DR. STEPHEN K. OPUNI

FDB/DER/SM. 25/VOL1/10 March 1, 2010

THE HEAD OF REGULATORY AFFAIRS
NOVARTIS PHARMA AG.
LICHTSTRASSE 35,
CH-4056
BASEL

Dear Sir/ Madam,

BOXED WARNING - EXJADE (DEFERASIROX)

The Food and Drugs Board (FDB) has become aware of the recent changes in the prescribing information for Exjade, indicated for the treatment of chronic iron overload due to blood transfusions in patients two (2) years of age and older. New language was added to the contraindications, warnings and precautions, and drug interactions sections of the prescribing information, including a boxed warning that the product may cause the following:

1. Renal impairment, including failure
2. Hepatic impairment, including failure
3. Gastrointestinal haemorrhage

The FDB registered Exjade for use in Ghana since July 2006 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.