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E-ALERT | Food & Drug

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SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

JANUARY 2014

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 prescription drugs, medical devices, and biologics.

In January 2014, FDA's Office of Prescription Drug Promotion (OPDP) posted the following enforcement letter on FDA's website[1]:

- Untitled letter to DaraBiosciences, Inc. re: NDA #021807 Soltamox® (tamoxifen citrate) oral solution MA #21 (December 20, 2013) ("DaraBiosciences Untitled Letter")

The Office of Compliance (OC) in FDA's Center for Devices and Radiological Health (CDRH) posted the following letter on FDA's website:

- Warning letter to SkinRex Co., Ltd., re: Cavi-Lipo, CMS #414838 (December 12, 2013) ("SkinRex Warning Letter")

The 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. It 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.

LETTER ISSUED BY OFFICE OF PRESCRIPTION DRUG PROMOTION (OPDP)

DaraBiosciences Untitled Letter

OPDP alleged that a sales aid regarding Soltamox solution was misleading because it omitted material facts, made unsubstantiated superiority claims, and omitted important risk information.

Omission of Material Facts: According to OPDP, the sales aid should have included the full approved indication of Soltamox because it included the following statement:

[1] Only enforcement letters posted to FDA's website in January 2014 are included herein. Letters issued in December but not posted to the website by January 31, 2014 will be summarized in our alerts for the months in which those letters are posted.

"**DOSAGE AND ADMINISTRATION**

For patients with breast cancer, the recommended daily dose is 20-40 mg. Dosages greater than 20 mg per day should be given in divided doses (morning and evening). . . ."[2]

Although the above statement was taken directly from the Dosage and Administration section of the approved prescribing information, OPDP alleged the statement "makes a representation about the use of Soltamox in the treatment of cancer." As a result, FDA alleged that the failure to include the full approved indications for Soltamox was a misleading omission.

Unsubstantiated Superiority Claims: The sales aid included the following claims:

- "**Compliance and adherence** to prescribed tamoxifen therapy is a critical issue in patient care and may affect treatment outcomes."[3]
- "**Difficulty swallowing pills** may affect both compliance and adherence to prescribed courses of oral solid medications."[4]
- "**Liquid medication may be preferred vs. pills by many patients**"[5]
- "**Soltomox** [sic], **the only tamoxifen citrate oral solution that may support long-term adherence**"[6]
- "For many reasons patients may have difficulty swallowing their medication. . . ."

OPDP alleged that the above claims implied that Soltamox solution offers a "therapeutic advantage" over tablet formulations of tamoxifen, including "a positive impact on long-term patient compliance, adherence to treatment, patient preference, convenience, and treatment outcomes." OPDP acknowledged that Soltamox was the only tamoxifen citrate oral solution available at the time and that tablets may pose challenges to patients. However, OPDP stated that this did not support above claims of improved patient compliance, adherence, convenience, treatment outcomes, or patient preference.

Omission of Risk Information: According to OPDP, the sales aid should have included important risk information, including warnings, precautions, and adverse reactions associated with Soltamox therapy. OPDP acknowledged that the back page of the sales aid referenced accompanying prescribing information and presented information regarding a Boxed Warning, contraindications, and some serious risks; however, OPDP stated this did not mitigate the misleading omission of important risk information in the body of the sales aid.

LETTER ISSUED BY OFFICE COMPLIANCE (OC) IN CDRH

Skinrex Warning Letter

OC alleged that claims on Skinrex's website relating to the device "Cavi-Lipo," which the company had listed as a Class I device under the classification regulation for Electric Therapeutic Massagers, exceeded the limitations on the exemption from premarket notification set forth in that regulation. The exemption for Electric Therapeutic Massagers in 21 C.F.R. § 890.5660 states that such devices

[2] Bolded emphasis in sales aid, and underlined emphasis supplied by OPDP.
[3] Emphasis in sales aid.
[4] Emphasis in sales aid.
[5] Emphasis in sales aid.
[6] Emphasis in sales aid.

are intended to utilize mechanical vibration to manipulate tissue. However, according to OC, the following statements on the website indicated that the Cavi-Lipo is intended for a different use:

- "Cavi-Lipo is one of the most advanced cavitation system [sic] and completed ultrasound machanisms [sic]."
- "Cavi-Lipo be applied [sic] to dissolve cellulites and discharge wastes out of body [sic]."
- "Cavi-Lipo with stable cavitation, [sic] is currently the most evolved system for the treatment of adipose areas and cellulites."
- "Frequency Cavitation system (28KHZ)."
- "[Cavi-Lipo is] designed to perform reduction treatment of adipose areas and cellulites, with results that can be compared to liposuction in surgery room."

According to OC, the above claims indicated that Cavi-Lipo is intended not as a therapeutic massager, but as an ultrasonic diathermy device, which is classified under 21 C.F.R. § 890.5300 as either a Class II (if intended to treat "selected medical conditions such as relief of pain, muscle spasms, and joint contractures") or Class III device (if intended to treat "all other uses"). According to OC, because the claims for Cavi-Lipo go beyond the "selected medical conditions" identified in the classification regulation as Class II uses, the device is subject to premarket approval requirements as a Class III device.

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