

# Final Prescribing Information Email, June 20, 2011 - Laviv

From: Zhu, Yao-Yao  
Sent: Monday, June 20, 2011 1:53 PM  
To: Tull, Lori Cc: Schneider, Bruce  
Subject: FW: BLA 125348 Amendment 046 - Final Prescribing Information

Attachments: demographics.doc

-----Original Message-----

From: Zhu, Yao-Yao  
Sent: Sunday, June 19, 2011 12:24 AM  
To: '[jnovak@cbrintl.com](mailto:jnovak@cbrintl.com)'; Schneider, Bruce; Dana Weinberger Cc: Kevin Hennegan; Lee Buttrill  
Subject: RE: BLA 125348 Amendment 046 - Final Prescribing Information

Jeanne,

Please see attached demographics from integrated safety data and from the two pivotal trials (005 and 006). It appears that the upper limit of age in control group in the integrated safety population (79 yo) did not match the upper age in the pivotal trial 006 (81). Please provide an explanation.

Yao-Yao

-----Original Message-----

From: Jeanne Novak [mailto:[jnovak@cbrintl.com](mailto:jnovak@cbrintl.com)]  
Sent: Sunday, June 19, 2011 12:21 AM  
To: Schneider, Bruce; Jeanne CBR; Dana Weinberger Cc: Kevin Hennegan; Zhu, Yao-Yao; Lee Buttrill  
Subject: Re: BLA 125348 Amendment 046 - Final Prescribing Information

Bruce,

As we look into this and if we have questions can I call you? It would be tomorrow. If so, is there a good number?

Jeanne M. Novak, Ph.D.  
CEO and President  
Principal Consultant

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Sent wirelessly via BlackBerry from T-Mobile.

-----Original Message-----

From: "Schneider, Bruce" <[Bruce.Schneider@fda.hhs.gov](mailto:Bruce.Schneider@fda.hhs.gov)>  
Date: Sat, 18 Jun 2011 23:42:09  
To: '[jnovak@cbrintl.com](mailto:jnovak@cbrintl.com)'>; Dana Weinberger<[dweinberger@cbrintl.com](mailto:dweinberger@cbrintl.com)>  
Cc: Kevin Hennegan<[khennegan@cbrintl.com](mailto:khennegan@cbrintl.com)>; Zhu, Yao-Yao<[Yao-Yao.Zhu@fda.hhs.gov](mailto:Yao-Yao.Zhu@fda.hhs.gov)>; Lee Buttrill<[lbuttrill@cbrintl.com](mailto:lbuttrill@cbrintl.com)>  
Subject: RE: BLA 125348 Amendment 046 - Final Prescribing Information

Page Last Updated: 07/20/2011

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