DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 20, 2005

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

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

Dear Mr. Davis:

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. Under FDA Guidelines for Ensuring the Quality of Information Disseminated to the Public the goal is to respond to each request for correction within 60 days of receipt either by providing a decision on the request or, if the request will require more than 60 days to complete, informing the complainant that more time is required.

We wrote to you on July 22, 2005, indicating that we would need additional time to complete our response to your request and expected to reply by September 20, 2005. Unfortunately, we will not be able to meet this date. At this time we are continuing to prepare our response and anticipate responding by November 18, 2005.

Sincerely,

Laurie Lenkel

Laurie Lenkel
Office of the Ombudsman
Food and Drug Administration