

Record of Telephone Conversation - November 20, 2009 - Prevnar 13

System Info - 112912 SMITH, MICHAEL J 07-Dec-2009 11:29:36 SMITHM

RECORD OF TELEPHONE CONVERSATION

Submission Type: Original Application Submission ID: 125324/0 Office: OVRR

Product:

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Applicant:

Wyeth Pharmaceuticals Inc.

Telecon Date/Time: 20-NOV-2009 12:00 AM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):

Other

Author: MICHAEL SMITH

Telecon Summary:

RE: Email UNII codes sent to sponsor

FDA Participants: Michael Smith and Julienne Vaillancourt

Non-FDA Participants: Jack Love and Carmel Devlin

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Smith, Michael (CBER)
Sent: Friday, November 20, 2009 4:57 PM
To: 'Love Jack'; Devlin Carmel

Cc: Vaillancourt, Julienne
Subject: RE: UNII codes

Jack and Carmel,

I am sending you the UNII codes that CBER has generated for Prevnar 13 (see below).

Also, this link (<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>) is to a FDA website that contains the guidance document and implementation guide for Structured Product Labeling Resources (SPL). The UNII codes are needed to list the product after approval. If you have any questions on UNII codes you can email CBER's UNII code team at (SPL@fda.hhs.gov).

Also, Lydia Falk at Wyeth/Pfizer used to work on SPL and UNII codes before she left CBER and she would be a good point of contact on this topic too.

Prevnar 13 UNII codes are listed below:

13 active ingredients each of which are also active moieties

STREPTOCOCCUS PNEUMONIAE TYPE 1 CAPSULAR POLYSACCHARIDE
54EC0SE5PZ
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 14 CAPSULAR POLYSACCHARIDE
SK54I0S386
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 18C CAPSULAR POLYSACCHARIDE
XK87D9J012
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 19A CAPSULAR POLYSACCHARIDE
B970MQT365
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 19F CAPSULAR POLYSACCHARIDE
2E1M7F958B
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 23F CAPSULAR POLYSACCHARIDE
25N8E57V6T
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 3 CAPSULAR POLYSACCHARIDE
2VF3V7175U
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 4 CAPSULAR POLYSACCHARIDE
TGJ6YZC4W7
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 5 CAPSULAR POLYSACCHARIDE
5SKG37872O
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 6A CAPSULAR POLYSACCHARIDE
Z9HK08690W
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 6B CAPSULAR POLYSACCHARIDE
4M543JVT7G
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 7F CAPSULAR POLYSACCHARIDE
0K0S2P98ZJ
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

STREPTOCOCCUS PNEUMONIAE TYPE 9V CAPSULAR POLYSACCHARIDE
5Q768OY0GI
DIPHtheria CRM197 PROTEIN CONJUGATE ANTIGEN

Let me know if you have any questions or contact the CBER UNII code team through the email address above.

Mike

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