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Guidance for Industry and Food and Drug Administration Staff

Blood Lancet Labeling

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Preface

Public Comment

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Guidance for Industry and Food and Drug Administration Staff

Blood Lancet Labeling

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Introduction

This guidance recommends changes in the labeling of blood lancet (e.g., fingerstick) devices (21 CFR 878.4800) (included under manual surgical instruments for general use). FDA is concerned about the risk of transmission of hepatitis and other bloodborne pathogens when blood lancets are used to obtain blood from more than one patient. FDA is recommending that all blood lancets designed to be used more than once (for example, when a blade attached to a reusable base device is changed) be labeled for use only on a single patient obtaining personal blood samples. Manufacturers of blood lancets should clearly state in their labeling that blood lancets are intended only for single use or, in the case of lancet devices designed to be used more than once, for multiple uses in only a single patient.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Scope

This guidance document applies to all blood lancet devices (21 CFR 878.4800).

FDA is issuing this guidance with labeling recommendations for single patient use only of blood lancets. FDA has concerns that both healthcare providers and patients may not be aware of the serious adverse health risks associated with the use of a blood lancet device for the assisted withdrawal of blood from more than one patient and when sharing the same device, including among family members, even when the lancet blade is changed for each blood draw. FDA is also recommending labeling changes for single use only blood lancets.

Background

On August 26, 2010, the FDA and the Centers for Disease Control and Prevention (CDC) issued communications warning that the use of blood lancets to obtain blood from more than one patient poses a risk of transmitting bloodborne pathogens. The FDA and CDC recommend that blood lancet devices should never be used to obtain blood samples from more than one person. Additionally, on August 27, 2010, the Centers for Medicare and Medicaid Services (CMS) issued a Survey and Certification Memorandum for Point of Care Devices and Infection Control in Nursing Homes identifying the use of lancet devices for more than one patient as an infection control standards deficiency.

FDA and CDC are concerned about the risk of transmitting hepatitis and other bloodborne pathogens resulting from the use of blood lancet devices in multiple patients in various healthcare provision settings. These include acute care hospitals, long term care facilities, assisted living facilities, and non-residential care settings. CDC has noted increasing reports of outbreaks of hepatitis B transmission due to the use of blood lancet devices on multiple patients.

Blood lancet devices may be unsafe when used to draw blood from more than one patient for several reasons. Improper device design, device malfunction or user error may leave the blood from one patient on the reusable lancet device base and in a position to contaminate a new lancet blade. Healthcare users of blood lancets may have difficulty ensuring that all blood contamination has been successfully removed from a reusable lancet base device. The cleaning and disinfection instructions provided with reusable lancet devices may not be adequately validated for efficacy or may not be followed in their entirety by healthcare users.

In addition, single use only lancets, which minimize the risk of transmitting bloodborne pathogens arising from multiple patient use, should contain language in the labeling identifying the device as “single use only” and instructing for their safe disposal.

Read the FDA Initial Communication at:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

Read the CDC Clinical Reminder at:
http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Read the CMS Survey and Certification Memorandum at:
http://www.cms.gov/surveycertificationgeninfo/downloads/SCLetter10_28.pdf

Additional information on the safe use of blood glucose meters and other "Point of Care" (POC) devices is available at:
http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
http://www.cdc.gov/hepatitis/Settings/GlucoseMonitoring.htm

Recommended Blood Lancet Device Labeling

FDA recommends that all blood lancet devices be labeled for use only on a single patient. A statement limiting use to a single patient should appear on the labeling attached to the device, if possible.

The device labeling, including the Instructions for Use, for all blood lancet devices should clearly and prominently state that the device is intended for "single patient use only." We recommend that all written, printed, and graphic matter that accompanies the blood lancet device also contain the same language.

Recommendations for Multiple Use-Capable Blood Lancets

For a blood lancet device designed to be used multiple times, the reusable base portion of the device should carry labeling with the limitation, "single patient use only."

In addition, the Instructions for Use of these devices should contain language that multiple use devices should not be used for assisted blood draws by healthcare providers or at healthcare provision sites[*], and should never be shared with anyone else, even a family member.

Blood lancet devices designed for multiple use also should provide manufacturer-validated user instructions[5] for the cleaning and the disinfection of the reusable lancet device base after every use by the individual patient. Manufacturers of blood lancets with a reusable device base and single use lancet blades should include in the labeling, including the Instructions for Use and the written, printed, and graphic matter that accompanies the blood lancet device, instructions for the safe disposal of the single use lancet blades.

Recommendations for Single Use Only Blood Lancets

[*] Any setting where fingerstick procedures are performed, including assisted living or residential care facilities, skilled nursing facilities, clinics, health fairs, shelters, detention facilities, senior centers, schools, and camps.

Single use only, disposable blood lancets minimize the risk of transmitting bloodborne pathogens. The labeling of single use disposable blood lancets, which may include a self-disabling feature, should include language that only single use disposable blood lancets should be used for assisted blood draws by healthcare providers or at healthcare provision sites. These devices should be clearly labeled as "single use only". Manufacturers of single use disposable blood lancets should include in the labeling, including the Instructions for Use and the written, printed, and graphic matter that accompanies the blood lancet device, instructions for the safe disposal of these blood-contaminated devices. If the device contains a sharps safety/self-disabling feature, the Instructions for Use should include a description of its use.

References

1. Centers for Disease Control and Prevention. Transmission of hepatitis B virus among persons undergoing blood glucose monitoring in long-term-care facilities – Mississippi, North Carolina and Los Angeles County, California, 2003-2004. MMWR 2005; 54: 220-223

2. Patel AS, White-Comstock MB, Woolard D, Perz JF. Infection Control Practices in Assisted Living facilities: A Response to Hepatitis B Virus Infection Outbreaks. ICHE 2009; 30(3): 209-214

3. Thompson ND, Perz JF. Eliminating the Blood: Ongoing Outbreaks of Hepatitis B Virus Infection and the Need for Innovative Glucose Monitoring Technologies. J Diabetes Sci Technol 2009; 3 (2): 283-288

4. Thompson ND, Perz JF, Moorman AC, Holmberg SD. Nonhospital Health Care-Associated Hepatitis B and C Virus transmission: United States, 1998-2008. Ann Int Med 2009; 150: 33-39

5. Labeling reusable medical devices for reprocessing in health care facilities: FDA reviewer guidance (1996). http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080268.pdf