

**Dr. Eric Abadie**  
**European Medicines Agency (EMA)**  
**7 Westferry Circus**  
**Canary Wharf**  
**LONDON, E14 4HB**  
**UK**

13 June 2008

**Withdrawal of AFLUNOV® - EMA/H/C/804**

Dear Dr. Abadie,

We would like to inform you that, at this point in time, Novartis Vaccines has taken the decision to withdraw the application for Marketing Authorisation of AFLUNOV®, which was intended to be used for active pre-pandemic immunization against avian H5N1 subtype of Influenza A virus.

This withdrawal is based on the need for additional clinical data in order to achieve the size of the clinical database as required by the pre-pandemic guideline (EMA/CHMP/VWP/263499/2006). The timeframe provided by the centralized procedure does not permit the collection of this additional clinical data within this review procedure.

We would like to assure you that there are no consequences for individuals currently included in clinical trials arising from our decision.

Novartis Vaccines may re-submit the application for Marketing Authorisation of a pre-pandemic vaccine once the requested data are available.

We agree to the publication of this letter on the EMA website.

Yours sincerely,

Regulatory Affairs Manager

Novartis Vaccines and  
Diagnostics GmbH & Co. KG  
Rechtsform: Kommanditgesellschaft

Sitz der Gesellschaft: Marburg  
Handelsregister: Marburg HRA 2159  
Persönlich haftende Gesellschafterin:  
Novartis Vaccines and Diagnostics  
GmbH Verwaltungsgesellschaft

Geschäftsführer:  
Dr. med. Markus Leyck Dieken,  
Sitz Marburg  
Handelsregister:  
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