DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

A Major Difference
C/O Ms. Elanor Kolton
Regulatory Consultant
Greenberg Traurig, LLP
2101 L Street, N.W., Suite 1000
Washington, DC 20037

MAY 20 2009

Re: C080085
Product Name: Difference ionCleanse® Premier™ and ionCleanse® Solo™ Vitality
Dated: October 14, 2008
Received: October 17, 2008

Dear Ms. Kolton:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the Difference ionCleanse® Premier™ and ionCleanse® Solo™ Vitality. As described in your submission, we believe that your product is not a "device" as that term is defined in Section 201(h) of the Act. Our decision was significantly influenced by your stated intended use for your product which cited no medical claims, only stated that your product may increase energy, reduce stress levels, increase comfort, and increase one's sense of well being. These indications for use are substantially different from your existing labeling which claims that the ionCleanse assists in weight loss and headache relief, slows down aging, and helps relieve pain and tension. Therefore, you are not required to comply with the requirements of the Act. Please note, if you later revise your indications to add medical claims such as the ones in your existing labeling, you will need a premarket notification [510(k)] submission.

If you have any questions regarding this letter, please contact Mr. Bryan Benesch, Special Assistant to the Director, Office of Compliance (OC), at 240-276-0141, or for general questions please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman

Christy L. Foreman, M.S.
Deputy Director for Engineering and Review Policy
Office of Device Evaluation
Center for Devices and Radiological Health