

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Friday, September 21, 2012 10:42 AM
To: Ananyeva, Natalya; Barash, Faith; Brown, La'Nissa; Campbell, Karen M; Cato, Dennis; Horbowyj, Roxolana; Hudson, Peter; Khuc, Kristine; Kirschbaum, Nancy; Lindsey, Kimberly; Melhem, Randa; Nguyen, Loan; Scott, John; Waites, Nancy
Cc: Shields, Mark
Subject: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0
Importance: High
Follow Up Flag: Follow up
Due By: Monday, September 24, 2012 9:00 AM
Flag Status: Flagged

Hello All,

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 STN 125392/0. **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 ASAP. If you do not reply by Monday, September 24th, 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,

Tracy Tilghman, MPH

Lieutenant, United States Public Health Service
Regulatory Project Manager

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				From	Subject	Recei...	Size	
Subject: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0 (13 items)								
				Tilghman, Tracy	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Wed 9/2...	7 KB	
				Campbell, Karen M	No: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Mon 9/2...	7 KB	
				Horbowyj, Roxolana	RE: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	9 KB	
				Kirschbaum, Nancy	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Ananyeva, Natalya	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Khuc, Kristine	No: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Shields, Mark	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Nguyen, Loan	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Melhem, Randa	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Barash, Faith	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Scott, John	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Brown, La'Nissa	Yes: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	
				Waites, Nancy	No: FDAAA Section 916 (Action Packages), Officer/Employee List for STN 125392/0	Fri 9/21/...	7 KB	