

Officer/Employee List Email, October 4, 2012 - Ducord

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From: Davidson, Mark

Sent: Thursday, October 04, 2012 10:53 AM

To: CBER-OCOD-Action Packages

Cc: Burk, Suzann

Subject: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125407
Hi OCOD Staff,

According to Section 916 of the Food and Drug Administration Amendments Act (FDAAA) includes a new requirement to identify by name each officer or employee who participated in the decision to approve an application for which an "Action Package" is prepared (i.e., NDA/BLA original application). This provision also requires that the employee's consent must be obtained to list his/her name. To implement this provision, an *Officer/Employee List* memo will be prepared and included as part of the Action Package. Approval documents to follow this afternoon.

The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list.

Kimberly Benton

Raj Puri

Wilson Bryan

Mary Malarkey

Denise Gavin

Mercy Quagraine

Cheng-Hong Wei

Safa Karandish

Keith Wonnacott

Yao Yao Zhu

Changting Haudenschild

Ilan Irony

Atm Shamsul Hoque

Boguang Zhen

Renee Rees

Lisa Stockbridge

Loan Nguyen

Carolyn Renshaw

Nancy Waites

Dennis Cato

Mark Davidson

Patrick Riggins

Lori Tull

Thanks

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