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E-ALERT | Food & Drug

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SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

JANUARY 2013

This e-alert is part of a series of monthly e-alerts summarizing publicly-available FDA enforcement letters (i.e., warning letters and untitled letters) relating to the advertising and promotion of drugs, biologics, and medical devices. In January 2013, the Office of Compliance in FDA's Center for Devices and Radiological Health (CDRH) posted the following enforcement letters on FDA's website:[1]

- "LASIK Warning Letters"
  - Warning letter to 20/20 Institute, Indianapolis Lasik re: WaveLight Allegretto Wave Eye-Q Laser (December 18, 2012) ("20/20 Warning Letter")[2]
  - Warning letter to Eye Center of Texas re: VISX laser (December 18, 2012) ("Eye Center of Texas Warning Letter")
  - Warning letter to Rand Eye Institute re: VISX Star S4 laser (December 18, 2012) ("Rand Warning Letter")
  - Warning letter to ScottHyver Visioncare, Inc. re: WaveLight Allegretto Wave Eye-Q Laser (December 18, 2012) ("ScottHyver Warning Letter")
  - Warning letter to Woolfson Eye Institute re: WaveLight Allegretto Wave Eye-Q Laser and VISX Star S4 laser (December 18, 2012) ("Woolfson Warning Letter")
- Warning letter to Curatronic Ltd. re: BioMove 3000, BioMove 5000 (collectively, "the BioMove devices"), Curatron 2000 HT, Curatron 2000 XP, Curatron 2000PC, and Curatron Ultra-Power 3-D Pulsed Electro-Magnetic Field Therapy (PEMF) (collectively, "the Curatron PEMF devices") (January 9, 2013) ("Curatronic Warning Letter")

During January 2013, FDA's Office of Prescription Drug Promotion (OPDP) and Office of Compliance and Biologics Quality (OCBQ) in FDA's Center for Biologics Evaluation and Research (CBER) did not post any enforcement letters relating to advertising and promotion on FDA's website.

This alert merely summarizes the allegations contained in FDA's letters, presented under the corresponding heading used by the agency in its letters. This alert does not contain any analysis, opinions, characterizations, or conclusions by or of Covington & Burling LLP. As a result, the information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

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[1] Only enforcement letters posted to FDA's website in January 2013 are included herein. Letters issued in January but not posted to the website by January 31, 2013 will be summarized in our alerts for the months in which those letters are posted.

[2] The dates referenced for the letters are the issue dates.

LASIK Warning Letters

Lasers such as the WaveLight Allegretto Wave Eye-Q Laser and VISX laser are restricted devices used in refractive procedures (e.g., laser-assisted in-situ keratomileusis (LASIK)). The Office of Compliance at CDRH reviewed websites for numerous US companies and stated in warning letters that their websites were misleading because they failed to reveal material facts regarding these LASIK devices.

Omission of Material Facts:[3] The LASIK warning letters stated that the websites omitted material facts, including relevant risk information associated with the use of the LASIK devices. For example, CDRH pointed to claims on the websites such as:

- **20/20 Warning Letter**: "While LASIK is a relatively quick and seemingly easy procedure from the patients [sic] prospective [sic], like any other surgical procedure, it requires expertise on the part of the surgeon and it comes with both risks and benefits. . . . In general the risk of complication in LASIK is less than one half (1/2) of one percent (1%), however you should discuss your individual risks and benefits with your doctor."
- **Eye Center of Texas Warning Letter**: "The most common side effects are dry eyes, a 'halo' effect, and some glare at night around lights. However, these problems are no worse than what most contact lens and eyeglass wearers often experience and usually diminish or disappear within 4-6 months of surgery."
- **Rand Warning Letter**: "Most LASIK patients no longer need glasses or contacts while driving, playing sports or watching movies and television. People pursuing careers that require excellent vision—such as police officers, paramedics, physicians and athletes—have benefited greatly from LASIK."
- **ScottHyver Warning Letter**: "The combination of speed, control and precision of the WAVE® Eye-Q laser means that patients are likely to enjoy LASIK outcomes that are equal to or even better than what they experience using glasses and contact lenses."
- **Woolfson Warning Letter**: "[L]ess than 1% of LASIK patients develop complications that can reduce the quality of their corrected vision. . . . The appropriate risks, benefits and expectations specific to your case will be addressed at your pre-operative exam and again before you go into surgery."

While the websites contained statements that promoted the benefits of the LASIK devices (see, for example, the ScottHyver Warning Letter), according to CDRH, the websites omitted material facts concerning the consequences that could result from the use of the devices, including dry eye syndrome, the possible need for eye glasses or contact lenses after surgery, debilitating visual symptoms, and vision loss. According to CDRH, "[i]t is critical to disclose risk information appropriately and effectively to consumers in all advertising and labeling concerning a restricted device[,] . . . information [which] may include contraindications, warnings, precautions, and adverse events." For those websites that did mention certain risks associated with the LASIK devices (see, for example, the Eye Center of Texas Warning Letter), CDRH stated that the websites failed to disclose the severity of the symptoms and their long-term persistence, and omitted other relevant risk information.[4] CDRH stated that these omissions misbranded the LASIK devices.

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[3] The letters issued by CDRH do not explicitly use this heading, but the allegations in the enforcement letters fit within it.

[4] CDRH also stated that the Eye Center of Texas website's claim that the side effects experienced by LASIK patients were "no worse than that what most contact lens and eyeglass wearers experience" was unsubstantiated.

Curatronic Warning Letter

Curatronic's BioMove devices are cleared for several indications, including stroke rehabilitation by muscle re-education, prevention or retardation of disuse atrophy, increasing local blood circulation, and maintaining or increasing range of motion. After reviewing Curatronic's website, CDRH stated that the website contained unsubstantiated claims and claims outside the cleared uses for the BioMove devices. Additionally, CDRH stated that Curatronic was marketing the Curatron PEMF devices on its website without the necessary clearance.

Unsubstantiated Claims:[5] CDRH stated that the website's comparative claims regarding the BioMove devices were unsubstantiated. Specifically, CDRH pointed to the claim "[t]he BioMove 5000 is not only the best Stroke Rehabilitation system in the world but also the easiest stroke therapy device for use by the stroke survivor." CDRH stated that this kind of claim required clinical data and a new 510(k) submission.

Claims Outside Cleared Use: Curatronic's website also included claims such as:

- "The BioMove 5000 is equally well suited for muscle rehabilitation therapy after Spinal Cord Injury [SCI] and Cerebral Palsy (CP)."
- "The BioMove 3000 system . . . works by detecting the EMG signals still left in muscles . . . . This method teaches the brain to re-develop spontaneous and voluntary muscle control."

CDRH stated that these claims represented new intended uses that required clearance of a premarket notification. CDRH also explained that, during the review of the 510(k) for the BioMove 5000 device, CDRH had advised Curatronic that the "spinal cord injury" setting was not a proposed indication, nor was it cleared under the predicate device, and thus safety and efficacy data were required. In response to this correspondence during the 510(k) review, Curatronic had revised the indication settings for the device. CDRH stated that the website's claims rendered the devices adulterated and misbranded.

Lack of Necessary Clearance: Additionally, Curatronic's website contained claims regarding the Curatron PEMF devices, including "PEMF promotes healing of soft tissue injuries, inflammatory joints, delayed and non-union fractures, and improves circulation and cellular metabolism." CDRH explained that the Curatron PEMF devices are bone-growth stimulators that incorporate pulse electromagnetic field technology, and thus were Class III devices that required PMA approval. Curatronic had not obtained marketing clearance or approval for these devices, and CDRH stated that the website's claims rendered the devices adulterated and misbranded.

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[5] The letter issued by CDRH does not explicitly use these headings, but the allegations in the enforcement letter fit within them.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

Michael Labson	+1.202.662.5220	mlabson@cov.com
Erika Lietzan	+1.202.662.5165	elietzan@cov.com
Scott Cunningham	+1.202.662.5275	scunningham@cov.com
Scott Danzis	+1.202.662.5209	sdanzis@cov.com
Julia Post	+1.202.662.5249	jpost@cov.com