

(System Info - 233074 SCHWAB DAVID 04/11/2013 14:23:34 SCHWABD)

From: Berkhausen, Katherine  
Sent: Thursday, April 11, 2013 2:17 PM  
To: Schwab, David  
Subject: FW: PNR for Heplisav-B

Importance: High

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From: Berkhausen, Katherine  
Sent: Wednesday, April 10, 2013 12:30 PM  
To: Turner, William; 'Alambra, Elaine'  
Cc: Daemer, Richard J.; Major, Marian  
Subject: PNR for Heplisav-B  
Importance: High

Dear Bill and Elaine,

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB), we conclude that your proposed proprietary name, HEPLISAV-B, is acceptable under the Federal Food, Drug, and Cosmetic Act and applicable regulations.

However, consider directly incorporating the modifier in the proposed proprietary name (e.g., HEPLISAVB) to minimize any potential for ambiguity or medication errors when the modifier is dropped.

We will perform another proprietary name review of HEPLISAV-B closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.

Kind regards,  
Katherine