NOVARTIS
VACCINES

Att:

Dr. Eric Abadie
European Medicines
Agency (EMA)
7 Westeferry Circus
Canary Wharf
London, E14 4HB –UK

Siena, 10 February 2012

Re: Withdrawal of Fluad® Paediatric: Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59C.1
EMA Reference No.: EMEA/H/C/002299

Dear Dr. Abadie,

Novartis Vaccines and Diagnostics (NVD) would like to inform EMA of its decision to withdraw its application for the Pediatric Use Marketing Authorisation (PUMA) of Fluad® Paediatric which was intended to be used for the active immunization against influenza in infants and young children.

The withdrawal is based on the fact that NVD is unable to address the questions raised in the CHMP Day 180 List of outstanding Issues (LoI), within the required timelines. NVD acknowledges the concerns raised and is committed to working with the Agency on these matters. NVD is dedicated to developing the next generation of safe and effective adjuvanted influenza vaccines to protect infants and young children. These populations are particularly vulnerable to influenza and have been shown to be poorly responsive to conventional non-adjuvanted vaccines. In this regard we wish to continue to work with the Agency to address the questions and concerns raised for any future submissions.

This decision will have no consequences for patients enrolled in any ongoing NVD sponsored clinical trials. We reserve the right to make further submissions at a future date on this or other indications.

I agree for this letter to be published on the EMA website.

Your sincerely,