Guidance for Industry and Food and Drug Administration Staff - Blood Lancet Labeling

U.S. Food & Drug Administration

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Center for Devices and Radiological Health
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Preface

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 [3]

* 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.

SOURCE [4]

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