



1275 K Street, NW, Suite 1000
Washington, DC 20005-4006
Phone: 202/789-1890
Fax: 202/789-1899
apicinfo@apic.org
www.apic.org

May 24, 2016

Ms. Leslie Kux
Assistant Commissioner for Policy
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-N-0400; General and Plastic Surgery Devices; Reclassification of Blood Lancets, proposed rule.

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Food and Drug Administration (FDA) for the opportunity to provide input to its proposed rule “General and Plastic Surgery Devices; Reclassification of Blood Lancets.” APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. We are pleased that the FDA continues to demonstrate its commitment to improving patient safety regarding the use of lancets.

APIC supports the FDA’s proposal to reclassify single patient use only blood lancets with and without integral sharps injury prevention, from class I (general controls) to class II (special controls). APIC agrees that this reclassification is prudent in order to provide reasonable assurances of safety and effectiveness of these devices prior to them being brought to the market.

However, APIC is concerned that blood lancing devices labeled as multiple use blood lancets for single patients are not being moved to class III (premarket approval) devices. Numerous hepatitis B outbreaks related to assisted monitoring of blood glucose have implicated these devices as a probable route of transmission due to reuse of these types of devices on multiple patients.^{1,2} These devices cannot be rendered safe for use since the base, orifice, and exit track of the lancet cannot be adequately cleaned and disinfected between patient uses, making the device unsafe for use in its current design.

Recommendation:

- APIC recommends designating blood lancing devices labeled as multiple use blood lancets for single patients as Class III to allow the FDA to evaluate their design and to further evaluate their risk related to off-label use as multiple patient devices.



APIC supports the FDA's proposal to reclassify multiple patient use blood lancets for multiple patients from class I (general controls) to class III (premarket approval). There is ample evidence that these devices require further evaluation by the FDA in both their design and instructions for use related to cleaning and disinfection. APIC feels this reclassification would minimize the potential risks of illness or injury to patients more than if the devices did not have premarket approvals to ensure their safety with proper use.

APIC appreciates the opportunity to provide input on the reclassification of blood lancets on behalf of our members. We look forward to continuing to work with FDA to safeguard patient safety with appropriate controls on the manufacture and use of medical devices.

Sincerely,

A handwritten signature in cursive script that reads "Susan Dolan".

Susan Dolan, RN, MS, CIC
2016 APIC President

¹ CDC. Notes from the Field: Deaths from Acute Hepatitis B Virus Infection Associated with Assisted Blood Glucose Monitoring in an Assisted Living Facility – North Carolina, August – October 2010. MMWR 2011;60(06);182 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6006a5.htm>. Accessed on April 25, 2016.

² CDC. 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. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a2.htm> accessed on April 25, 2016.