

**INSTRUCTIONS:** Use this form when a single information collection document involves multiple reporting and recordkeeping requirements. The totals of the figures in cols. should be entered in item 13 of OMB-83-1: cols. (D) &/or (I) = 13a (respondent is only counted once); cols. F & I = 13b; cols. H & K = 13c.

(F)Total/(D)Total = (E)Average  
 (H)Total/(F)Total = (G)Average (K)Total/(I)Total = (J)Average  
**NOTE:** The columns will calculate automatically. If Col. E's response is something other than annually, i.e., 1/6 years, list as "1/6" & decimal will display.

**TITLE OF INFORMATION COLLECTION DOCUMENT**  
 VIRUS-SERUM-TOXIN ACT AND REGULATIONS  
 VSTA Records and Reports Specific to International  
 Standards for Pharmacovigilance

**OMB NO.**  
 0579-0209

**DATE PREP**

IDENTIFICATION OF REPORTING OR RECORDKEEPING REQUIREMENT		FORMS NO (S) (If "none" so state)	ANNUAL BURDEN						
SECTION OF REGS.  (A)	DESCRIPTION  (B)		REPORTS					RECORDS	
			NO. OF RESPONDENTS (D)	NO OF RESPONSES PER RESPONDENT (E)	TOTAL ANNUAL RESPONSES (Col. D x E) (F)	HOURS PER RESPONSE (G)	TOTAL HOURS (Col. F x G) (H)	NO. OF RECORD-KEEPERS (I)	ANNUAL HOURS PER RECORD-KEEPER (J)
116.9	Adverse Event Report - Business	APHIS 2080	3,333	1.00	3,333.00	0.33	1,100.00		
116.9	Adverse Event Report - State	APHIS 2080	3,333	1.00	3,333.00	0.33	1,100.00		
116.9	Adverse Event Report - Individuals	APHIS 2080	3,333	1.00	3,333.00	0.33	1,100.00		
116.9	Adverse Event Report Followup - Business	APHIS 2081	2,000	1.00	2,000.00	0.33	660.00		
116.9	Adverse Event Report Followup - State	APHIS 2081	2,000	1.00	2,000.00	0.33	660.00		
116.9	Adverse Event Report Followup - Individuals	APHIS 2081	2,000	1.00	2,000.00	0.33	660.00		
	<b>SUBTOTAL</b>				15,999.00		5,280.00	0.00	
	<b>TOTAL OF ALL PAGES</b>				15,999		5,280	0.00	
<b>TOTAL - COLUMNS "F" AND "I" = OMB 831, 13 b; COLUMNS "H" AND "K" = OMB 831, 13c</b>					<b>15,999</b>		<b>5,280</b>		

AREC

TOTAL

RECORD-  
KEEPING HOURS  
(Col. I x J)

(K)

0.00

0.00

0.00

0.00

0.00

0.00

0.00

0.00

0.00
0.00