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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

International Workshop on the Standardization of Whole Blood Coagulation Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a workshop entitled "International Workshop on the Standardization of Whole Blood Coagulation Devices." The focus of the workshop is to define the issues relating to the calibration of whole blood coagulation assays. Workshop participants will be asked to develop a proposal for standardizing the calibration of these devices. The proposal will be referred to a standards development organization.

DATE: The workshop will be held on August 13, 1999, 1 p.m. to 6 p.m.

ADDRESSES: The workshop will be held at the Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Sheila J. Murdock, Office of Surveillance and Biometrics (HFZ-510), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3060, FAX 301-594-2968, e-mail "coagulation@cdrh.fda.gov".

SUPPLEMENTARY INFORMATION: Whole blood clotting assays are used increasingly in the point of care testing environment. The calibration of these assays against plasma methods is achieved through a variety of approaches. Consequently, the consistency of results between different devices and the traceability of results to plasma methods are variable. Limited correlation between assays can be particularly problematic when monitoring anticoagulant drugs.

The workshop will focus on defining the issues relating to the calibration of whole blood coagulation devices. Workshop participants will collaborate on a proposal for the development of

a standardized approach to the calibration of these assays. The proposal will be referred to a standards development organization.

In order to make the best use of limited workshop time, guest speakers will be asked to write a draft standardization proposal prior to the date of the workshop. This document will be posted on the CDRH website after July 15, 1999, at “<http://www.fda.gov/cdrh/meetings/coag.html>”. Members of the public will be encouraged to e-mail comments and recommendations about this document to “coagulation@cdrh.fda.gov”. Summaries of all e-mailed comments sent with author’s name will be posted to the website in order to provide a forum for ongoing discussion up to the week of the workshop.

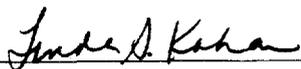
Those persons interested in attending the workshop should fax or e-mail their registration including name, title, affiliation (i.e., end-user, government nonregulatory, government regulatory, industry, professional organization, proficiency testing organization, trade press, standards development organization), mailing address, telephone number, fax number, e-mail address, and area of interest. There is no charge to attend the workshop, however, advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Shirley L. Meeks at least 7 days in advance of the meeting, at the Office of Systems Management (HFZ-17), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 105, FAX 301-827-2929, e-mail “SLM@CRDH.FDA.GOV”.

Registration forms and the preliminary agenda may also be accessed at the CDRH website at “<http://www.fda.gov/cdrh/meetings/coag.html>”. The workshop agenda includes presentations by guest speakers, small breakout group discussions and deliberation and refining of a standardization proposal. The final plenary session will include reports to the assembly from the smaller group discussions. Time will be provided for public comments at the end of this session. The draft standardization proposal will be finalized according to the recommendations of workshop participants. A summary report of the workshop will be available on CDRH’s website

approximately 15 working days after the workshop. The CDRH home page may be accessed at
“<http://www.fda.gov/cdrh>”.

Dated: 7/23/99

July 23, 1999



Linda S. Kahan
Deputy Director for
Regulations Policy
Center for Devices and
Radiological Health

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