Email to On-line Distributors About Unlawful Marketing of Decorative Contact Lenses

U.S. Food & Drug Administration

Date: Feburary 28, 2013

From: FDA Center for Devices and Radiological Health (FDADECORATIVELENS-CDRH@fda.hhs.gov)

Date: February 28, 2013

To: (contact Email address)

Subject: Urgent Message from the Food and Drug Administration Regarding Decorative Contact Lenses Marketed by Your Firm

The purpose of this Email is to provide you with important information about regulatory requirements and safety concerns associated with the sale, marketing, and distribution of decorative or cosmetic contact lenses in the United States.

Please read the attached immediately.

Anastacia M. Bilek, Ph.D.
Director
Division of Enforcement A
Office of Compliance
Center for Devices and Radiological Health

ATTACHMENT

TO: (domain name; contact Email address)

FROM: Food and Drug Administration and Federal Trade Commission

RE: Unlawful Marketing of Decorative Contact Lenses

DATE: February 28, 2013

The purpose of this letter is to provide you with important information about regulatory requirements and safety concerns associated with the sale, marketing,

and distribution of decorative or cosmetic contact lenses in the United States.

The United States Food and Drug Administration's (FDA) Office of Criminal Investigations, in coordination with the staff of the Federal Trade Commission (FTC), recently reviewed your website and has determined that your website offers decorative contact lenses for sale without a valid prescription.

On November 9, 2005, section 520(n) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360j(n), was added by Public Law 109-96 to establish that all contact lenses, including non-corrective and decorative or cosmetic contact lenses, are devices under section 201(h) of the FDCA, 21 U.S.C. § 321(h).

As FDA-regulated devices, all contact lenses, including non-corrective and decorative contact lenses that are intended only to change the perceived appearance of the eye, are required to have in effect an approved premarket approval application (PMA) or a cleared premarket notification (510(k)) before they may be legally marketed. The sale, marketing, and distribution of any contact lenses in the absence of the appropriate FDA approval or clearance renders the products adulterated and/or misbranded. 21 U.S.C. §§ 331, 351, 352. All currently approved or cleared decorative contact lenses are prescription devices and, therefore, may be sold only to or on the prescription of a licensed practitioner. 21 CFR 801.109. As a vendor of contact lenses, it is your responsibility to ensure compliance with federal laws and regulations governing the sale, marketing, and distribution of these devices.

You should take immediate action to ensure that your firm is not marketing and distributing decorative or cosmetic contact lenses that have not been approved or cleared by FDA. It is your responsibility to ensure that the products you market and distribute are in compliance with the FDCA and its implementing regulations. We advise you to review your websites, product labels and labeling, and promotional materials to ensure that the claims you make do not adulterate or misbrand your products in violation of the FDCA. 21 U.S.C. §§ 331, 351, 352. Failure to promptly correct violations of the FDCA may result in enforcement action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Firms that fail to take corrective action may also be referred to FDA's Office of Criminal Investigations for possible criminal prosecution for violations of the FDCA and other federal laws.

If you are not located in the United States, please note that unapproved or uncleared devices offered for importation into the United States are subject to detention and refusal of admission. The appropriate regulatory and law enforcement officials in the country from which you operate will be advised that FDA considers your devices to be unapproved or uncleared and cannot be legally marketed and distributed in the United States.

Additional information on the regulatory requirements for decorative contact lenses can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071572.htm [1].

You are also advised that your sale of decorative or cosmetic contact lenses to consumers may be in violation of the Fairness to Contact Lens Consumers Act ("the Act"), 15 U.S.C. § 7601 et seq., and the Contact Lens Rule ("the Rule"), 16 C.F.R. Part 315. The Rule defines contact lenses to mean any contact lenses for which state or federal law requires a valid prescription, 16 C.F.R. § 315.2, which includes cosmetic contact lenses.

The Rule provides that contact lenses may be sold to consumers only in accordance with a valid prescription that is presented by the consumer or verified with the prescriber. To verify a prescription, the Rule requires a seller to send the prescription information it receives from its customer to the prescriber for verification. The sale of cosmetic contact lenses without either obtaining a copy of a valid prescription from the customer or verifying his or her prescription information with the prescriber constitutes a violation of the Rule.

A valid and verified prescription helps ensure that consumers have been examined for overall eye health and proper fitting by a licensed eye care professional. Without guidance or supervision by a licensed eye care professional, consumers may develop serious injuries or complications from decorative contact lenses, including:

- Pain and discomfort of the eyes;
- Red or swollen eyes;
- Blurred or decreased vision;
- Corneal abrasion (cut or scratch on top layer of eye);
- Allergic reactions (itchy, watery, red eyes);
- Infection; and
- Blindness

This letter places you on notice that violations of the Rule may result in legal action, which may in turn lead to civil penalties of up to $16,000 per violation. You should review the Rule and revise your practices as necessary to ensure that they comply with the Rule's requirements. A business guidance publication produced by FTC, "The Contact Lens Rule: A Guide for Prescribers and Sellers," which contains a copy of the Rule and information about how to comply with the Rule, is available on the FTC website at www.ftc.gov [2].

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations associated with your firm's business practices. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA and FTC. Your firm should investigate and determine the causes of the violations, take prompt actions to correct the violations, and bring the products into compliance.

Sincerely yours,

Anastacia M. Bilek, Ph.D.
Director

Division of Enforcement A
Office of Compliance
Center for Devices and Radiological Health

Richard L. Cleland
Assistant Director
Division of Advertising Practices
Federal Trade Commission

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