DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1350 Piccard Drive
Rockville MD 20850

July 31, 2006

Jasper Benke
Vice President, Quality and Regulatory Affairs
BlueSky Medical Group, Inc.
5924 Balfour Ct. Suite 102
Carlsbad, CA 92008
Phone (760) 603-8130
Fax (760) 760-833

Dear Mr. Benke:

This letter is in response to your letter dated May 15, 2006 (received May 23, 2006), to Ms. Laurie Lenkel, J.D., FDA Ombudsman. Your letter requests corrections under the Federal Data Quality Act to an article published by an FDA staff member in Nursing 2005 that also appears on the FDA Website and to an FDA Patient Safety News webcast based on the article. We repeat your comments preceding our responses.

> *"We request that the term "Negative Pressure Wound Therapy" or "NPWT" be used whenever generalizing about, or referring to, the field as a whole."*

The Nursing 2005 article and the FDA Patient Safety News webcast used the term "vacuum-assisted wound closure" to refer to this technology. The FDA Patient Safety News webcast used both "vacuum-assisted wound closure" and "negative pressure wound therapy." The FDA Patient Safety News webcast also used the term "negative pressure wound therapy." You object to the use of this terminology because "V.A.C.® Vacuum-Assisted Closure refers to a specific, commericalized device and is avoided by clinicians and publications for this reason." [Letter to Laurie Lenkel, p. 2.] However, a Pub-Med search conducted by FDA staff demonstrated that both of these terms are commonly used. Common practice in risk communication is to employ a variety of commonly used terms for the same technology so that users recognize the technology by a familiar term. Because the trademark name, "V.A.C.® Vacuum-Assisted Closure" was never used, and because the use of multiple terms for the same technology is accepted practice, we do not feel that there is a need to modify either the video or the transcript. We will, however, be mindful of your concerns in future risk communications on this topic.

> *"We request that distinction be made regarding the available technologies (e.g. foam, Chariker-Jeter, etc.) for NPWT."*

The information published by FDA was a risk communication meant for clinicians, practitioners, and healthcare professionals. In the present case, FDA believes that users of all vacuum-assisted wound closure devices need to be aware of adverse event information in order to provide optimal patient care.

Your request is based on the fact that the product discussed in the article is used with a foam dressing, while Blue Sky's products are not. FDA's concerns with this technology are based on reports of bleeding following the use of various vacuum-assisted wound closure devices. The Nursing 2005 article illustrates the problem by outlining one case report. Although the case reported involved the use of foam dressing packed in the wound cavity, the article does not state that there is a direct causal link between the use of foam and the subsequent bleeding and we are not aware of any evidence that indicates such a link. With over 1,000,000 uses per year of this technology, FDA believes it appropriate to communicate this potential risk over the entire class of vacuum-assisted wound closure devices, irrespective of type of technology used.

You also state that bleeding is not a complication with the BlueSky device because you have received no adverse event reports. However, we believe it is important to caution users about the potential for bleeding across all types of vacuum assisted wound closure devices.You are correct in stating that not all vacuum-assisted wound closure devices use foam. Hence, this clarification will be made in a revised version of the article that will appear in Nursing 2006 and will be noted on the FDA website.

- *"Please clarify how the above warnings apply to users of the Versatile ITM Wound Vacuum System and Chariker-Jeter Wound Sealing Kits."*

No clinical studies have been submitted to FDA that demonstrate that the non-adherent gauze in the Chariker-Jeter Wound Sealing Kits is sufficient to prevent bleeding problems from occurring. Users should be aware of the problem and take precautions consistent with their professional judgment and sound clinical practice.

- *"Please confirm device labeling should include, as part of the NPWT protocol, the use of a separate, non-adherent layer for protection of the wound bed."*

FDA believes all users of vacuum-assisted wound closure devices should be aware of bleeding as a potential complication. However, FDA is not requiring labeling changes for these devices at this time.

To summarize, based on your comments we will make an addendum to the Nursing 2005 article to state that not all vacuum-assisted wound closure devices use foam as part of their construction. Once completed, this article and the addendum will appear on the FDA website.

In accordance with FDA's implementing guidelines, if you do not agree with this decision on your complaint, you may send a request for reconsideration within 30 days of receipt of this decision. Your request for reconsideration should be designated as an

"Information Quality Appeal" and should include a copy of your original request as well as this decision. Your appeal should state the reason why you believe this response to your complaint is inadequate.

Sincerely,

Director, Office of Surveillance and Biometrics
Center for Devices and Radiological Health

/s/

Cc: Les Weinstein
CDRH Ombudsman (HF-5)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Laurie Lenkel
Ombudsman (HF-7)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857