

Bioresearch Monitoring Inspection Results - Rotarix

MEMORANDUM

DATE: March 3, 2008

FROM: Anthony Hawkins, Bioresearch Monitoring, HFM-664

Division of Inspections and Surveillance

Office of Compliance and Biologics Quality

THROUGH: Patricia Holobaugh, Bioresearch Monitoring Branch Chief, HFM-664

TO: Laraine Henchal, Chair, BLA Committee, HFM-478

SUBJECT: Bioresearch Monitoring Inspection Results

STN: 125265/0

Product: Human Rotavirus (strain 89-12; RIX4414; Vero Cells) Vaccine, Live, Attenuated, Oral

Sponsor: GlaxoSmithKline Biologicals, SA

SUMMARY STATEMENT

The bioresearch monitoring inspections of six clinical sites did not reveal problems that impact the data submitted in the application.

BACKGROUND

Six clinical investigator inspections were performed in support of this Biologics License Application (BLA). Study subject population, geographic distribution, and field resource considerations were among the factors used to select the inspected sites. Information from the BLA was compared to source documents, during the inspections.

CLINICAL INVESTIGATORS

	Site #	#Subjects	483	Inspection Classification
Dr. Alexandre Linhares Instituto Evandro Chagas Belém - Pará, Brazil	050	3,218	No	NAI
Dra. Maribel Rivera Hospital Escuela Tegucigalpa, Honduras	250	4,195	Yes	VAI
Dra. Mercedes Macias-Parra Instituto Nacional de Pediatría Mexico City, Mexico	450	3,247	Yes	VAI

STUDY TITLE

A phase III, double-blind, randomized, placebo-controlled, multi-country and multi-center study to assess the efficacy, safety and immunogenicity of two doses of GSK Biologicals' oral live attenuated human rotavirus (HRV) vaccine in healthy infants. (Study Rota-023)

CLINICAL INVESTIGATORS, continued

Site #	#Subjects	483	Inspection Classification
--------	-----------	-----	---------------------------

CLINICAL INVESTIGATORS, continued

	Site #	#Subjects	483	Inspection	Classification
Dr. Tiina Korhonen Tampere rokotuskliniikka Tampere, Finland	7915	296	No		NAI
Dr. Niklas Lindblad Turku Rokotetutkimukset Turku, Finland	7975	293	No		NAI
Dr. Anna-Maija Hanni Oulun Rokotetutkimuskliniikka Oulu, Finland	7991	260	No		NAI

STUDY TITLE

A phase IIIb, double-blind, randomized, placebo-controlled, multi- country and multi-center study to assess the efficacy, safety and immunogenicity of two doses of GSK Biologicals' oral live attenuated human rotavirus (HRV) vaccine in healthy infants in co-administration with specific childhood vaccines. (Study Rota-036)

SPONSOR ISSUES

No sponsor or monitoring issues were noted.

NOTEWORTHY INSPECTIONAL FINDINGS

Part of one subject's electronic case report form (CRF) was deleted to include a serious adverse event (SAE), intussuseption, which occurred after the study subject was enrolled but before treatment with the study vaccine. The sponsor acknowledged that, at the time of the study, there was no clear instruction for completion of a CRF in case a subject was enrolled and randomized but did not receive the study vaccine (Dra. Rivera).

BIMO ADMINISTRATIVE FOLLOW-UP

We issued closeout letters to Drs. Linhares, Rivera, Macias-Parra, Korhonen, Lindblad and Hanni. If you have any questions or comments about this memo or any aspect of Bioresearch Monitoring, please contact me at (301) 827-6338.

Anthony Hawkins
Consumer Safety Officer