



Ann Bryson-Eldridge
Clinical Liaison
BDI Pharma

February 8, 2011

Dear Ms. Bryson-Eldridge:

I am sending this letter to follow up on your recent request for information regarding IXIARO (Japanese Encephalitis Vaccine, Inactivated, Adsorbed) Suspension for Intramuscular Injection (Japanese Encephalitis Vaccine) and IXIARO Material Safety Data Sheet. Please find the information requested on page 3 of this letter.

IXIARO is indicated for active immunization against Japanese encephalitis virus (JEV) for persons 17 years of age and older.

Individuals who had a severe allergic reaction after receiving a previous dose of IXIARO should not be given subsequent doses of the vaccine. IXIARO contains Protamine sulfate, a compound known to cause hypersensitivity reactions in some individuals.

In clinical trials, the most common adverse events occurring after vaccination were headache, muscle pain and injection site reactions such as pain and tenderness. Safety and effectiveness have not been established in pregnant women and nursing mothers. To report inadvertent use in pregnant women and nursing mothers contact Novartis Vaccines at 800-244-7668.

Vaccination with IXIARO will not protect against encephalitis caused by viruses other than JE virus. As with any vaccine, vaccination with IXIARO may not result in protection against Japanese encephalitis in all cases. Novartis Vaccines and Diagnostics, Inc. does not recommend the use of IXIARO vaccine that deviates from its FDA-approved labeling.

Before administering, please refer to the enclosed IXIARO Prescribing Information for complete details regarding indicated usage, dosing recommendations, precautions, and adverse events.

To assist you with other questions regarding IXIARO, Novartis Vaccines and Diagnostics, Inc. offers the following resources:

- The Novartis Vaccines website at www.novartisvaccines.com. The Prescribing Information can be viewed by selecting Products/IXIARO.

- Medical Communications, for product and medical information, at 1-800-244-7668, or via e-mail at vaccineinfo.us@novartis.com.

Further information regarding risk assessment for travelers can be found at the Centers for Disease Control and Prevention's Travelers Health website:

<http://wwwn.cdc.gov/travel/destinationList.aspx>

Please quote reference number NA11-000384 if you have further questions regarding your inquiry. This information has been provided for your reference and is not intended to constitute therapeutic advice or substitute for your professional judgment.

Sincerely,

Anne Hurley, Pharm.D.

Enclosures:

IXIARO (Japanese Encephalitis Vaccine, Inactivated, Adsorbed) Suspension for Intramuscular Injection: Full Prescribing Information, September 2010. (Short Version)

IXIARO Material Safety Data Sheet

Drugs are exempt from this requirement, according to the Occupational Safety and Health Administration (OSHA) as cited in 29 CFR 1910.1200(b)(5)(iii) as follows:

(5) This section does not require labeling of the following chemicals:

- (iii) Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture.

The package inserts for prescription drug products meet the labeling requirements under the Act by the Food and Drug Administration, thereby fulfilling the MSDS requirements by OSHA.

Reference:

1. 29 CFR 1910.1200(b)(5)(iii)
2. IXIARO® (Japanese Encephalitis Vaccine, Inactivated, Adsorbed) Suspension for Intramuscular Injection. Prescribing Information, Revised Sept. 2010.