

DR. STEPHEN K. OPUNI

FDB/DER/SM. 25/VOL1/10

March 1, 2010

THE HEAD OF REGULATORY AFFAIRS  
NOVARTIS PHARMA SERVICES SCIENTIFIC OFFICE (NIG)  
P.O.Box 4310  
IKEJA  
LAGOS

Dear Sir/ Madam,

**NEW REQUIREMENTS FOR SAFE USE OF LONG-ACTING BETA-AGONISTS**

The Food and Drugs Board (FDB) has become aware of a new safety information regarding the efficacy of long-acting beta-agonists (LABAs) when used alone. The new findings revealed that LABAs should not be used alone to treat asthma in children or adults unless it is used in combination with another asthma controller medication.

The FDB has registered **Foradil Certihaler** containing Formoterol for use in Ghana in June 2007 and in line with the FDB requirements for safety monitoring, you are required to communicate promptly any change in the safety information on the product to the FDB.

You are therefore requested to comment on the ongoing safety information to the FDB as soon as possible to enable it take the appropriate regulatory action.

Counting on your co-operation in this regard.

Yours faithfully,

DR. STEPHEN K. OPUNI  
CHIEF EXECUTIVE

Cc: THE SUPERINTENDENT PHARMACIST, NOVARTIS PHARMA SERVICES  
(GHANA OFFICE), P. O. BOX 6460, ACCRA