TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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DAVID L. LAKEY, M.D.
COMMISSIONER

August 14, 2012

Dr. Michael A. Carome, M.D and Dr. Sidney M. Wolfe, M.D.
Health Research Group
Public Citizen
1600 20th Street, NW
Washington, D.C. 20009

Dear Dr. Carome and Dr. Wolfe:

This letter is in response to your August 1, 2012, letter to Dr. David L. Lakey, M.D., Commissioner, Texas Department of State Health Services, expressing concerns about the distribution and use of LipoTron devices in Texas. Your letter has been referred to the Department's Drugs and Medical Devices Group for review and acknowledgement.

Based upon our evaluation of the information you provided, we believe it is appropriate for us to supplement our ongoing investigations into this matter. We certainly appreciate you bringing this additional information to our attention. Due to the nature of these investigations and the potential need for coordination between multiple regulatory jurisdictions in the state, we will continue to evaluate options for investigating and resolving these complaints, including any appropriate actions to prevent unapproved devices from entering Texas commerce.

If you have questions concerning this response or need further clarification regarding the status of these investigations, please contact Ms. Jonnetta Wheaton, Compliance Officer at (512) 834-6755 or by e-mail at *jonnetta.wheaton@dshs.state.tx.us*. In addition, please visit the Drugs and Medical Devices Group website at *http://www.dshs.state.tx.us/dmd/* for available information concerning all of our program areas.

Sincerely,

Tom Brinck, Manager
Drugs and Medical Devices Group
Policy, Standards and Quality Assurance Unit
Environmental and Consumer Safety Section
Division for Regulatory Services