

Record of Telephone Conversation, July 11, 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: 11-Jul-2012 10:02 AM Initiated by FDA? Yes
Telephone Number:
Communication Category(ies):
1. Information Request

Author: BRENDA BALDWIN
Telecon Summary:
NVD management response regarding Flucelvax manufacturing timeline
FDA Participants: Wellington Sun
Non-FDA Participants: Kaia Agarwal
Trans-BLA Group: No

Related STNs: None
Related PMCs: None
Telecon Body:
From: Agarwal, Kaia [mailto:kaia.agarwal@novartis.com]
Sent: Wednesday, July 11, 2012 10:02 AM
To: Sun, Wellington
Subject: Response to CBER questions - MDCK derived flu vaccine BLA
Sensitivity: Confidential

Dear Dr. Sun,

Thank you for the call last week and for agreeing to a response this week. I have captured your question and then the response in bold text as follows:

- 1) Please confirm your intentions to distribute the MDCK cell vaccine in the US

**Novartis confirms that we have been planning to manufacture and gain approval for the annual strain update for our MDCK derived flu vaccine for the -----(b)(4)-
----- season.**

For this submission which will be filed as an amendment to the BLA, we have been working to following internal timeline:

Action	Proposed Submission Timing
1 st batch MPH Strain H1N1 A Brisbane/10/10 produced	Jul 12
1 st A/Victoria/361/2011 like produced batch MPH Strain H3N2	Jul 12
1 st B/Wisconsin/1/2010 produced batch MPH Strain	Jul 12
SRID Method Validated, SRD results validated	15 Aug12
Annual Strain Update submission	August 12
First batch formulated and filled (Commercial)	----- (b)(4) -----
QA submission Receipt of questions/response/approval	Sept 12
Approval	October 12
First internal release (includes CBER)	October 12

2) When will Novartis be fully manufacturing this MDCK derived vaccine in the Holly Springs facility?

It is Novartis' intention to file an sBLA for the change of process to Holly Springs USA in the 1H of ---, -----(b)(4)-----, assuming regulatory approvals consistent with US influenza vaccination distribution timelines.

Please let me know if we have answered your questions and please feel free to as always to contact me for anything further.

Kind regards
Kaia