

Label Review Memorandum, March 30, 2012 - MenHibrix

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date March 30, 2012
Maryann Gallagher
Consumer Safety Officer

From Advertising and Promotional Labeling Branch (APLB)
Division of Case Management (DCM)
Office of Compliance and Biologics Evaluation (OCB)

Through Lisa L. Stockbridge, Ph.D.
Branch Chief, APLB/DCM/OCBQ

To Daron Freedberg, Chairperson, OVRR/DBPAP/LBP
David Staten, RPM, OVRR/DVRPA/CMC3
Label Review

Subject **MENHIBRIX (Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Con)**
BLA: 125363/01

Background: The sponsor submitted:

☐ New Approval
☐ Changes Being Effectuated (CBE) supplement
☒ Prior Approval Supplement (PAS) Amendment
☐ Major Amendment

Submission contains:

☒ Prescribing Information (PI)
☐ Patient Package Insert (PPI)
☒ Carton and/or container labels
☐ Other

Submission Date: December 1, 2011

PDUFA Action Date: June 1, 2012

APLB Comments/Recommendations

On December 1, 2011, GlaxoSmithKline submitted the MENHIBRIX BLA 125363 with the proposed indication for active immunization of infants and toddlers 6 weeks through

15 months of age for the prevention of invasive diseases caused by *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroups C and Y.

APLB reviewed the draft labeling for MENHIBRIX from a promotional and comprehension perspective. We have the following recommendations:

General

Revise the label to use active voice (i.e., use command language).

HIGHLIGHTS

INDICATIONS AND USAGE

Please revise the indication to move the age after the product's indication, i.e., MENHIBRIX is a vaccine indicated for active immunization for the prevention of invasive diseases caused by *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroups C and Y and in infants and toddlers 6 weeks through 15 months of age.

WARNINGS AND PRECAUTIONS

Update to be consistent with the full prescribing information section **5 warnings and PRECAUTIONS**.

DRUG INTERACTIONS

Please revise the cross reference to 7.2.

Please ensure that the HIGHLIGHTS and CONTENTS sections are consistent with the FULL PRESCRIBING INFORMATION.

FULL PRESCRIBING INFORMATION (FPI)

1 INDICATIONS AND USAGE

Please revise the indication to move the age after the product's indication, i.e., MENHIBRIX is a vaccine indicated for active immunization for the prevention of invasive diseases caused by *Haemophilus influenza* type b and *Neisseria meningitidis* serogroups C and Y and. in infants and toddlers 6 weeks through 15 months of age.

2 DOSAGE AND ADMINISTRATION

Directly beneath this section header, place the following bolded statement:

For intramuscular use only

5 WARNING AND PRECAUTIONS

Subsections 5.3 and 5.5 do not impart useful information outside of the practice of medicine. Consider deleting these sections.

6 ADVERSE REACTIONS

- According to 21CFR201.57(c)(7), an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence (see also *Guidance for Industry: Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products-Content and Format*). Revise sections discussing adverse experiences to include only adverse reaction and not adverse events.
- Directly beneath the section heading and before subsection 6.1 Clinical Trials Experience, state the most common adverse reactions along with the cut-off frequency. We recommend including the statement from the ADVERSE REACTIONS section of the HIGHLIGHTS. For example
Common solicited adverse reactions (>20% for each of the 4 doses) were pain and redness at the injection site, irritability, drowsiness, and loss of appetite.

13 NONCLINICAL TOXICOLOGY

This section is not required and should be deleted if there are no data.

17 PATIENT COUNSELING

Use bullets, simple sentences and command language wherever possible. For example:

- Inform the parent/guardian of the importance of completing the immunization series.
- Inform the parent/guardian of the potential for adverse reactions with MENHIBRIX.
- Encourage the parents/guardian to report any suspected adverse reactions to the healthcare provider and/or VAERS.
- Provide the Vaccine Information Statements (VIS) which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization.

Delete the issue date at the end of the FPI. This is replaced by the revision date at the end of the HIGHLIGHTS and should not appear in both places.

Carton and Container Labels

On October 20, 2009, APLB provided a review of the proposed carton and container labels that were submitted on August 12, 2009. At that time, APLB recommended including the indicated age group, i.e., "For 6 weeks through 15 months of age" and route of administration with sufficient prominence to mitigate medication errors with Menomune, Menactra and Menveo. The November 30, 2011 submission did not provide labels incorporating our previous comments. We highly recommend the prominent addition of the indicated age group and route of administration.

If you have any questions with regard to this review please contact Maryann Gallagher, Consumer Safety Officer, at 301-827-6330.