

INSTRUCTIONS:				TITLE OF INFORMATION COLLECTION DOCUMENT				OMB NO.		
				Viruses, Serums, Toxins, and Analogous Products; Records and Reports				0579-0209		
				DATE PREPARED						
				April 30, 2018						
IDENTIFICATION OF REPORTING OR RECORDKEEPING REQUIREMENT			ANNUAL BURDEN							
			REPORTS				RECORDS			
SECTION OF REGS	DESCRIPTION	FORM NO's (if none, so state)	NO. OF RESPONDENTS	NO. OF RESPONSES PER RESPONDENT	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)	RECORD KEEPING HOURS (Col. I x J) (K)
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)
9 CFR 116.9	Adverse Event Report (Business)	APHIS 2080	3,333	1	3,333	2.000	6,666	0	0	0
116.9	Adverse Event Report (State)	APHIS 2080	3,333	1	3,333	2.000	6,666	0	0	0
116.9	Adverse Event Report (Individual)	APHIS 2080	3,333	1	3,333	2.000	6,666	0	0	0
116.9	Adverse Event Report Followup (Business)	APHIS 2081	2,000	1	2,000	2.000	4,000	0	0	0
116.9	Adverse Event Report Followup (State)	APHIS 2081	2,000	1	2,000	2.000	4,000	0	0	0
116.9	Adverse Event Report Followup (Individual)	APHIS 2081	2,000	1	2,000	2.000	4,000	0	0	0
SUBTOTAL					15,999		31,998	0		0
TOTAL OF ALL PAGES				9,999	15,999		31,998	0		0
TOTAL COLUMNS F + I = OMB 831, 13b COLUMNS H + K = OMB 831, 13c					15,999		31,998			