Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

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

DATE: January 20, 2012

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

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

SUBJECT: USA Far Ocean Group Inc. Recall

SUGGESTED

ACTION: **Unclassified Recall; Two products sold as cosmetic under the names Vagifresh Ball and Vagifresh Gel; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The recalled products were sold via herbal stores, beauty shops, drug stores, internet and mail order. 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.

USA Far Ocean Group Inc. Issues Voluntary Nationwide Recall of Vagifresh Ball and Vagifresh Gel , Marketed Individually or Under a Mixed Package Named Female One

Contact:
Consumer:
Special Service Department
626-560-2435

FOR IMMEDIATE RELEASE - January 18, 2012 - USA Far Ocean Group Inc. (U.S.A. Far Ocean), is voluntarily recalling the Company's two products sold as cosmetic under the names Vagifresh Ball and Vagifresh Gel. These two products were also sold under the mixed package named Female One, which contained Vagifresh Ball, Vagifresh Gel and Vagifresh Liquid (this recall does not involve Vagifresh Liquid). Vagifresh Ball and Vagifresh Gel products are applied by inserting deeply into the vagina for a prolonged period of time. The Company has been informed by representatives of the Food and Drug Administration (FDA) that lab analysis by FDA of Vagifresh Gel sample found the product contains benzocaine, the active ingredient for many anesthetic drug products. In addition, FDA analysis of Vagifresh Ball sample found the product contains bacteria including Staphylococcus lentus, S. sciuri, Bacillus Lantus, Alloiococcus otitis, Aerococcus viridans, Aeromonas salmonicid, Gemella spp, Leuconostoc spp.

The effect of the absorption of the amount of Benzocaine contained in Vagifresh Gel is unknown, but there is the possibility of an adverse reaction or unknown drug-drug interaction. The effect of the bacterial contamination in VagiFresh Ball is unknown and difficult to assess. No illnesses have been reported to the Company to date in connection with these products. The FDA has also determined that marketing material for these products contained unsubstantiated therapeutic claims related to various gynecologic conditions that could have caused women taking these products from seeking appropriate medical care for potentially serious medical conditions.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Following products are involved in this voluntary recall:

Product	**Package Size**	**UPC Codes**
Vagifresh Ball	3 tablets individual pack/packed with Female One	689076499156
Vagifresh Gel	2 fl.oz. tube individual pack/Packed with Female One	689076499057

All lots of the listed products are affected by this recall.

These products were sold via herbal stores, beauty shops, drug stores, internet and mail order. U.S.A. Far Ocean is taking necessary steps to contact wholesalers, retailers and customers for the return of these products. Consumers in possession of these products should stop using it immediately and contact their physician if they experienced any problem that may be related to using any of these products.
Consumers in possession of products should also return any unused products to their immediate supplier for a direct refund. Customers with questions can call USA Far Ocean Group, Inc. at 626-560-2435 Monday through Sunday between 9 a.m. and 5 p.m. (PST) for further instructions or information with respect to the return and refund process.

U.S.A. Far Ocean is committed to providing our customers with high quality, pure and safe products. We are investigating the root cause in the manufacturing processes that has lead to this voluntary recall. We are taking every measure to ensure the quality and purity of any product made by our manufacturers so that this will never happen again in the future. We are extremely sorry and hope that you will not lose faith in our brand.

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

- Online: http://www.fda.gov/MedWatch/report.htm[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2].
- Fax: 1-800-FDA-0178

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RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]