GLAXOSMITHKLINE PLC
Form 6-K
February 19, 2010

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For period ending February 2009

GlaxoSmithKline plc
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS
(Address of principal executive offices)

Indicate by check mark whether the registrant files or
will file annual reports under cover Form 20-F or Form 40-F

Form 20-F x Form 40-F

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Indicate by check mark whether the registrant by furnishing the
information contained in this Form is also thereby furnishing the
information to the Commission pursuant to Rule 12g3-2(b) under the

Securities Exchange Act of 1934.

Yes No x
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Issued: Thursday, 18 February 2010, Research Triangle Park, NC

GSK statement on FDA's proposed label revisions for some asthma medicines

GlaxoSmithKline is reviewing label changes proposed today by the US Food and Drug Administration (FDA) for asthma medications containing long-acting beta-agonists (LABAs), such as GSK's Advair (salmeterol / fluticasone propionate). GSK and makers of the other affected medicines containing LABAs have 30 days to agree with the proposed changes or state why they are not warranted.

"We will work with FDA to ensure that the final label for these products protects the interest of patients who suffer with this chronic and serious disease," said Dr. Katharine Knobil, vice president for respiratory clinical research at GSK. "It is important that doctors have flexibility to make the proper clinical decisions to help patients gain and maintain optimal control of their asthma."

The FDA's action relates to asthma and does not pertain to the chronic obstructive pulmonary disease (COPD) indication for Advair.

The available data were reviewed by three FDA advisory committees that met jointly in December 2008 and voted unanimously that Advair has a positive benefit-risk profile as currently labelled for adult patients. No new data have entered into FDA's decision-making.

There is no evidence from more than 10 years of data from clinical trials, observational studies and worldwide clinical experience exceeding 30 million patient-years of use that Advair is associated with an increased risk of asthma-related death, hospitalization or other serious respiratory-related outcomes in any age group. There have been no asthma-related deaths in clinical trials involving nearly 18,000 patients taking Advair.

Combination asthma medicines, such as Advair, that contain a LABA and an inhaled corticosteroid (ICS) play an important role in the treatment of asthma because they treat both main causes of asthma symptoms – inflammation and bronchoconstriction.

National Institutes of Health and international asthma treatment guidelines currently recommend use of combination medicines (ICS plus LABA) for patients whose asthma is not controlled on low-dose ICS and in patients whose disease is severe enough to warrant beginning treatment with a combination medicine.

Data show that Advair has a favorable safety profile and is effective in treating asthma by improving lung function, reducing and helping to prevent symptoms, and reducing the need for rescue medicine compared to ICS. There was no

evidence in clinical trials for Advair of increased risk for asthma-related death, asthma-related hospitalization, asthma-related intubation or all cause death compared to other treatments options.

Observational studies showed a significant decrease in asthma-related hospitalization in adults receiving Advair versus ICS alone, and a significant decrease in asthma-related hospitalizations and emergency department visits in children receiving Advair versus ICS alone and versus ICS plus montelukast.

As with all medications, the decision to stop or change any therapy should be discussed with a physician.

S M Bicknell

Company Secretary

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

Enquiries:

UK Media enquiries:	Philip Thomson	(020) 8047 5502
	Claire Brough	(020) 8047 5502
	Stephen Rea	(020) 8047 5502
	Alexandra Harrison	(020) 8047 5502
	Jo Revill	(020) 8047 5502
US Media enquiries:	Nancy Pekarek	(919) 483 2839
	Mary Anne Rhyne	(919) 483 2839
	Kevin Colgan	(919) 483 2839
	Sarah Alspach	(919) 483 2839
European Analyst/Investor enquiries:	David Mawdsley	(020) 8047 5564
	Sally Ferguson	(020) 8047 5543
	Gary Davies	(020) 8047 5503
US Analyst/ Investor enquiries:	Tom Curry	(215) 751 5419
	Jen Hill Baxter	(215) 751 7002

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that

may affect GSK' s operations are described under 'Risk Factors' in the 'Business Review' in the company' s Annual

Report on Form 20-F for 2008.

Registered in England & Wales:

No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex

TW8 9GS

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorised.

GlaxoSmithKline plc
(Registrant)

Date: February 18 2009

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc