DEPARTMENT OF HEALTH & HUMAN SERVICES

U.S. Food and Drug Administration
10903 New Hampshire Ave
WO66-5564
Silver Spring, MD 20993

NOTICE and REQUESTED ACTION

Date: September 20, 2010

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Subject: Multiple-use lancing devices: requested actions

Dear Medical Device Manufacturer:

This is to inform you of the potential for transmitting blood-borne infections with multiple-use lancing (fingerstick) devices and to request that you take certain actions to mitigate the risk. You are receiving this letter because you are currently registered and listed with U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) as a lancet manufacturer.

On August 26, 2010, the FDA and the Centers for Disease Control and Prevention (CDC) released health notifications stating that lancing (fingerstick) devices should never be used on more than one patient because of the risk for transmitting bloodborne pathogens. These notifications describe a progressive increase in the reports of bloodborne infection transmission over the past 10 to 15 years (primarily hepatitis B virus), resulting from the shared use of lancing and POC blood testing devices, including a significant increase in hepatitis B virus infection outbreaks related to the shared use of multiuse lancing devices and POC blood testing devices in long term care/assisted living settings. The FDA and CDC notifications are attached and are available on the internet at
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
and http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

Even when instructions for cleaning and disinfection are provided with lancing devices, it may not be feasible for healthcare staff to assure that the devices are rendered safe for use in multiple patients. The FDA is concerned that some lancing devices are labeled for use in multiple patients and the labeling of other lancing devices does not adequately warn against use in multiple patients.

Requested Actions

If your lancing device is capable of being used more than once, we request that you inform us in writing of the models of this type that you manufacture or market. Please also indicate what actions you intend to take to address health risks described in the FDA and CDC communications, including revisions to device labeling, to caution against using the device on multiple patients. Specific guidance on labeling revisions will be forthcoming from the FDA.

To ensure that relevant manufacturers receive this information, attached for your signature is an acknowledgement form. Within 15 business days of the date that you received this letter, please complete and return the form to acknowledge receipt of this letter and confirm your status as a lancing device manufacturer. Send a copy of your communication to: Geetha Jayan, Network Leader, WO66 RM5564, 10903 New Hampshire Ave, Silver Spring, MD 20993. Please include your Establishment Registration Number on all correspondence with the FDA on this matter.

Future FDA Actions

FDA plans further communications, including a labeling guidance on lancing devices, to assist manufacturers to address the risks identified in the FDA and CDC communications. FDA will take additional actions if a manufacturer does not take appropriate steps to address these health risks.

If you have questions relating to this matter, please feel free to call Mr. Thomas Knott at (301) 796-5462, or log onto our web site at www.fda.gov for general information relating to FDA medical device requirements.

If you have already provided FDA with a correction plan, we will review and comment on the plan shortly. If you have any questions regarding the content of this letter, please contact Mr. Thomas Knott, Branch Chief, OC/DOEA/GSDB, WO66 RM3520 10903 New Hampshire Ave, Silver Spring, MD 20993.

Sincerely yours,

Jonathan Sackner-Bernstein, MD
Associate Center Director, Post Market Operations
Center for Devices and Radiological Health

Acknowledgements Related to September 20, 2010
NOTICE of Action – Regulatory Compliance

Establishment Registration Number:

To: Geetha Jayan, Network Leader, WO66 RM5564

10903 New Hampshire Ave, Silver Spring, MD 20993.

____ I hereby acknowledge the receipt of the September 20, 2010 letter from FDA entitled "NOTICE and RECOMMENDED ACTION".

____ I hereby acknowledge that I manufacture the following lancing (fingerstick) devices. (Please list the names and model numbers below. If additional space is needed, continue on the next page.)

Name of device	Model number	Is this a multiple use lancing device? (Yes or No)
1.		
2.		

____ I hereby acknowledge I was a manufacturer of lancing (fingerstick) devices, but no longer manufacturer lancing (fingerstick) devices.

I hereby acknowledge that my company will provide revised labeling in accordance with the FDA and CDC notifications: Yes ____ No ____ Not Applicable____.

_____ _____
Signature of Recipient Signatory's Printed Name

_____ _____
Company Name Company Address & Phone Number

_____ _____
Signatory's Title Signatory's Direct Contact Postal and Phone Information

Name of device	Model number	Is this a multiple use lancing device? (Yes or No)
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		