

**Olin, Rebecca**

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**From:** Olin, Rebecca  
**Sent:** Friday, October 30, 2009 11:47 AM  
**To:** CBER Compliheck

**Attachments:** Novartis\_EIR\_Siena\_Rev\_2.pdf



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**ESTABLISHMENT EVALUATION REQUEST**

**Date:**  
October 30, 2008

**Request Type (Check One):**  
Original ☒ Follow-up

**Reviewer's Name, Division, Mail Code, Phone Number:**  
Rebecca Olin, DMPQ, HFM-676, 301-827-3031

**Application Number and Type (BLA, PMA, NDA, ANDA) or Supplement Number and Type (i.e., PAS, CBE, CBE30):**  
BLA STN 125297/0

**Brief Description of the Application or Detailed Summary of the Supplement, including product(s) and establishment(s) (indicate if the supplement represents an improvement or change intended to help the applicant or location achieve compliance):**  
For the active immunization of persons 18 years of age and older against influenza disease

**Applicant:**  
Novartis Vaccines and Diagnostics, Inc.

**Address:**

Novartis Vaccines and Diagnostics  
Via Fiorentina 1  
53100 Siena, Italy

es and Diagnostics S.r.l.

(b)(4)

(Siena)

**U.S. License Number (if any):** 1751

**FEI Numbers:** (b)(4)

**ADD:** November 28, 2009 (Dr. Baylor would like the approval package by October 30, 2009)