Federal judge orders Flawless Beauty to stop distributing unapproved drugs, recall certain products

Company sold injectable skin whitening and other unapproved products

For Immediate Release

September 26, 2017

A federal judge ordered a New Jersey company that sold injectable skin whitening and other beauty products to stop selling and recall some of its products because they are unapproved new drugs that may be unsafe, putting consumers at risk.

U.S. District Judge Peter G. Sheridan entered a consent decree of permanent injunction today between the United States and Flawless Beauty LLC of Ocean Township and Asbury Park, New Jersey, the company's co-owners, Jack H. Gindi and Susana B. Boleche, and an affiliated company owned by Mr. Gindi, RDG Imports LLC.

According to the complaint for permanent injunction, which the U.S. Department of Justice filed on the FDA's behalf, Flawless Beauty sold unapproved and improperly labeled (misbranded) drugs which present serious public health risks, particularly purportedly sterile injectable skin whitening drug products. Intravenous and intramuscular administration of these unapproved drugs, for which sterility cannot be assured, could result in serious health risks. These risks include nerve or blood vessel damage, infection or toxic systemic reactions. The company also sold several products that are labeled to contain human placenta, which can result in serious illness.

Some of the products sold by Flawless Beauty also implied FDA approval or endorsement, which the company did not have.

"Despite repeated warnings, Flawless Beauty continued to put patients at risk by selling potentially dangerous and unproven treatments to consumers," said Donald D. Ashley, J.D., director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research. "We urge consumers to beware of these and other unproven drug products that use deceptive marketing tactics to sell their unsafe products."

The consent decree prohibits Flawless Beauty, RDG Imports and its owners from directly or indirectly importing, manufacturing and/or distributing any drug products until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Under the consent decree, the company has 20 days to recall all ampules or lyophilized vials, including those sold as part of whitening kits, and all injectable products. These include

products sold under the Relumins, Tatiomax, TP Drug Laboratories, Laennec, Saluta, Tationil and Laroscorbine brands, among others.

Additionally, under the consent decree, Flawless Beauty, RDG Imports and its owners must also hire an expert to review their drug products and receive written permission from the FDA before they can resume distributing drugs. The company and its owners will be assessed monetary damages if they fail to meet any of the terms of the consent decree, the FD&C Act or applicable regulations.

Federal law requires a new drug to undergo the FDA drug approval process to be legally marketed in the United States. The drug approval system is designed to prevent patients from being exposed to the risks associated with potentially unsafe, ineffective and poor quality drugs. The FDA has not approved any injectable drugs for skin whitening or lightening.

In September 2014, U.S. Marshals seized various unapproved and improperly labeled drug products sold and distributed by Flawless Beauty at the request of the FDA, including numerous injectable skin whitening products such as the Relumins Advanced Glutathione kits and Tatiomax Glutathione Collagen Whitening kits. Despite this seizure action, the company and its owners continued marketing and distributing unapproved drugs, which prompted federal authorities to seek further enforcement action.

The FDA urges health care professionals and consumers to report any adverse events related to products sold by Flawless Beauty to its MedWatch Adverse Event Reporting program by:

- Completing and submitting the report online at MedWatch online voluntary reporting form; or
- Downloading and completing the form, then submitting it via fax at 1-800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###