



Mitchell E. Daniels, Jr.  
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.  
State Health Commissioner

**DATE:** January 23, 2012

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:**   
A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program

**SUBJECT:** Perfect Image Solutions, LLC Recall

**SUGGESTED**

**ACTION:** Unclassified Recall; All lots of Men's Minoxidil 15% Azelaic 5% Hair regrowth topical, 60mL; Men's Minoxidil 10% Azelaic 5% Hair regrowth topical, 60mL; Men's Minoxidil 5% Azelaic 5% Hair regrowth topical, 60mL; Women's Minoxidil 3% Azelaic 5% Hair regrowth topical, 60mL; and Hair regrowth shampoo enhanced with Ketoconazole and salicylic acid, 180mL, to the consumer level. The products are deemed "unapproved new drugs" under the law and U.S. Food and Drug Administration regulations and may present potential health hazards; Information provided in case of consumer inquiry.

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The recalled products were distributed nationwide or worldwide via the internet. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

**Perfect Image Solutions, LLC Issues Voluntary Recall of Unapproved Product Due to Potential Health Risk**

**Contact:**

Consumer:

Perfect Image Solutions, LLC

916-791-3230

dave@perfectimagesolutions.com

Media:

David Petrillo

916-791-3230

**FOR IMMEDIATE RELEASE** - January 19, 2012 -Perfect Image Solutions, LLC is voluntarily recalling all lots of Men's Minoxidil 15% Azelaic 5% Hair regrowth topical, 60mL; Men's Minoxidil 10% Azelaic 5% Hair regrowth topical, 60mL; Men's Minoxidil 5% Azelaic 5% Hair regrowth topical, 60mL; Women's Minoxidil 3% Azelaic 5% Hair regrowth topical, 60mL; and Hair regrowth shampoo enhanced with Ketoconazole and salicylic acid, 180mL, to the consumer level. The products are deemed "unapproved new drugs" under the law and U.S. Food and Drug Administration regulations and may present potential health hazards.

Use of these topical products containing 15% and 10% Minoxidil have not been shown to be safe, and could pose a risk to the general public due to the possibility of systemic absorption. Skin abrasions or irritations, such as psoriasis or sunburn, could increase the systemic absorption of topically administered Minoxidil. Minoxidil 15% and 10% could cause low blood pressure, heart palpitations and associated cardiac symptoms. Azelaic acid contained in the topical products could make the skin where it is applied more sensitive to sunburn. Ketoconazole contained in the shampoo product could cause hair discoloration and abnormal hair texture, removal of the curl from permanently waved hair, itching, rash, skin irritation and dry skin. Salicylic acid contained in the shampoo could cause mild, temporary burning, itching, irritation, or stinging.

Perfect Image Solutions, LLC has not received reports of serious injuries associated with the products subject to this voluntary recall.

These products are used to slow or stop hair loss and promote hair regrowth and are packaged in glass-dropper containers or plastic shampoo bottles, and are sold in single units. They are used by men and women generally in middle to late adulthood. The affected product lots include the following lot numbers and expiration dates:

Product Name	Lots	Expiration	UPC Number
Men's Minoxidil 15% Azelaic 5% Hair regrowth topical, 60mL.	All	Up until Oct. 2013	736211275813
Men's Minoxidil 10% Azelaic 5% Hair regrowth topical, 60mL.	All	Up until Oct. 2013	736211276018
Men's Minoxidil 5% Azelaic 5% Hair regrowth topical, 60mL.	All	Up until Sept. 2014	736211276117
Women's Minoxidil 3% Azelaic 5% Hair regrowth topical, 60mL.	All	Up until Nov. 2013	736211274519
Hair regrowth shampoo enhanced with Ketoconazole and salicylic acid, 180mL.	All	Up until Dec. 2013	736211276414

The product can be identified by the name Perfect Image Solutions on the container. Product was distributed nationwide or worldwide via the internet.

Perfect Image Solutions, LLC is notifying its distributors by phone and in writing, and is arranging for return of all recalled products. Consumers that have product which is being recalled should discard it.

Consumers with questions regarding this voluntary recall can contact Perfect Image Solutions, LLC by phone number (916) 791-3230 or e-mail address [dave@perfectimagesolutions.com](mailto:dave@perfectimagesolutions.com), Monday–Friday from 9 AM–5 PM PST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)<sup>1</sup>
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)<sup>2</sup>. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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[RSS Feed for FDA Recalls Information](#)<sup>3</sup> [what's this?<sup>4</sup>]

[Photo: Product Labels](#)<sup>5</sup>