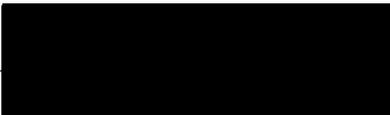


Committee on Energy and Commerce
U.S. House of Representatives
 Witness Disclosure Requirement - "Truth in Testimony"
 Required by House Rule XI, Clause 2(g)

1. Your Name: <i>CHRISTY L. FOREMAN</i>		
2. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
3. Are you testifying on behalf of an entity that is not a government entity?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
4. Other than yourself, please list which entity or entities you are representing: <i>U.S. FOOD & DRUG ADMINISTRATION</i>		
5. Please list any Federal grants or contracts (including subgrants or subcontracts) that you or the entity you represent have received on or after October 1, 2011: <i>NONE</i>		
6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing:		
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8. If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed:		
9. Please attach your curriculum vitae to your completed disclosure form.		

Signature: 

Date: 3/20/13

Christy Lynn Foreman

WORK EXPERIENCE

Director, Office of Device Evaluation

FDA/CDRH

3/2010 – Present

As the Director, I oversee the operations of the Office of Device Evaluation (ODE), an office of approximately 400+ scientific, professional and administrative personnel. I serve as the primary representative and spokesperson for the Office. I establish the strategic direction and priorities for ODE at both the policy and operational levels. I provide supervisory oversight of ODE review divisions and PMO. I provide final ODE sign-off on all PMA/HDE documents that are not delegated to the Division Directors. I decide all Office-level appeals. I provide final ODE sign-off on first-of-a-kind PMA applications, 510(k) SE with Limitations, horizontal regulations and guidance, I also oversee major initiatives such as the internal review of the 510(k) program. Additional duties include overseeing the office budget and hiring process. ODE is responsible for the premarket review of medical devices. The regulatory applications include Premarket Notification (510(k)), Premarket Approval Applications (PMA), Investigational Device Exemptions (IDE), Humanitarian Device Exemptions, Product Development Protocols, De Novo Applications and Requests for Classifications (513(g)).

Deputy Director for Science and Review Policy

FDA/CDRH/ODE

6/2008 - 3/2010

As the Deputy Director for Science and Review Policy, I served as the chief scientific officer for the office as well as oversaw the regulatory policies of the 510(k), PMA, HDE and IDE programs. I was also responsible for overseeing the 513(g) program, De Novo and the combination products that are reviewed in CDRH. I served as the office representative to the Science Prioritization and Oversight Committee. I was also responsible for office level sign-off for guidance documents. Additionally, I reviewed office generated publications and presentations for conformance with current office policy.

Deputy Director

FDA/CDRH/OC/DOEB

12/2002 - 12/2008

Planned, organized, developed, conducted and evaluated programmatic operations supporting the enforcement of the Federal Food Drug and Cosmetic Act, the Medical Device Amendments of 1976 including the Safe Medical Devices Act of 1990, the Food and Drug Modernization Act of 1997 and the Medical Device User Fee and Modernization Act of 2002, as they relate to Cardiovascular, Neurology, Orthopedic, Physical Medicine, Anesthesiology and Radiology devices and Radiological Health Products (Prior to a reorganization in which responsibilities were transferred to OCER) such as microwaves and laser products. Supervise compliance activities for the division including Quality System regulation reviews for premarket applications and establishment inspection reports, recall classifications, seizures, injunctions and civil money penalties. Supervise an interdisciplinary staff including Branch Chiefs, experts in the areas of Quality Systems, Software and Case Management and division support staff. Contribute to Office-wide policies and procedures to assist staff and industry.

Branch Chief

FDA/CDRH/OC/DOEB/OPMADB

12/2001 - 12/2002

Planned, organized, developed, conducted and evaluated programmatic operations supporting the enforcement of the Federal Food Drug and Cosmetic Act, the Medical Device Amendments of 1976 including the Safe Medical Devices Act of 1990, the Food and Drug Modernization Act of 1997 and the Medical Device User Fee and Modernization Act of 2002, as they related to orthopedic, physical medicine and anesthesiology devices to ensure the safety and effectiveness of medical devices and to promote and protect the public health. Supervised and coordinated activities associated with regulatory actions such as seizures, injunctions, civil money penalties, recalls and warning letters and supervised and coordinated reviews of premarket approval applications and establishment inspection reports to ensure compliance with the Quality System Regulation.

Leadership Development Program

FDA/CDRH/ODE

4/2000 - 12/2001

Selected for a highly competitive Agency level program designed to provide leadership development training and opportunities. Concurrent with duties as a scientific reviewer

- Acting Deputy Director, Division of Enforcement B, Office of Compliance
 - Detail to Health Canada to compare and contrast regulatory processes for a better understanding of global medical device regulation
 - Executive Secretary, Office of Science Coordination and Communication
- Served as the FDA Exec Sec for the FDA Science Board
- Acting Supervisor, Investigations Branch, Minnesota District Office, ORA, FDA

Managed an interdisciplinary team located at the district office as well as in two remote resident posts. The functions of the branch included inspections for all FDA regulated commodities as well as import operations.

Biomedical Engineer
FDA/CDRH/ODE/ADDG
5/1996 - 12/2001

Employed as a scientific reviewer in the Center for Devices and Radiological Health. Specific job functions include reviewing medical device submissions for marketing clearance and developing guidances for medical devices. Device areas included ventilators, oxygen therapy devices, CPAP devices, defibrillators and cardiac resynchronization therapy.

Biomedical Engineer
Naval Medical Research Institute Bethesda, MD
6/1989 - 5/1996

Diving and Environmental Physiology Department
Employed as a researcher with goals of improving cognitive performance of the military in thermally challenging conditions. Specific research experiments included assessing cognitive decrements of Navy divers and Navy SEALs attributable to cold weather operations and exploring the pathophysiology of non-freezing cold injury.

EDUCATION

The Catholic University of America
Washington, DC US
Master's Degree - 5/2000
Major: Biomedical Engineering

The Catholic University of America
Washington, DC US
Bachelor's Degree - 5/1993
Major: Biomedical Engineering

JOB RELATED TRAINING

Leadership for a Democratic Society, Federal Executive Institute, 2012
Brookings Institution - Science and Technology Policy Issues
Leadership Development Training as part of the FDA LDP Program
Food and Drug Law
Import Operations
Compliance Law
Emergency Medical Technician (EMT-B)
First Responder
Biostatistics
Crucial Conversations
Understanding Individual Differences
Formula for Achieving Managerial Excellence I
Formula for Achieving Managerial Excellence II
AAMI Quality Systems Regulations
AAMI Process Validation
AAMI Corrective and Preventive Actions
AAMI Design Controls

PROFESSIONAL PUBLICATIONS, GUIDANCE AND POLICIES

Publications:

Modernizing Device Regulation - Letter to the Editor
New England Journal of Medicine
RM Kretzer, CL Foreman, JE Shuren

Book chapter on the regulation of hyperbaric chambers as medical devices. Hyperbaric Facility Safety: A Practical Approach; 1999, edited by W.T. Workman

Guidances Authored/Significant Contributions:

Draft Manufacturing Site Change Supplements: Content and Inspectional Considerations, to publish eminently

Proposed Rule for Upclassifying Oxygen Regulators and Oxygen Conserving Devices including the Special Controls Guidance, February 27, 2007

OC/OIVD Procedures for Premarket Establishment Inspection Report Reviews, effective date July 26, 2006

OC/OIVD Procedures for PMA Review, effective Date November 1, 2004

Signature Authority Guidance for OC staff for Premarket Approval Applications, effective Date November 1, 2004

Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions, issued February 21, 2000 to support downclassification from Class III to Class II.

ADDITIONAL INFORMATION

Presentations:

Numerous presentations to industry and FDA panel meetings regarding FDA regulatory requirements for premarket submissions including specific presentations on 510(K), PMA and IDE policies, hyperbaric chambers, biventricular pacemakers, high frequency ventilators, Quality System regulation requirements for premarket submissions, purchasing controls, and process validation activities.

Guest Lecturer in Biomedical Engineering at The Catholic University of America

Thermal and physiological responses to chronic administration of DPAT. M.H. Quesada, S.T. Ahlers, C.L. Foreman, and K.P. Sausen. Presented to the Federation of American Societies for Experimental Biology, April 1995.

Measurement of brain temperature in multiple sites during cold stress reveals dynamic and nonunitary changes. S.T. Ahlers, C.L. Kish, and J.R. Thomas. Presented to The Society for Neuroscience, 23rd Annual Meeting, November 1993.

Standards Committees:

- NFPA Committee on Hyperbaric and Hypobaric Facilities
- ASME PVHO - Subcommittee on Medical Hyperbaric Systems
- ASTM G4 Committee on Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres

Significant Awards:

Outstanding Service Award, 2007

John C. Villforth Award, 2003

Numerous other individual achievement and group performance awards