
From: Norris Pyle [mailto:norris.h.pyle@gsk.com]
Sent: Thursday, May 10, 2012 9:02 AM
To: Prutzman, Kirk C; Staten, David; Temenak, Joseph
Cc: Jody Gould
Subject: MenHibrix/Hiberix: Auxiliary label for combo box

Hello everyone,

Regarding the auxiliary label proposed for use on the combo box for both Hiberix and MenHibrix, as requested, please find attached some "demo" labels to assist you in the review of the labeling. I marked the sample labels with representative lot numbers and expiration dating which were approved by GSK packaging group. Although these labels are for MenHibrix, the same lot numbering/expiration dating would apply to Hiberix. My one disclaimer is that since the labeling is under review/negotiations, the exact text of some of the labels might not be what will be ultimately approved, but this information should suffice to give you an idea of how the lot numbering and expiration dating would look.

There was a question as to how the initial launch supplies for Hiberix were packaged, and if they had the auxiliary label. The initial launch supplies for Hiberix did not have the combo box. They were distributed in individual cartons. So no auxiliary label was used for the initial launch of Hiberix.

The auxiliary label cannot be moved from its current positioning without delays that would extend past June 1, 2012. I am seeking input from GSK packaging as to when we could be in a position to implement -----(b)(4)----- for Hiberix and MenHibrix in order to eliminate the use of the -----(b)(4)----- . I should be able to provide this information shortly. If CBER was to allow for the use of the auxiliary label for initial BLA approval, and then have a commitment to -----(b)(4)-----, how would CBER want this change reported? There would be imprinting equipment installed on the packaging line, and the -----(b)(4)----- artwork would need to be modified to include lot/exp dating. I'm thinking CBE-0, but want to confirm.

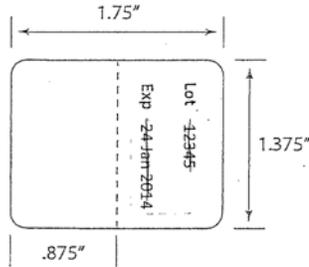
Thank you - Norris



DEMO

Auxiliary label for combo box

Lot (b)(4) Exp. 06/13/2013



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Specifications	
Kind Size: XATP 1814	Colors Front: DIE COLOR
Model: x	
Dimensions: 1.75" x 1.375"	
Colors Back:	
DPA Operator: JL	
Neg#:	
Item#:	

1 page redacted (b)(4)

DEMO

Lot (b)(4) XXXX,
Exp. 01/01/2015



Vendor to supply GS1 Databar with proper bar width reduction:
Scan Data: 011035810009054
Encoded Data: 1035810009054
X-dimensions: 12mm (1.012")

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GlaxoSmithKline Artwork Information Panel		Market Trade Name: Menhixrix		No. of Colours: 3 <small>(does NOT include Varials, if applicable)</small>	
Item Number: 451614		List Colours: <small>(include sample to fully describe, e.g. Pantone / spot / CMYK equivalent)</small>		K 477 728	
Manufacturing Site: GSK-BEL-Wavre-BEWAV-Marietta		Technical Reference No(s): BIO_DRW533 <small>(do NOT include the technical reference number)</small>		RSC A/W Version: 3	
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DEMO

Lot

(b)(4)

Exp. 01/01/2015



Actual Size



200%

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Encoded Data: 10358160809016
X-dimension: 9mil (.009")

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GlaxoSmithKline Artwork Information Panel Item Number: 451613	Market Trade Name: Menhibrix	No. of Colours: 2 (Does NOT include Varsha, if applicable)	
Manufacturing Site: GSK-BEL-Wavre-BEWAV-Marietta	List Colours: (Exclude sample in Fields provided, e.g. spot / spot-CMYK equivalent)	K 477	
Market or Pack Owner: United States-USA	Technical Reference No(s): BIO DRWS01 (do NOT include the technical reference desc) version: null	RSC A/W Version: 2	
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