Vaccines, Blood & Biologics

Menveo - Untitled Letter

May 7, 2010

VIA FACSIMILE AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John P. Barry, Ph.D.
Drug Regulatory Affairs
Novartis Vaccines and Diagnostics, Inc.
350 Massachusetts Avenue
Cambridge, MA 02139

Re: **Menveo [Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine] BLA STN# 125300**

Dear Dr. Barry:

The Office of Compliance and Biologics Quality (OCBQ) in the Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) has reviewed an audio news release (ID# NVDMEN326) for Menveo [Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine]. Novartis Vaccines and Diagnostics Inc. (Novartis) submitted the audio news release under cover of Form FDA 2253 and CBER obtained an MP3 recording of the audio news release from MultiVu.

This promotional material is false or misleading because it minimizes the risks associated with Menveo. Therefore, this material misbrands Menveo under sections 502(a) and (c) and 201(n) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §352(a) and (c) and §321(n), and FDA implementing regulations, *Cf.* 21 CFR 202.1(e)(5)(iii) and (e)(7)(viii).

Background

According to the FDA-approved prescribing information (PI), Menveo is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menveo is approved fo use in persons 11 to 55 years of age. Menveo does not prevent *N. meningitidis* serogroup B infections.

Menveo is contraindicated for individuals who have had a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Menveo, any component of this vaccine, or any other CRM_{197}, diphtheria toxoid or meningococcal-containing vaccine.

The Warnings and Precautions section of the PI includes, but is not limited to, the following risks for Menveo:

Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of Menveo.

Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with Menveo.

Safety and effectiveness of Menveo have not been evaluated in immunocompromised persons. If Menveo is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.

Following vaccination with a U.S.-licensed meningococcal quadrivalent polysaccharide conjugate vaccine, an evaluation of post-marketing adverse events suggested a potential for an increased risk of Guillain-Barré Syndrome (GBS). Data are not available to evaluate the potential risk of GBS following administration of Menveo.

The most frequently occurring adverse events in subjects who received Menveo were pain at the injection site, headache, myalgia, malaise, and nausea.

Minimization of Risk Information

Promotional materials are misleading if they fail to reveal facts that are material in light of representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials, and if they fail to present information about risks of a drug with a prominence reasonably comparable wit the presentation of information relating to the effectiveness of the drug.

Specifically, the audio news release presents the efficacy claims for Menveo in a slow and deliberate manner that is understandable in terms of the pacing and articulation. However, the risk information is presented in a fast and

inarticulate manner. The risk information is presented at a pace that does not allow the audience to hear and process it which hinders the audience's comprehension of the risks presented.

In addition, we have concerns about whether the risk information is being presented with the audio news release. The heading on the hard copy of the audio news release states "free hard copy of the **60 second** audio news release available on CD or as an MP3." (Emphasis added.) The efficacy claims take approximately 1 minute and 13 seconds with the risk information following for an additional 46 seconds. If the audio news release with a total play time of 1:59 is being presented as a 60-second piece, it is very possible that the risk information is actually omitted in its entirety.

Conclusion and Requested Actions

For the reasons discussed above, your promotional material misbrands Menveo under sections 502(a) and (c) and 201(n of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §352(a) and (c) and §321(n), and FDA implementing regulations *Cf.* 21 CFR 202.1(e)(5)(iii) and (e)(7)(viii).

We request that Novartis immediately cease the dissemination of this violative promotional material for Menveo, as wel as promotional materials with the same or similar representations. Please submit a written response within ten (10) business days of the date of this letter, stating whether you intend to comply with this request, listing all violative promotional materials for Menveo and explaining your plan for discontinuing use of such materials. Please direct your response to Ms. Ele Ibarra-Pratt, RN, MPH, Branch Chief at the Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, Division of Case Management, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. In all future correspondence regarding this matter, please refer to the BLA/STN number. We remind you that only written communications are considered official responses.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Menveo comply with each applicable requirement of the Act and FDA implementing regulations.

If you choose to revise your promotional materials, APLB is willing to assist you in assuring that your revised materials comply with applicable provisions of the Act by reviewing your revisions before you use them in promotion.

Sincerely,

/signature/

Robert A. Sausville
Director, Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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