

# Record of Internal Labeling Meeting 1 - May 27, 2009 - Prevnar 13

**Date:** May 27, 2009  
**Time:** 3:30-5:30 PM EST  
**Location:** WOC-2 Conference Room 2 (with Dial-in)  
**File:** BLA STN: 125324  
**Product:** Prevnar 13 [Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)]  
**Sponsor:** Wyeth Pharmaceuticals Incorporated  
**Purpose:** Internal Labeling Meeting #1  
**Participants:** Julienne Vaillancourt  
Lucia Lee  
Doug Pratt  
Tina Khoie  
Catherine Miller  
Jingyee Kou  
Claudia Wrzesinski  
Mike Smith  
Colleen Sweeney

First internal labeling meeting concerning the original draft labeling included in the BLA. Of note, the clean-running, line-numbered, Word version of the original draft labeling, which was submitted to the BLA on April 23, 2009 (amendment seven), was used during this meeting.

Discussion focused on the following:

## **Review of the Highlights of Prescribing Information and Full Prescribing Information**

### ***INDICATIONS AND USAGE***

- Clarification of Guidance for Indexing Content of Labeling of SPL

### ***DOSAGE AND ADMINISTRATION***

- Revision of sequence of language
- Revision of the table entitled, "Vaccination Schedule for Unvaccinated Children ≥7 Months of Age."
- Clarification of the stated indication

### ***DOSAGE FORMS AND STRENGTHS***

- Suggested language revisions

### ***CONTRAINDICATIONS***

- Suggested language revision

### ***ADVERSE EVENTS***

- Correction of reporting contact

**Adjourn:** 1530

**Action**

1. Review team members will meet again ASAP to continue this first internal review of the original draft labeling. An announcement for such an internal meeting will follow the present meeting.
2. An initial set of comments on the original draft labeling will be prepared, based on discussion during these first labeling review meetings. Comments will be internally distributed for concurrence prior to being sent to the sponsor.

Notes:

1. This is the first internal labeling review meeting and others will follow.
2. The pending set of initial labeling comments, will reflect the detailed discussion, which occurred during this meeting.