

RECORD OF TELEPHONE CONVERSATION

Submission ID:
125525/0

Office:
OVRR

Product Information: Diphtheria and Tetanus Toxoids and Acellular Pertussis
Adsorbed and Inactivated Poliovirus Vaccine
Applicant: Sanofi-Pasteur Ltd

Telecon Date/Time: 23-MAR-2015 11:56 AM **Initiated by FDA?:** Yes
Telephone Number: (416)667-2068

Author: MATTHEW STEELE

Purpose: Information Request (IR)

FDA Participants:
MATTHEW STEELE

Sponsor Participants:
Dana Harrison

Summary:
Request for expiration dates of the DAPTACEL and IPOL lots used in the control arm of study M5I02. Applicant responded with an e-mail.

Body of telecon:

I called the contact and requested the expiration dates for the DAPTACEL and IPOL lots used in the control arm of study M5I02. Applicant responded with an e-mail:

From: Dana.Harrison@sanofipasteur.com [mailto:Dana.Harrison@sanofipasteur.com]
Sent: Monday, March 23, 2015 11:53 AM
To: Steele, Matthew
Cc: Lacayo, Juan; Dana.Harrison@sanofipasteur.com
Subject: Quadracel 5th Dose US Clinical Study M5I02 - Control Vaccine Expiry Dates

Dear Matt,

As requested, the expiry dates for the control vaccines used in Quadracel 5th Dose US Clinical Study M5I02 are:

DAPTACEL® lot C3718AA – 25 March 2013
IPOL® lot G1068-1 – 25 February 2013

Please let me know if you have any further questions.

Kind Regards,
Dana

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