

MEMO TO FILE

PID #: D040771

FROM: Evelyn R. Farinas, R.Ph., MGA, Safety Evaluator
Office of Surveillance and Epidemiology (OSE)

DATE: October 13, 2006

RE: Sirolimus (Rapamune®): AERS 1-year post Pediatric Exclusivity
Consult Correction

NDA: 21-110, 21-083

Upon review of the February 2006 consult written by Evelyn R. Farinas, [REDACTED] ([REDACTED]) noticed a discrepancy regarding the interval defined as the “pediatric exclusivity period” in the document. Specifically, on page 5 within the Table 4 heading, the dates were listed as November 17, 2004 through February 28, 2005, whereas in the rest of the document the “pediatric exclusivity period” covered the interval between November 17, 2004 and December 18, 2005.

A review of the documents and AERS standard reports that served as the basis for the February 2006 consult confirmed that the information in Table 4 covered the period defined throughout the consult as the “pediatric exclusivity period”. It was determined that the discrepancy in the dates in the Table 4 heading resulted from a typographical error.

A copy of the original February 2006 document is attached.

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Evelyn Farinas
10/13/2006 02:35:12 PM
DRUG SAFETY OFFICE REVIEWER

please revise cc list

Melissa Truffa
10/13/2006 02:47:25 PM
DRUG SAFETY OFFICE REVIEWER