



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Jasper Benke
Vice President, Quality and Regulatory Affairs
BlueSky Medical Group, Inc.
5924 Balfour Court, Suite 102
Carlsbad, CA 92008

July 21, 2006

RE: Request for Correction of Information – FDA Patient Safety News Alert
“Preventing Bleeding with Vacuum-Assisted Wound Closure”

Dear Mr. Benke:

This letter is an interim response to your letter date May 15, 2006, (received May 23, 2006) in which you request correction pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub.L. No.106-554, 114 Stat. 2763A-153 (2000), hereinafter referred to as the “Information Quality Act.” Your complaint requests correction to information that appears on the FDA Web Site regarding vacuum-assisted wound closure.

FDA’s data quality guidance, which is part of the Department of Health and Human Services Guidelines for Ensuring the Quality of Information Disseminated to the Public, states that FDA will respond to a data quality complaint within 60 days, either by issuing a decision or by providing you with an estimated decision date.

We have not yet completed our response to your complaint because of other agency priorities and the need to coordinate agency review of the response. We anticipate providing 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
FDA Office of the Ombudsman