DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

February 28, 2013

Sammy Almshat, M.D., MPH
Sarah Sorscher, J.D., MPH
Sidney Wolfe, M.D.
Public Citizen's Health Research Group
1600 20th Street, NW
Washington D.C. 20009

Dear Dr. Almshat, Ms. Sorscher, and Dr. Wolfe,

Thank you for your letter of February 13, 2013 addressed to Commissioner Margaret A. Hamburg, M.D. and Jeffrey E. Shuren, M.D., J.D. regarding the classification of Intra-Aortic Balloon Pump (IABP) Devices (21 C.F.R. § 870.3535). Your letter was referred to the Food and Drug Administration's (FDA) Office of Device Evaluation (ODE) of the Center for Devices and Radiological Health (CDRH) for reply.

IABP devices are preamendment class III devices and are a device type which is being evaluated as part of our 515 program initiative. Sections 513(e) and 515(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) govern the processes for device reclassification and requiring premarket approval for preamendment class III devices, respectively. Sections 513(e)(1) and 515(b)(1) of the FD&C Act set forth the public process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device or requiring premarket approval for a preamendments class III device, the following must occur: (1) Publication of a proposed order in the Federal Register; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket.

The classification of IABP devices was considered by the Circulatory Systems Devices Panel on December 5, 2012. In the near future, a proposed order will be published in the Federal Register, and I encourage you to submit your comments and/or letter to the public docket. The docket number and public comment link will be provided in the proposed order along with specific instructions for posting your response.

The FDA will consider your comments and carefully review the material you submit in the development of the final order regarding the classification of IABP devices.

Thank you for contacting us concerning this matter and if we can be of further assistance, please contact Ms. Angela Krueger at 301-796-6380 or email Angela.Krueger@fda.hhs.gov.

Sincerely,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Separate Page: History Page

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Draft: Karen Ulisney, CDRH/ODE/DCD/CSDB, 2/25/13
Revised: Karen Ulisney, CDRH/ODE/DCD/CSDB, 2/26/13
Reviewed: Angela Krueger , CDRH/ODE, 2/28/13
Reviewed ,Cleared and Signed: Bram Zuckerman, CDRH/ODE/DCD, 2/28/13