

# Record of Telephone Conversation - January 4, 2010 - Prevnar 13

(System Info - 115485 SHONE DEANNA 01/04/2010 08:04:28 SHONEDE)

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125324/0 Office: OVRR

Product:

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Applicant:

Wyeth Pharmaceuticals Inc.

Telecon Date/Time: 04-Jan-2010 12:00 AM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: COLLEEN SWEENEY

Telecon Summary:

Clinical Information Request

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Memorandum

FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

**Date:** January 4, 2010

**To:** Carmel Devlin, Associate Director  
Global Regulatory Affairs,  
Wyeth Pharmaceuticals Inc.

**From:** CDR C. Sweeney, RN, MS, Regulatory  
Coordinator

**CC:** Tina Khoie, M.D., M.P.H., Clinical  
Reviewer  
Lucia Lee, M.D., Team Leader, VCTB,  
DVRPA  
Julienne Vaillancourt, R.Ph., M.P.H., Chair

**Subject:** STN: 125324/0: Clinical Information  
Request

We note that you have submitted available safety data regarding adverse events and serious adverse events occurring in all infant studies to BLA 125324 (module 5.3.5.3). In addition, we note that post-infant series data (i.e. between infant series and toddler dose, toddler dose, and 6-month follow-up) from study 3005 were not included in the integrated

summary of safety. CBER requests that you please provide the information that is needed to complete the tables below. We note that in your email communication dated November 17th that you are able to perform these calculations without counting subjects multiple times. Please include post-infant series, toddler dose, and 6-month follow-up data from study 3005 in your calculations.

Table 1. Incidence of Adverse Events by Combined MedDRA Preferred Terms and Other Events of Interest, Integrated Analysis\*

System Organ Class Preferred Term	Infant Series		Between Infant Series and Toddler Dose		Toddler Dose		6-month Follow-Up	
	13vPnC N= n (%)	PCV7 N= n (%)	13vPnC N= n (%)	PCV7 N= n (%)	13vPnC N= n (%)	PCV7 N= n (%)	13vPnC N= n (%)	PCV7 N= n (%)
Combined AE Terms								
Wheezing								
Pneumonia								
Gastroenteritis								
Convulsions								
Meningitis								
Allergic Reactions								
Croup								
Breath holding								
Crying								
Abscess								
Anaemia								
Otitis media								

\* The integrated safety analysis consists of data available for the 13vPnC clinical program as of 12-Oct-08. It includes pooled infant series safety data from thirteen 6096A1 protocols [003, 004, 006, 007, 008, 009, 011, 500, 501, 3000, 3005, 3007, and 3008], pooled post-infant series data from ten 6096A1 studies [003, 004, 006, 007, 008, and 3005], and pooled six-month follow-up data from 6 studies: 003, 004, 006, 009, 500, 501, and 3005.

Pneumonia combined terms: pneumonia, bronchopneumonia, pneumonia primary atypical, pneumonia viral, pneumonia respiratory syncytial viral, lobar pneumonia, pneumonia bacterial, and pneumonia aspiration.

Anaemia combined terms: anaemia, iron deficiency anaemia, microcytic anaemia, haemolytic anaemia

Otitis media combined terms: otitis media, otitis media acute, otitis media chronic, and otitis media viral.

Abscess combined terms: abscess, abscess neck, abscess oral, perianal abscess, perirectal abscess, rectal abscess.

Wheezing combined terms: asthma, bronchiolitis, bronchitis, wheezing, bronchial hyperreactivity, bronchospasm, status asthmaticus, allergic respiratory disease, and stridor

Convulsion combined terms: infantile spasms, convulsion, epilepsy, febrile convulsion, partial seizures, postictal paralysis,

Gastroenteritis combined terms: gastroenteritis, vomiting, diarrhea (nausea, abdominal pain, esophagitis, gastritis, infantile spitting up, regurgitation,

Croup combined terms: croup infectious, laryngotracheobronchitis (LLT or verbatim)

Allergic reactions combined terms: hives/urticaria, anaphylactic reaction, swelling face, bronchospasm, laryngospasm, and stridor

Breath holding combined terms: breath holding, apnoea, apnoeic episode, sleep apnoea syndrome, apnoeic attack

Meningitis combined terms: meningitis, meningitis aseptic, meningitis bacterial, meningitis enteroviral, meningitis meningococcal, meningitis pneumococcal, meningitis viral, meningococcal sepsis.

Source: 125324, m5.3.5.3.28, Integrated Summary of Safety, pages 48-75 (Table 8-7), pages 158-161 (Table 8-15)

Table 2. Incidence of Serious Adverse Events by Combined MedDRA Preferred Terms and Other Events of Interest, Integrated Analysis\*

System Organ Class Preferred Term	Infant Series		Between Infant Series and Toddler Dose		Toddler Dose		6-month Follow-Up	
	13vPnC N= n (%)	PCV7 N= n (%)	13vPnC N= n (%)	PCV7 N= n (%)	13vPnC N= n (%)	PCV7 N= n (%)	13vPnC N= n (%)	PCV7 N= n (%)
Combined SAE Terms								
Wheezing								
Pneumonia								
Gastroenteritis								
Convulsions								
Meningitis								
Allergic Reactions								
Croup								
Breath holding								
Abscess								
Anaemia								
Otitis media								

\* The integrated safety analysis consists of data available for the 13vPnC clinical program as of 12-Oct-08. It includes pooled infant series safety data from thirteen 6096A1 protocols [003, 004, 006, 007, 008, 009, 011, 500, 501, 3000, 3005, 3007, and 3008], pooled post-infant series data from ten 6096A1 studies [003, 004, 006, 007, 008, and 3005], and pooled six-month follow-up data from 6 studies: 003, 004, 006, 009, 500, 501, and 3005.

Wheezing combined terms: asthma, bronchiolitis, bronchitis, wheezing, bronchial hyperreactivity, bronchospasm, status asthmaticus, allergic respiratory disease, and stridor. Pneumonia combined terms: pneumonia, bronchopneumonia, pneumonia primary atypical, pneumonia viral, pneumonia respiratory syncytial viral, lobar pneumonia, pneumonia bacterial, and pneumonia aspiration.

Gastroenteritis combined terms: gastroenteritis, vomiting, diarrhea (nausea, abdominal pain, esophagitis, gastritis, infantile spitting up, regurgitation.

Convulsion combined terms: infantile spasms, convulsion, epilepsy, febrile convulsion, partial seizures, postictal paralysis.

Meningitis combined terms: meningitis, meningitis aseptic, meningitis bacterial, meningitis enteroviral, meningitis meningococcal, meningitis pneumococcal, meningitis viral, meningococcal sepsis.

Allergic reactions combined terms: hives/urticaria, anaphylactic reaction, swelling face, bronchospasm, laryngospasm, and stridor.

Croup combined terms: croup infectious, laryngotracheobronchitis (LLT or verbatim).

Breath holding combined terms: breath holding, apnoea, apnoeic episode, sleep apnoea syndrome, apnoeic attack.

Abscess combined terms: abscess, abscess neck, abscess oral, perianal abscess, perirectal abscess, rectal abscess.

Anaemia combined terms: anaemia, iron deficiency anaemia, microcytic anaemia, haemolytic anaemia.

Otitis media combined terms: otitis media, otitis media acute, otitis media chronic, and otitis media viral.

Source: 125324, m5.3.5.3.28, Integrated Summary of Safety, pages 162-171 Table 8-16