CDRH INITIATIVES FOR AGING IN PLACE

NIH Aging in Place Workshop

September 10-11, 2014

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I WILL ADDRESS:

Final Guidance for Home Use Devices

Final Guidance for Mobile Medical Applications

Research Recommendations to Further Policy

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HOME USE FINAL GUIDANCE

Design Considerations for Devices Intended for Home Use

Guidance for Industry and Food and Drug Administration Staff

Document issued on [insert publication date of FR Notice].

The draft of this document was issued on December 13, 2012.

For questions about this document regarding CDRH-regulated devices, contact Mary Brady at 301-796-6089 or by e-mail at mary.brady@fda.hhs.gov; or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

HOME USE FINAL GUIDANCE

- Provides definitions
  - Home Use device
  - User
  - Lay
  - Qualified health care professional
  - Professional health care facility

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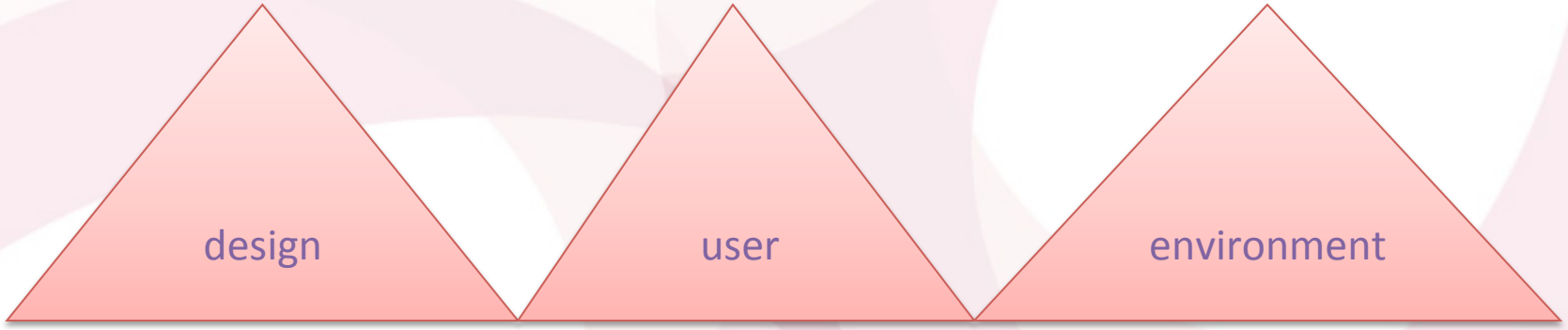
HOME USE FINAL GUIDANCE



Leads to useful and usable labeling

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DESIGN CONSIDERATIONS

- Risk management
- Software
- Lock-out mechanisms
- Maintenance
- Calibration
- Mechanical
- Electrical issues (supply mains, power sources, permanently installed devices, outlets, adapters, outages, EMC, wireless, alarm systems)

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USER CONSIDERATIONS

- Physical
  - Size, mobility, dexterity, strength, stamina
- Sensory/perceptual
  - Vision, hearing, tactile
- Cognitive
  - Literacy, comprehension, learning
- Emotional
  - New diagnosis, treatment, device

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ENVIRONMENTAL CONSIDERATIONS

- Location
- Contaminants
- Water supply
- Temperature
- Dampness and humidity
- Atmospheric pressure changes
- Air flow
- Travel
- Fluid exposure
- Storage

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OTHER SECTIONS IN THE FINAL GUIDANCE

- Human factors
- User training
- Labeling
- Handling the device in an emergency
- Disposal
- Hygienic maintenance
- Post market considerations

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MOBILE MEDICAL APPLICATIONS FINAL GUIDANCE

Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on: September 25, 2013

The draft of this guidance was issued on July 21, 2011.

For questions regarding this document, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov . For questions regarding this document concerning devices regulated by CBER, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 301-827-1800.

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TWO CATEGORIES OF MOBILE APPLICATIONS

- Those that meet the definition of a medical device
  - pose a risk to the patient's safety
  - referred to as "mobile medical apps"
- Those that do not meet the definition of a medical device
  - not regulated by FDA

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MOBILE MEDICAL APPS INTENDED USE

- To be used as an accessory to a regulated medical device
- To transform a mobile platform into a regulated medical device

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CRITERIA FOR FDA TO EXERCISE REGULATORY OVERSIGHT

- Connecting to a medical device to control the device
- Displaying, storing, analyzing, or transmitting patient-specific medical device data
- Transforming the mobile platform into a regulated medical device
- Providing patient-specific diagnosis or treatment recommendations.

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CRITERIA FOR FDA TO EXERCISE ENFORCEMENT DISCRETION

- Providing supplemental clinical care
- Providing patients the tools to enable easy access, track and organize their health information
- Helping patients document and communicate to providers potential medical conditions
- Performing calculations used in clinical practice
- Enabling individuals to interact with PHR or HER systems

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RESEARCH RECOMMENDATIONS

- Readmission rates of people with technology
- Purchasing equipment after a period of reimbursement

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QUESTIONS???

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