



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

RHODE ISLAND DEPARTMENT OF HEALTH,  
MICHAEL FINE, M.D., IN HIS CAPACITY  
AS DIRECTOR OF THE RHODE ISLAND  
DEPARTMENT OF HEALTH

V.

KAREN GRANDE, M.D.LIC# MD 09511  
IN HER CAPACITY AS MEDICAL DIRECTOR OF  
SKIN ESSENTIALS MEDICAL AESTHETICS AND WELLNESS SPA

**IMMEDIATE COMPLIANCE ORDER**

Now comes the Director of the Department of Health of the State of Rhode Island (hereinafter the "Director"), and pursuant to Rhode Island General Laws, § 23-1-21 makes the following findings and enters the following Order:

1. Karen Grande, M.D., is the Medical Director of a domestic corporation known as Skin Essentials Medical Aesthetics and Wellness Spa, Inc., (hereinafter "Skin Essentials") operating at 1909 Mineral Spring Avenue, North Providence, Rhode Island 02904.
2. On or about October 4, 2012, the New England Compounding Center ("NECC") in Massachusetts issued a voluntary recall of pharmaceutical products to Skin Essentials, instructing it to remove certain pharmaceutical products from use, as they were potentially dangerous to the public.
3. Subsequent to the notice by NECC, Skin Essentials received notice from the United States Food and Drug Administration to immediately remove all NECC products from use, and segregate and quarantine them. Skin Essentials certified that it did not possess any NECC recalled products.
4. Inspections of Skin Essentials' facility at Mineral Spring Avenue on October 24, 2012 and November 23, 2012 revealed that Skin Essentials still retained several recalled products, and had not segregated or quarantined them from use. Products were found in patient exam rooms on both dates.
5. Use of NECC recalled products poses an immediate and serious danger to the public.

Therefore, based on the foregoing, the Director orders in accordance with RIGL § 23-1-21, the Respondent shall initiate the following actions:

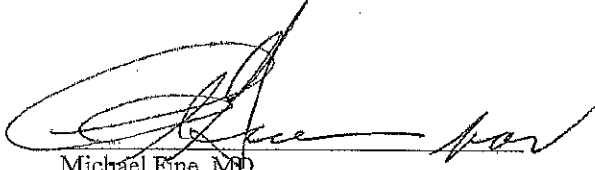
Respondent is herein ordered pursuant to R.I. Gen. Laws § 23-1-21 to IMMEDIATELY:

1. Cease and desist from the use of any products recalled by NECC in its voluntary recall dated October 4, 2012;

2. Immediately segregate and quarantine any remaining NECC recalled products in its possession, and notify the Rhode Island Department of Health for appropriate disposal;

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3. Notify any and all patients who have been treated with NECC recalled products, whether the treatment occurred before or after October 4, 2012;
4. The Department will monitor the Respondent's compliance. Notwithstanding any possible further findings, disciplinary actions, fines or other sanctions by the Department, this order remains in effect until further notice.



12/4/12

Michael Fine, MD  
Director  
R.I. Department of Health  
Cannon Building, Room 401  
Three Capitol Hill, Providence, RI 02908-5097  
Tel, (401) 222-2231; Fax (401) 222-6548

CERTIFICATION OF SERVICE

A copy of this Immediate Compliance Order was hand-delivered to Donna Tomassi by the undersigned on December 5, 2012, who herein documents delivery and receipt of this order.

Ronda Sullivan / 12/5/12  
(Signature) (Date)

*also emailed to Karen Grande, MD*