Approval Date: November 18, 2016

Product: Fluarix

Proper Name: Influenza Virus Vaccine

Manufacturer: GlaxoSmithKline Biologicals

Indication: For active immunization of persons 3 years of age and older for the prevention of disease caused by influenza virus subtypes A and type B contained in the vaccine.

Description: FLUARIX, Influenza Vaccine, for intramuscular injection, is a sterile colorless and slightly opalescent suspension.

BLA: BL 125127

Regulatory Milestone:

Fluarix was approved on August 31, 2005, under accelerated approval regulations for active immunization of adults aged 18 years and older against influenza disease. After submission of data from confirmatory clinical studies to verify and describe clinical benefit, Fluarix was granted 'traditional approval' on October 2, 2009. Expansion of the age indication for children aged 3 years and older was approved on October 19, 2009. Fluarix Quadrivalent was approved on December 14, 2012, based on demonstration of non-inferior immunogenicity to the previously licensed trivalent formulation. GSK proposed plans for harmonizing the monovalent bulk manufacturing process in a Type C meeting briefing package submitted on August 28, 2013. In pre-BLA negotiations between the Applicant and CBER, during a Type C meeting held on March 11, 2014, it was agreed that children aged 6 through 35 months would not be evaluated in this

supplement since this age group was not enrolled in the US and because Fluarix Quadrivalent is not approved in the US for use in this age group.

PDUFA Goal Date: November 20, 2016

Package Insert: Package Insert - Fluarix

Summary Basis for Regulatory Approval: November 18, 2016 Summary Basis for Regulatory Action - Fluarix

European Public Assessment Report: None

Advisory Committee:

A Vaccines and Related Biologics Products Advisory Committee (VRBPAC) meeting was not held for this supplement, as there were no issues or concerns that presented during the course of review of the supplement that required consult from the advisory committee.

NCT Numbers:

- NCT00753272
- NCT00764790
- NCT00772889
- NCT01416571
- NCT00693706
- NCT01788228
- NCT02242643
- NCT01974895
- NCT01196988
- NCT00765076
- NCT01910519
- NCT01954251
- NCT01949090
- NCT02207413
- NCT00529516
- NCT01204671
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- NCT00345579
- NCT01196975
- NCT00980005
- NCT01198756
- NCT00510874
- NCT00383123
- NCT01978093
- NCT00385255
- NCT01310413
- NCT00289783
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- NCT00377611
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- NCT00771615
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- NCT03281876
- NCT02096263
- NCT00616928
- NCT00197236

EudraCT Numbers:

- 2005-002044-26
- 2006-000939-97
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- Campbell, J. D., Chambers, C. V., Brady, R. C., Caldwell, M. C., Bennett, N. L., Fourneau, M. A., Jain, V. K., & Innis, B. L. (2011). Immunologic non-inferiority of a newly licensed

inactivated trivalent influenza vaccine versus an established vaccine: a randomized study in US adults. *Human vaccines*, *7*(1), 81–88. https://doi.org/10.4161/hv.7.1.13553

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