



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Dear Mr. Davis:

This letter responds to your May 23, 2005 Request for Correction of Information pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001<sup>1</sup> (Information Quality Act) and the implementing guidelines issued by the U.S. Department of Health and Human Services<sup>2</sup> and the Food and Drug Administration<sup>3</sup>.

Your request relates to a December 1, 2003 letter to Omega Laboratories from Steven Gutman, M.D., M.B.A., Director of the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD). This letter is posted on the Food and Drug Administration's website at <http://www.fda.gov/cdrh/oivd/letters/120103-omega.html>. You request the immediate removal of this letter from FDA's website, alleging that the letter is inaccurate and misleading. As stated in your Request for Correction of Information, you also responded to OIVD's letter in separate letters to Dr. Gutman on December 3, 2003 and FDA Commissioner Mark McClellan on December 4, 2003. The issues you raised in your December 2003 letters are also addressed in your May 2005 Request for Correction of Information.

In accordance with 21 CFR § 10.75, the Center for Devices and Radiological Health responded to your December 2003 letters on December 5, 2005. In our December 5, 2005 letter, we explained why the posting of our December 1, 2003 letter is not inaccurate. Therefore, we do not intend to remove this letter from our website.

<sup>1</sup> Pub. L. No. 106-554, 114 Stat. 2763A-153 (2000).

<sup>2</sup> *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Dissemination to the Public*, available at <http://aspe.hhs.gov/infoquality/Guidelines/part1.shtml>.

<sup>3</sup> *Guidelines for Ensuring the Quality of Information Disseminated to the Public*, available at <http://aspe.hhs.gov/infoquality/Guidelines/fda.shtml>.

If you have any questions regarding our December 5 letter, please contact Dr. Gutman at (301) 594-3084. Accordingly, we are enclosing a copy of our December 5, 2005 letter for your reference.

Sincerely,     *l*

/s/

Linda S. Kahan  
Deputy Director  
Center for Devices  
and Radiological Health