

Record of Telephone Conversation, November 30, 2012 - Q-Pan

Submission Type: BLA

Submission ID: 125419/0

Office: OVR

Product:

Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

Applicant:

ID Biomedical Corporation of Quebec

Telecon Date/Time: 30-Nov-2012 07:40 PM Initiated by FDA? Yes

Telephone Number: 610-787-3435

Communication Category(ies):

1. Information Request

Author: CARMEN COLLAZO-CUSTODIO

Telecon Summary:

Information request regarding the description of a reproductive and developmental toxicity study described in the PI.

FDA Participants: Jeremy Wally, Kirk Prutzman, Carmen Collazo-Custodio

Non-FDA Participants: Michael Schwartz, Robert Brobst, Jillian Horvath

Telecon Body:

The following was communicated to GSK via e-mail correspondence.

From:Collazo, Carmen

Sent: Friday, November 30, 2012 7:40 PM

To: Michael Schwartz; Robert Brobst; Jillian Horvath

Cc: Wally, Jeremy; Prutzman, Kirk C; Collazo, Carmen

Subject: STN 125419 Information Request

Importance: High

Dear Dr. Schwartz,

We have the following information request regarding the description of a reproductive and developmental toxicity study described in Section 8.1 *Pregnancy* of the Package Insert. You state the following:

“A reproductive and developmental toxicity study has been performed in female rats at a dose approximately 80 times the human dose (on a mcg/kg basis) and has shown no evidence of impaired fertility or harm to the fetus due to Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted. The effect of Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted on embryo-fetal and pre-weaning development was evaluated in rats. Animals were administered Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted by intramuscular injection once prior to gestation, during the period of organogenesis (gestation days 7, 9, and 12), later in pregnancy (gestation day 16) and during lactation (day 7), 0.2mL/dose/rat (approximately 80-fold excess relative to the

projected human dose on a body weight basis). No adverse effects on mating, female fertility, pregnancy, parturition, lactation parameters, and embryo-fetal or pre-weaning development were observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis.”

Please clarify the following:

1. From the studies described in the BLA, please indicate the study number and title that you are referring to in the statement above (“A reproductive and developmental toxicity study has been performed…”).
2. Please indicate the calculations that were conducted to conclude that the dose administered to the rats was approximately 80 times the human dose (on a mcg/kg basis), to include:
 1. The body weight assumption made for a human.
 2. The body weight assumption made for a rat.
 3. The volume and dose for both H5N1 (mcg HA) an AS03 adjuvant used in the study.
 4. Please discuss how the volume and dose used in the study relate to the human dose.
3. Please state if there were any limitations in the study design and/or conduct in terms of the dose administered to the rats due to animal welfare concerns.

Regards,

Carmen M. Collazo-Custodio, Ph.D.

Office of Vaccines Research and Review

Center for Biologics Evaluation and Research

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