

FDA DRAFT Questions
June 26, 2013 meeting of the
General Surgery Devices Panel of the Medical Devices Advisory Committee
Blood Lancet Classification

1. FDA has identified the following risks to health for blood lancets based upon the information discussed by the panel during the original classification proceedings, as well as published literature, and reported outbreaks of hepatitis B:
 - **Bloodborne pathogen transmission due to lancet misuse**
 - **Sharp object injuries**
 - **Local skin infections**
 - **Adverse skin reaction (not infection)**
 - a. Please comment on whether this is a complete and accurate list of the risks to health presented by blood lancets.
 - b. Please comment on whether you disagree with inclusion of any of these risks, or whether you believe that any other risks should be included in the overall risk assessment of blood lancets, considering both single and multiple patient uses.

2. According to the statutory definitions (Section 513 of the Food, Drug, and Cosmetic Act (FD&C Act)), answers to the following questions will determine the appropriate classification. Please discuss the following:
 - a. FDA believes that general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness for any of the four types of blood lancets. If you disagree, please discuss how general controls alone are sufficient to provide a reasonable assurance of safety and effectiveness for a specific type of blood lancets.

General controls may include:

 - Prohibition against adulterated or misbranded devices,
 - Good Manufacturing Practices (GMPs),
 - Registration of manufacturing facilities,
 - Listing of device types,
 - Recordkeeping, etc.
 - b. FDA believes that blood lancets are not “life-supporting or life-sustaining, or of substantial importance in preventing impairment of human health.” Do you agree with this assessment? If not, please explain why.
 - c. Considering the risks and benefits of these devices, please discuss whether blood lancets when used for single use only or single patient use only present a “potential unreasonable risk of illness or injury”.

d. FDA believes sufficient information exists to establish special controls for blood lancets intended for single patient use with an integral sharps feature.

- Based on the information presented today, please discuss whether you believe that sufficient information exists to establish special controls that can provide a reasonable assurance of safety and effectiveness of single patient use blood lancets with an integral sharps feature.
- FDA proposes the following special controls that would provide reasonable assurance of safety and effectiveness:
 - i. Labeling
 - ii. Biocompatibility testing
 - iii. Sterility
 - iv. Performance testing including verification of design characteristics

If you agree sufficient information exists to establish special controls, please comment on whether you believe any other special controls are necessary to mitigate the risks to health and provide reasonable assurance of device safety and effectiveness or whether you disagree with the inclusion of any of these special controls.

e. FDA believes sufficient information exists to establish special controls for blood lancets intended for single patient use without an integral sharps feature.

- Based on the information presented today, please discuss whether you believe that sufficient information exists to establish special controls that can provide a reasonable assurance of safety and effectiveness of single patient use blood lancets without an integral sharps feature.
- FDA proposes the following special controls that would provide reasonable assurance of safety and effectiveness:
 - i. Labeling
 - ii. Biocompatibility testing
 - iii. Sterility
 - iv. Performance testing including verification of design characteristics

If you agree sufficient information exists to establish special controls, please comment on whether you believe any other special controls are necessary to mitigate the risks to health and provide reasonable assurance of device safety and effectiveness or whether you disagree with the inclusion of any of these special controls.

f. FDA believes sufficient information exists to establish special controls for blood lancets intended for multiple uses on a single patient.

- Based on the information presented today, please discuss whether you believe that sufficient information exists to establish special controls that can provide a reasonable assurance of safety and effectiveness of blood lancets intended for multiple uses on a single patient.

- FDA proposes the following special controls that would provide reasonable assurance of safety and effectiveness:
 - i. Labeling
 - ii. Biocompatibility testing
 - iii. Sterility
 - iv. Performance testing including verification of design characteristics and cleaning / disinfection validation testing

If you agree sufficient information exists to establish special controls, please comment on whether you believe any other special controls are necessary to mitigate the risks to health and provide reasonable assurance of device safety and effectiveness or whether you disagree with the inclusion of any of these special controls.

- g. Considering the risks and benefits of these devices, please discuss whether blood lancets when used for multiple patients present a “potential unreasonable risk of illness or injury”.
- h. FDA believes sufficient information does not exist to establish special controls for blood lancets intended for multiple patient uses as the risks to health are inherent and significantly higher as compared to other blood lancets. Further, FDA believes that the safety of multiple use blood lancets for multiple patients is not well established. FDA bases this determination on the valid scientific evidence that demonstrates an unreasonable risk of illness or injury (transmission of bloodborne pathogens) for this device.

If you do not agree, please explain by identifying and discussing the following:

- i) the valid scientific evidence available in support of a reasonable assurance of safety and effectiveness of multiple use blood lancets for multiple patients; and
- ii) special controls that you believe would be sufficient to mitigate the risks to health and provide a reasonable assurance of safety and effectiveness of multiple use blood lancets for multiple patients.