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FDA NEWS RELEASE

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FDA Issues Warning Letters for Drugs Promoted in Fat Elimination Procedure

Agency says false or misleading statements made in touting of 'lipodissolve' products

The U.S. Food and Drug Administration today issued warning letters to six U.S. based medical spas and a company in Brazil for making false or misleading statements on their Web sites about drugs they claim will eliminate fat in a procedure called "lipodissolve," or for otherwise misbranding lipodissolve products.

The U.S. companies involved have made claims that the drugs they use for their lipodissolve procedures are safe and effective; however, these products have not been evaluated or approved by the FDA for this use.

Lipodissolve is a procedure involving a series of drug injections intended to dissolve and permanently remove small pockets of fat from various parts of the body. It also is known as mesotherapy, lipozap, lipotherapy, or injection lipolysis. The most commonly injected drugs are phosphatidylcholine and deoxycholate, usually in various combinations with one another.

In some cases, other ingredients, including drugs or components of other products such as vitamins, minerals, and herbal extracts are added to the mixture. The FDA is not aware of any credible scientific evidence that supports the effectiveness of any of these substances for fat elimination, and their safety when used alone or in combination is unknown.

The FDA is requesting a written response from the U.S. companies within 15 business days of receipt of the warning letters stating how they will correct these violations and prevent similar violations in the future. Each U.S. company has been informed in its warning letter that failure to promptly correct the violations may result in legal action.

Each of the companies involved has been cited for a variety of regulatory violations, including making unsupported claims that the products have an outstanding safety record and are superior to other fat loss procedures, including liposuction. Additionally some of the letters indicate that the companies have made claims that lipodissolve products can be used to treat certain medical conditions, such as male breast enlargement, benign fatty growths known as lipomas, excess fat deposits and surgical deformities. The FDA is not aware of clinical evidence to support any of these claims.

"We are concerned that these companies are misleading consumers," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "It is important for anyone who is considering this voluntary procedure to understand that the products used to perform lipodissolve procedures are not approved by the FDA for fat removal."

The FDA has received reports of adverse effects in persons who have had the procedure using these drugs, including permanent scarring, skin deformation, and deep painful knots under the skin in areas where the lipodissolve products have been injected.

The warning letters were issued to the following U.S. companies: Monarch Medspa, King of Prussia, Pa; Spa 35, Boise, Idaho; Medical Cosmetic Enhancements, Chevy Chase, Md.; Innovative Directions in Health, Edina, Minn. PURE Med Spa, Boca Raton, Fl.; and All About You Med Spa, Madison, Ind. The Brazilian company receiving a warning letter markets lipodissolve products on two Web sites: zipmed.net and mesoone.com.

The FDA will notify regulatory authorities in Brazil of this action. The agency has issued an import alert against the zipmed.net and mesoone.com entities to prevent the importation and distribution of unapproved lipodissolve drug products into the United States. Importing and distributing unapproved drug products is a violation of the Federal Food, Drug, and Cosmetic Act.

Health care professionals and consumers may report serious adverse events (side effects) or quality problems with the use of these products to the FDA's MedWatch Adverse Event Reporting program either online, by

regular mail, fax, or phone.

- Online: [MedWatch](#)¹
- Regular Mail: use postage-paid, pre-addressed [Form FDA 3500](#)². Mail to address on the pre-addressed form.
- ³• Fax: 800-FDA-0178
- ⁴• Phone: 800-332-1088

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