
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

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 (0.12")

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GlaxoSmithKline Artwork Information Panel Item Number: 451614 Manufacturing Site: GSK-BEL-Wavre-BE-WAV-Marietta Market or Pack Owner: United States-USA		Market Trade Name: Menhixrix No. of Colours: 3 (Does NOT include Variable, if applicable) List Colours: K 477 728 Technical Reference No(s): BIO_DRW533 RSC A/W Version: 3	
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DEMO

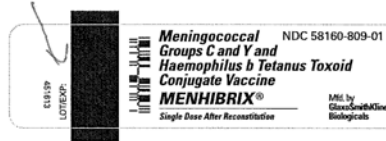
Lot

(b)(4)

Exp. 01/01/2015



Actual Size



200%

Vendor to supply RSS Barcode with proper bar width reduction:

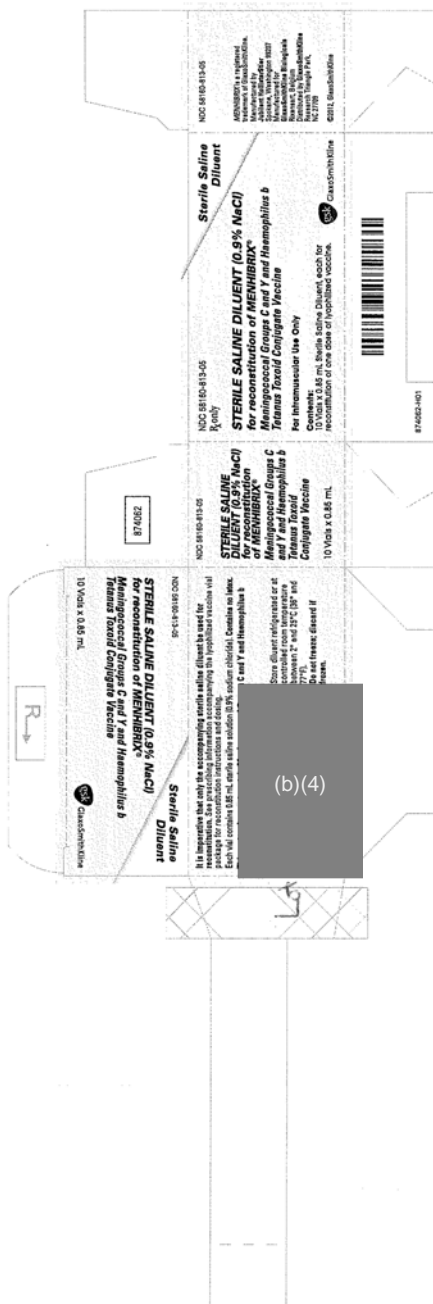
Scan Data: 0110358160809016

Encoded Data: 10358160809016

X-dimension: 9mil (.009")

PAGE 1 OF 1

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GlaxoSmithKline Artwork Information Panel Item Number: 451613 Manufacturing Site: GSK-BEL-Wavre-BEWAV-Marietta Market or Pack Owner: United States-USA		Market Trade Name: Menhix No. of Colours: 2 (GSK NOT include Variable, if applicable) List Colours: K 477 Technical Reference No(s): BIO DRWS01 (do NOT include the technical reference doc version number) RSC A/W Version: 2	
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Scan Data: 0100358160813054

Encoded Data: 00358160813054
X-dimension: 10mil (.010")

PAGE 1 OF 2

GlaxoSmithKline Work Information Panel		Market Trade Name: Menbix		No. of Colours: 3 (including white)	
Item Number: B74082		List Colours: Please see website at www.gsk.com		K 477	
Manufacturing Site: GSK-BEL-Wave-BEVAU-US-Hollister-Spoke		Technical Reference No(s): DRW 1005		BSC-AW Version:	
Market or Pack Owner: United States-USA		Please refer to the attached <i>technical-reference file(s)</i>			

Attention: Samples to be provided for printing purposes.
 If you are unable to provide samples, please provide a technical reference file(s) to be used for printing purposes.

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\$40.00 per Maximum Size Box

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Encoded Data: 00358160813016

X-dimension: 10mil (.010")

PAGE 1 OF 2

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Formulation, Tablet embossing, Storage conditions, Shelf Life

GlaxoSmithKline Artwork Information Panel		Market Trade Name: Menhlibrix		No. of Colours: 3 <small>(does NOT include Varnish, if applicable)</small>	
Item Number: 873194		List Colours: <small>(include sample in fields provided; specify CMYK equivalent)</small>		<div> <div>K</div> <div>477</div> </div>	
Manufacturing Site: GSK-BEL-Wavre-BEWAV-US-HollisterStier-Spokane		Technical Reference No(s.): DRW 1004 <small>(for 2007 include the technical reference design version no(s))</small>		RSC A/W Version: 2	

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