



**SUPPLEMENT APPROVAL**

Our STN: BL **103850/5634**

GlaxoSmithKline Biologicals  
Attention: Patrick J. Thomas  
2301 Renaissance Boulevard  
P.O. Box 61540  
King of Prussia, PA 19406-2772

August 7, 2015

Dear Mr. Thomas:

We have approved your request to supplement your biologics license application for Hepatitis A and Hepatitis B [recombinant] vaccine (Twinrix<sup>®</sup>) manufactured at your (b) (4), Belgium facility, to remove all references to the Pregnancy Registry from the package insert.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h [OPTION: and FDA Form 2567 as appropriate].

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled, "SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Document Control Center  
10903 New Hampshire Ave.  
WO71-G112  
Silver Spring, MD 20993-0002

You must submit copies of your final advertisement and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

We will include the information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Wellington Sun, M.D.  
Director  
Division of Vaccine and  
Related Product Application  
Office of Vaccines and  
Research and Review  
Center for Biologics  
Evaluation and Research

Attachment: Approved Final Draft Labeling