

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206814Orig1s000

OFFICER/EMPLOYEE LIST

Fromm, Edward J

From: Fromm, Edward J
Sent: Thursday, December 11, 2014 6:59 AM
To: Stockbridge, Norman L; Blank, Melanie; Srinivasachar, Kasturi; Sapru, Mohan; Stephens, Olen; Miller, Denise; Sweeney, Neal J; Fortney, Russell; Stewart, Janine; Tu, Chi-Ming (Alice); Sabarinath, Sreedharan; Madabushi, Rajnikanth; Suarez, Sandra
Subject: Officer/Employee List for NDA 206814 (Potassium Chloride Oral Solution) FDAAA Section 916 (Action Packages)

Tracking:	Recipient	Response
	Stockbridge, Norman L	Yes: 12/13/2014 9:31 AM
	Blank, Melanie	
	Srinivasachar, Kasturi	Yes: 12/11/2014 9:04 AM
	Sapru, Mohan	Yes: 12/11/2014 10:10 AM
	Stephens, Olen	Yes: 12/11/2014 8:29 AM
	Miller, Denise	Yes: 12/11/2014 7:10 AM
	Sweeney, Neal J	Yes: 12/11/2014 9:16 AM
	Fortney, Russell	Yes: 12/11/2014 7:25 AM
	Stewart, Janine	
	Tu, Chi-Ming (Alice)	No: 12/11/2014 7:51 AM
	Sabarinath, Sreedharan	
	Madabushi, Rajnikanth	
	Suarez, Sandra	Yes: 12/11/2014 7:00 AM

Folks,

Vote Buttons:

- **Yes**, my name can be included on the Officer/Employee List
- **No**, I do not consent

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 applications and efficacy supplements). 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* 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 (**NDA 206814, Potassium Chloride Oral Solution**). 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 to this email, using the **Yes** vote button above, by **4:00 PM (Thursday 18 December 2014)**. **If you do not reply (by Thursday 18 December 2014), or if you reply using the No button above, 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.

Thanks,

Ed

Edward Fromm, R.Ph., RAC
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