FDA NOTE TO CORRESPONDENTS

For Immediate Release: Oct. 25, 2010
Media Inquiries: Shelly Burgess, 301-796-4651, shelly.burgess@fda.hhs.gov
Inquiries: 888-INFO-FDA

FDA laboratory receives accreditation

13 testing methods recognized under ISO/IEC 17025 standard

The U.S. Food and Drug Administration today announced that the American Association for Laboratory Accreditation has accredited the Laboratory Quality System program in the Center for Biologics and Evaluation Research (CBER) under ISO/IEC 17025 in the fields of biological and chemical testing.

The ISO/IEC 17025 is a standard developed by the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC) to merge requirements for technical competence in testing and calibration laboratories with requirements for quality systems.

CBER received accreditation for six methods to test influenza vaccines, including those for sterility and potency, and seven methods for evaluating blood donor screening kits that detect the presence of HIV, HBV, HCV, HTLV-I/II, Trypanosoma cruzi, and West Nile virus. These laboratory activities have a direct impact on regulatory decisions. The Laboratory Quality System program supports the development and evaluation of national reference materials and standards, as well as evaluation of manufacturers' assays.

Accreditation of CBER's Laboratory Quality System provides additional transparency and acknowledgement of a program that has been recognized as an international leader in biological products regulation.

For more information:

About the International Standards Organization
http://www.iso.org/iso/about.htm

About the International Electrotechnical Commission
http://www.iec.ch/helpline/sitetree/about/
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Filename: Document2
Directory:
Template: C:\Documents and Settings\Daniel Arrieta\Application Data\Microsoft\Templates\Normal.dot
Title:
Subject:
Author: Daniel Arrieta
Keywords:
Comments:
Creation Date: 10/25/2010 2:59 PM
Change Number: 1
Last Saved On:
Last Saved By:
Total Editing Time: 20 Minutes
Last Printed On: 10/25/2010 5:39 PM
As of Last Complete Printing
Number of Pages: 1
Number of Words: 313 (approx.)
Number of Characters: 1,786 (approx.)