

Ana Salazar Modela Tu Cuerpo Inc. Issues Nationwide Voluntary Recall of Lipofit Extreme Fat Burner 2.0 Due to Presence of Undeclared Fluoxetine and 2,4-Dinitrophenol (DNP)

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FOR IMMEDIATE RELEASE - August 28, 2026 - Davie, Florida – Ana Salazar Modela Tu Cuerpo Inc. is recalling Lipofit Extreme Fat Burner 2.0, Lot 25M12F, expiration date 09/2027, to the consumer level. The Food and Drug Administration (FDA) laboratory analysis has found Lipofit Extreme Fat Burner 2.0 to be tainted with undeclared fluoxetine in the daytime (AM) tablets and undeclared 2,4-dinitrophenol (DNP) in the nighttime (PM) tablets. Fluoxetine is an active ingredient in an FDA-approved drug used to treat conditions including depression, bulimia and obsessive-compulsive disorder. 2,4-Dinitrophenol (DNP) is a toxic substance (commonly used as a pesticide, dye, wood preservative and herbicide) that is illegally marketed as a weight-loss product and is not approved by the FDA for any use. Products containing fluoxetine and DNP cannot be marketed as dietary supplements. Lipofit Extreme Fat Burner 2.0 is an unapproved new drug for which safety and efficacy have not been established and, therefore, subject to recall.

Risk Statement:

Lipofit Extreme 2.0 Fat Burner, is a product promoted and sold for weight loss. When tainted with both fluoxetine and DNP, Lipofit Extreme 2.0 Fat Burner can cause a wide range of serious and potentially life-threatening adverse effects. Users may experience nausea, vomiting, sweating, dizziness, and headaches, as well as dangerous heart rhythm problems, rapid heart rate, and cardiac arrest, which can result in sudden death. Neurological effects including seizures may also occur, along with abnormal bleeding and suicidal thoughts. Long-term exposure carries additional risks, including damage to the eyes, skin, bone marrow, nervous system, and heart, as well as dangerously high body temperature and rapid breathing. When combined with certain other medications, the risk of fatal cardiac events is further elevated.

To date, Ana Salazar Modela Tu Cuerpo Inc. has not received any known reports of adverse events related to this recall.

The tainted Lipofit Extreme Fat Burner 2.0 is marketed as a dietary supplement and is packaged as AM and PM tablets. The recalled product is identified as **Lot 25M12F, expiration date 09/2027**.

The product was distributed in the United States directly to individual consumers through online sales.

Ana Salazar Modela Tu Cuerpo Inc. has stopped selling and promoting the affected product and has quarantined all remaining inventory under its control. Consumers who have the affected product should **stop using it immediately**, keep it separated from children and other people, and should not sell, give, or transfer it to anyone else.

Consumers who purchased the recalled product should contact Ana Salazar Modela Tu Cuerpo Inc. at **(954) 305-1004** or **yandrydy@gmail.com** for instructions regarding the disposition of the recalled product. Consumers should not mail or dispose of the product until appropriate return or disposition instructions are provided.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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.

- **Complete and submit the report Online: www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.**

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