



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Jay Davis
President
Omega Laboratories, Inc.
400 North Cleveland Avenue
Mogadore, Ohio 44260

May 16, 2006

RE: Request for Correction (Removal) of Information Found
On the OIVD Section of the FDA Web Site

Dear Mr. Davis:

This letter is an interim response to your request for correction pursuant to the Federal Data Quality Act, the HHS Information Quality Guidelines and the FDA's Guidelines for Ensuring the Quality of Information Disseminated to the Public. Your request for correction of information appearing on the FDA Website, specifically information by the Office of In Vitro Diagnostic Device Evaluation and Safety, is still under review.

We are continuing to prepare our response but need additional time to conduct a thorough review of the materials submitted and to hold internal discussions. We hope to provide you with a response within 60 days from the date of this letter.

Sincerely,

A handwritten signature in cursive script that reads "Laurie Lenkel".

Laurie Lenkel
Office of the Ombudsman
Food and Drug Administration