

Record of Telephone Conversation, September 7, 2012 - Flucelvax

Submission Type: BLA
Submission ID: 125408/0
Office: OVRR
Product: Influenza Vaccine (MDCK Cells)
Applicant: Novartis Vaccines and Diagnostics, Inc.
Telecon Date/Time: 07-Sep-2012 03:06 PM
Initiated by FDA? Yes
Telephone Number: Communicated via e-mail
Communication Category(ies): 1. Advice
Author: TIMOTHY FRITZ
Telecon Summary: UNII codes for 2012-2013 season.
FDA Participants: Timothy Fritz
Non-FDA Participants: Matthew Gollwitzer
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:

From: Fritz, Timothy
Sent: Friday, September 07, 2012 3:06 PM
To: 'Gollwitzer, Matthew'
Subject: Flucelvax UNII codes for 2012-2013
Importance: High
Attachments: Flucelvax 2012-2013 UNII codes.doc

Dear Mr. Gollwitzer-

CBER's review of Novartis' Biologics License Application STN 125408 is ongoing. Below please find a table with UNII code assignments for the 2012-2013 influenza strains and inactive ingredients.

| Active Ingredients | Name | UNII Code |
|---------------------------------|--|------------|
| Active Ingredient | INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) | DES33X6VK7 |
| Active Moiety/Basis of Strength | INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) | KFL1W6W9JB |
| Active Ingredient | INFLUENZA A VIRUS A/VICTORIA/361/2011 IVR-165 (H3N2) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE | EU4437779D |

| Active Ingredients | Name | UNII Code |
|---------------------------------|---|-----------------|
| Active Moiety/Basis of Strength | INACTIVATED) INFLUENZA A VIRUS A/VICTORIA/361/2011 IVR-165 (H3N2) HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) | K3ZB8T668I |
| Active Ingredient | INFLUENZA B VIRUS B/WISCONSIN/1/2010) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) | GWR474LL6U |
| Active Moiety/Basis of Strength | INFLUENZA B VIRUS B/WISCONSIN/1/2010) HEMAGGLUTININ ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED) | U2F63L17ZC |
| Inactive Ingredients | ------(b)(4)----- | -----(b)(4)---- |
| Inactive Ingredients | ------(b)(4)--- | -----(b)(4)---- |
| Inactive Ingredients | ------(b)(4)----- | -----(b)(4)---- |
| Inactive Ingredients | ------(b)(4)----- | -----(b)(4)---- |
| Inactive Ingredients | ------(b)(4)----- | -----(b)(4)---- |
| Inactive Ingredients | --(b)(4)--- | -----(b)(4)---- |

If you have any questions, please contact the Regulatory Project Manager, Drs Brenda Baldwin or Timothy Fritz, at 301-796-2640 or via e-mail.

Thank you.

Timothy A. Fritz, Ph.D.

Microbiologist

FDA/CBER/OVRR/DVRPA/CMC2

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