

# 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 <sup>st</sup> batch MPH Strain H1N1 A Brisbane/10/10 produced	Jul 12
1 <sup>st</sup> A/Victoria/361/2011 like produced batch MPH Strain H3N2	Jul 12
1 <sup>st</sup> 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