

Rana, Pratibha

From: Rana, Pratibha
Sent: Monday, November 19, 2012 5:25 PM
To: Kennedy, Michael; Stockbridge, Lisa L; Ou, Alan C.; Ortega, Lillian; Frazier, Douglas; Frost, Mitchell M; Kim, Jessica; Norton, Malgorzata; Struble, Evi; Zhong, Lilin; Virata, Maria Luisa; Zhang, Pei; Popat, Alpita; Winiecki, Scott; Olin, Rebecca; Campbell, Karen M; Sillivan, Destry
Subject: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125389/0/ Biotest

Importance: High

Follow Up Flag: Follow up
Due By: Wednesday, November 28, 2012 6:30 PM
Flag Status: Flagged

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.

You have been identified as having participated in the review and approval decision for (identify specific file). If you are willing to have your name appear on the list of employees that is a required part of the Action Package please respond with a **YES** to this email by COB (**November 28, 2012**). If you do not reply by (date), or if you reply **NO**, your name will not appear on this Officer/Employee List.

You should be aware:

- Your name will be included on the list only if you consent in writing (i.e., respond to this email). Your name will not be included on the list if you (1) respond that you do not consent or (2) do not respond to the inquiry by the date specified.
- The Officer/Employee List will be posted on the Web page when the Action Package is published.

There will be no change in redaction of employee names from FDA records. This means that, in most cases, your name will still be associated with the documents you have authored that are posted, and consequently will be publicly disclosed, even if your name is excluded from the Officer/Employee List.

Thank you.

Pratibha Rana

Pratibha Rana, M.S.

Regulatory Project Manager

FDA/CBER/OBRR

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received this document in error, please immediately notify the sender immediately by e-mail or phone."

Tracking:

Recipient	Response
Kennedy, Michael	
Stockbridge, Lisa L	
Ou, Alan C.	
Ortega, Lillian	Yes: 11/20/2012 8:01 AM
Frazier, Douglas	
Frost, Mitchell M	
Kim, Jessica	Yes: 11/20/2012 8:24 AM
Norton, Malgorzata	Yes: 11/19/2012 5:28 PM
Struble, Evi	
Zhong, Lilin	
Virata, Maria Luisa	Yes: 11/21/2012 4:23 PM
Zhang, Pei	Yes: 11/30/2012 8:17 AM
Popat, Alpita	Yes: 11/20/2012 1:44 PM
Winiecki, Scott	
Olin, Rebecca	
Campbell, Karen M	
Sullivan, Destry	Yes: 11/19/2012 7:10 PM