

From: Allard, Crystal
Sent: Thursday, April 28, 2011 12:25 PM
To: 'Urs Aeberli'
Cc: -----(b)(4)-----
Subject: 125384/0 - labeling review

Attachments: Revised labeling 14 FEB 2011 v8.doc

Hi Urs,

Please find attached our requests for updates to labeling for 125384/0.



Revised labeling 14
FEB 2011 v...

Please review the attached document and send your updated labeling as an amendment to 125384/0. Email is fine for the amendment. Please include a cover letter, and form.

Please also incorporate the labeling comments sent last week regarding the viral validation study into your updated labeling.

Feel free to contact me with any questions or concerns.

Thanks!

Crystal Allard, RAC
Regulatory Project Manager
U.S. Food & Drug Administration
CBER/ OBRR/ DBA/RPMB
WOC1; RM480N; HFM-380
1401 Rockville Pike
Rockville, MD 20852
Ph# 301.827.3927
Fax# 301.827.2857

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.