

Red Flags Rule Enforcement Delayed Until June

BY MARY ELLEN SCHNEIDER

The Federal Trade Commission once again has delayed enforcement of the Red Flags Rule, giving physicians until June 1, 2010, before they have to comply with new requirements aimed at preventing identity theft.

The rule, issued by the Federal Trade Commission (FTC) in 2007, most recently had been scheduled to go into ef-

fect Nov. 1. But this is not the first time that the FTC has delayed the enforcement date. The agency has been pushing back enforcement every few months for about a year. Most recently, the FTC issued a statement on Oct. 30 saying that it was again delaying enforcement at the request of members of Congress.

Congress has been working on a legislative solution to exempt some physician practices and other small business-

es from the identity theft requirements. On Oct. 20, the House passed a bill (H.R. 3763) that would exempt physician practices with 20 or fewer employees from the Red Flags Rule. The Senate has yet to act on the bill.

Rep. John Adler (D-N.J.), one of the chief sponsors of the legislation, said the regulations would be burdensome and expensive for small businesses and that physician practices were not meant to be

caught up in this regulation. "The Federal Trade Commission went too far and went beyond the intent of Congress," Rep. Adler said on the House floor.

The rule also is being challenged in court. The U.S. District Court for the District of Columbia ruled that the FTC cannot apply the regulation to lawyers.

Under the Red Flags Rule, all creditors, including physician practices, must establish a written identify theft-prevention program to protect consumers. The Red Flags Rule also requires physician offices and other health care institutions to conduct risk assessments to determine their vulnerabilities to identity theft and respond to those risks.

The rule has raised the hackles of organized medicine. Groups such as the American Medical Association have objected, saying that it is inappropriate to classify physician practices as creditors simply because they allow patients to defer payment while the practices bill insurance companies. The Red Flags Rule

Promiseb™ Topical Cream

For Topical Dermatological Use Only
For External Use Only

Rx only

Product Description:

Promiseb™ Topical Cream is an off-white, steroid-free, fragrance-free, water-based emulsion.

Indications for Use:

Under the supervision of a healthcare professional, Promiseb Topical Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Promiseb Topical Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Directions for Use:

Apply Promiseb Topical Cream to the affected skin areas 2 to 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover Promiseb Topical Cream with a dressing of choice.

Ingredients:

Promiseb Topical Cream is comprised of Purified Water, Isohexadecane, Butyrospermum parkii, Pentylene glycol, Ethylhexyl palmitate, Cera alba, PEG-30 Dipolyhydroxystearate, Bisabolol, Polyglyceryl-6 polyricinoleate, Tocopheryl acetate, Hydrogenated castor oil, Acifructol complex, Butylene glycol, Magnesium sulfate, Piroctone olamine, Allantoin, Magnesium stearate, Disodium EDTA, Vitis vinifera, Ascorbyl tetraisopalmitate, Glycyrrhethinic acid, Propyl gallate, and Telmesteine.

Caution:

The use of Promiseb Topical Cream is contraindicated in any patient with a known history of hypersensitivity to any of the ingredients. Promiseb Topical Cream does not contain milk, wheat, peanut or animal derivatives. Promiseb Topical Cream does contain shea butter (Butyrospermum parkii), a derivative of shea nut oil (not peanut oil). Patients with a known allergy to nuts or nut oils should consult their physician before using this topical preparation.

How Supplied:

30 g tube, NDC 67857-803-30

To Open: Puncture seal with pointed end of cap.

Important: The opening of this product is covered by a metal seal. Do not use if seal has been punctured or is not visible.

Store at controlled room temperature 68° to 77°F (20° to 25°C), excursions permitted between 59° and 86°F (15° and 30°C).

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References:

1. Data on file. A randomized pilot study to compare the safety and efficacy of Promiseb Topical Cream and desonide cream 0.05% in the treatment of mild to moderate seborrheic dermatitis of the face. Promius Pharma, LLC: Bridgewater, NJ; 2008. PSC0801.
2. Data on file. An open-label, single-center, pilot study to determine the antifungal activity of Promiseb Topical Cream after seven days of use in normal volunteers. Promius Pharma, LLC: Bridgewater, NJ; 2008. PSC0802.
3. Data on file. A multicenter pilot clinical study to evaluate the efficacy and safety of Promiseb in the management of mild to moderate seborrheic dermatitis in adults. Surrey, United Kingdom: Sinclair Pharmaceuticals, LTD; 2006.

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also would add financial and administrative burdens on practices, the AMA said, because it duplicates existing privacy and security requirements put in place under the Health Insurance Portability and Accountability Act.

"For over a year, the AMA has continued to make the case to FTC that physicians are not creditors, and the red flags rule should not apply to them—now attorneys and members of Congress are also rightly raising concern with the FTC's broad interpretation," Dr. Cecil Wilson, the AMA's president-elect, said in a statement. "The FTC's latest delay of 7 months should give them the time they need to take a good, hard look at the rule and finally revise the list of groups to which it applies."

The FTC has a list of frequently asked questions on its Web site at www.ftc.gov/bcp/edu/microsites/redflagsrule/faqs.shtm. ■

AAD Launches Web Site for Kids

The American Academy of Dermatology has launched a new Web site to teach children aged 8-12 years about healthy habits for their skin, hair, and nails. The site includes a game based on the life of Sammy the skin cell, a skin dictionary, and quick facts. The site also features safety tips for manicures, the dangers of tattoos, eczema treatments, and more. For more information, visit www.kidsskinhealth.org. ■