturers in either China, South Korea or India.

Notable Trends in 2013:

The most frequent allegations cited in CDRH promotion and marketing enforcement letters in 2013 were:

Allegation	2013
Promotion of an Uncleared / Unapproved Device	68%
Promotion of Device Beyond Exemption from Premarket Notification	23%
Promotion of a Cleared / Approved Device Beyond Clearance / Approval	14%
Device Modifications Requiring a New Premarket Notification	14%
Promotion of Specific Use when Device Cleared / Approved for General Use	9%

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Observations and Lessons Learned from 2013 CDRH Promotion and Marketing Enforcement Letters:

In 2013, CDRH appeared to focus it promotion and marketing-related enforcement on the promotion of uncleared and unapproved devices on the market.

In 2013, a disproportionate number of enforcement letters were issued to manufacturers marketing devices for which they had neither PMA approval nor 510(k) clearance. The majority of these letters cited fairly egregious claims. For example:

- In a January 9, 2013 Warning Letter, CDRH cited a company for marketing its uncleared and unapproved bone-growth stimulator device for the following uses: treatment of acute and chronic pain and rheumatic disorders, improvement of sleep, circulation and cellular metabolism, and promotion of healing of soft tissue injuries and inflammatory joints.

- In a July 1, 2013 Warning Letter, CDRH cited a company for marketing its uncleared and unapproved WaxVac for safe and quick removal of dirt particles and moisture from the ear.

- In a November 22, 2013 Warning Letter, CDRH cited a company for marketing its uncleared and unapproved Saliva Collection Kit and Personal Genome Service for personal health reports on 254 diseases and conditions, including the BRCA breast cancer gene, warfarin sensitivity and 5-fluorouracil toxicity.

- In a December 2, 2013 Warning Letter, CDRH cited a company for marketing an uncleared and unapproved ultrasound and radiofrequency device for reduction of localized adipositites (i.e., body fat), excess weight and cellulite and to firm, tone and increase circulation and lymphatic drainage.

In addition, CDRH issued a number of Warning Letters citing companies for promotion of devices beyond the scope of their exemption from premarket notification. In particular, CDRH appeared to target a number of companies marketing "aesthetic" and "general health" medical devices, including decorative contact lenses, dermabrasion devices, therapeutic massagers and other devices used for the treatment of various dermatologic conditions.

- In a March 1, 2013 Warning Letter, CDRH cited a company for marketing the "high frequency function effects" of its uncleared and unapproved "Beauty Instruments." Specifically, FDA took issue with the company's claims regarding impact of the device on hair growth, blood vessel expansion and metabolism.

- In another March 1, 2013 Warning Letter, CDRH cited a company for marketing its general dermabrasion device (a device exempt from premarket notification) for a number of non-exempt claims including skin regeneration and repair, skin cell repair, stem cell proliferation, increase in micro-circulation below the skin, collagen induction and acne treatment.

- In a March 13, 2013 Warning Letter, FDA cited a company for the marketing of its therapeutic massager, a device exempt from 510(k) requirements when intended for medical purposes such as relieving muscle aches and pains. The company's website marketed the device for indications outside the scope of the 510(k) exemption for the device, including stimulation of the lymphatic system; fat drainage; reduction of water retention and edema; fibromyalgia, restless legs and headache relief; and breast cyst reduction.

- On November 14, 2013, CDRH issued a Warning Letter to a company marketing uncleared and unapproved clinical lasers for hair removal, body contouring and "skin uplift."

- In a November 20, 2013 Warning Letter, CDRH cited a company for marketing disposable biopsy punches (devices exempt from premarket notification for use in general dentistry and oral surgery procedures) for non-exempt indications of correcting vitiligo (*i.e.*, skin depigmentation) and use in hair transplant.

- In a December 2, 2013 Warning Letter, CDRH cited a company for marketing a number of aesthetic medical devices (*e.g.*, therapeutic massagers, epilators, therapeutic deep heat devices, diathermy devices and various other dermatologic devices) without any clearance or approval or outside of the devices' exemptions from premarket notification. Specifically, CDRH cited the company for claims including: improvement of skin quality, improvement of muscle tone around the face and neck, activation of cellular renewal, skin decongestion, wrinkle reduction, removal of spider veins and vascular blemishes, reduction of fat deposits and cellulite, foreskin rejuvenation, and breast enlargement.

CDRH cited three companies for marketing cleared devices with uncleared modifications that introduce additional safety and effectiveness questions requiring a new 510(k) clearance.

- On November 20, 2013, CDRH cited a company for the addition of new wavelength and hand pieces to its surgical lasers, stating that the modifications introduce additional safety and effectiveness questions.

- In a December 2, 2013 Warning Letter, CDRH cited a company for distributing its therapeutic deep heat device with ultrasound frequencies of 28 kHz when the device was cleared for ultrasound frequencies of 1 and 3 MHz. CDRH stated that this lowered ultrasound frequency represented a major modification to the device requiring a new 510(k).

- In a December 16, 2013 Warning Letter, CDRH cited a company for modifying its light emitting diode (LED) skin care system by combining red and blue light for treating acne. CDRH stated that using a combination red and blue light system (rather than blue or red light alone) to treat acne requires submission of a new premarket notification for the device.

CDRH cited two companies for marketing devices for specific uses when the devices were cleared for only general uses.

- In a January 9, 2013 Warning letter, CDRH cited a company for promotion of its device cleared generally for the following uses: stroke rehabilitation by muscle re-education; prevention or retardation of disuse atrophy; increase of local blood circulation; muscle re-education and maintenance or increase or range of motion. Specifically, CDRH took issue with the company's claims regarding use of the device for specific conditions such as spinal cord injury and cerebral palsy.

- In a December 16, 2013 Warning Letter, CDRH cited a company for promoting its device for specific pain relief indications (*e.g.*, chronic pain (CTS, arthritis, etc.), post-operative pain, musculoskeletal pain (*e.g.*, back pain, neck pain, etc.)) when the device was cleared with a pain indication for general pain relief only. FDA stated that the specific indications for pain relief may require clinical data under a new premarket submission.

For your reference, we prepared a chart that provides: (1) a list of 2013 CDRH promotion and marketing-related enforcement letters and (2) highlights the promotional violations alleged in each letter. The chart is available online

in a searchable PDF document at:
http://www.kslaw.com/imageserver/KSPublic/library/publication/ca021914_table.pdf.

What to Watch For in 2014

In addition to likely continued concern about the alignment of marketing and promotional claims with the scope of applicable FDA clearances, approvals, or exemptions from premarket review, CDRH officials also announced in 2013 that organizational changes have been made in the Center's Office of Compliance to increase personnel dedicated to identifying device promotional violations more generally. Also, in conjunction with enhanced FDA attention to promotional practices, FTC signaled last year an intent to focus more attention on promotional use of patient testimonials in the coming months, particularly where testimonials reflect product results or experiences that are not representative of those that would be typically expected.

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