Non-Substantive Change Request to OMB Control Number 0920-0666; The National Healthcare Safety Network (NHSN)

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Circumstances of Change Request for OMB 0920-0666
CDC requests approval for a non-substantive change to OMB Control No. 0920-0666; The National Healthcare Safety Network (NHSN)

Form Name: Hemovigilance Module Monthly Reporting Denominators; CDC Form 57.303
HHS needs a standardized transfusion adverse reactions tracking system to monitor pathogen reduced blood products administered as part of a clinical trial. Currently, NHSN is the only system that tracks transfusion adverse reactions by standard methods. CDC/DHQP will analyze adverse reaction results of the clinical trial. Results will be shared with FDA so they can make a decision on approving pathogen reduction technology. This will impact the safety and sustainability of the blood supply in Puerto Rico and when Zika or another emerging pathogen affects the mainland.

Estimates of annualized burden hours for this change request will increase by ten minutes per response. Because there are expected to be 6,000 responses per year (500 respondents; 12 responses each), the total increase in burden will be 1,000 hours per year.

	Form Name	No. of Respondents	No. of responses per respondent	Avg. burden per response (hours)	Total burden (hours)
APPROVED	Hemovigilance Module Monthly Reporting Denominators	500	12	1	6,000
REQUESTED	Hemovigilance Module Monthly Reporting Denominators	500	12	70/60	7,000

For OMB clearance No. 0920-0666, the total burden will increase from 4,621,542 hours to 4,622,542 hours.

Description of Changes
Changes to Table 2 include the addition of pathogen reduced blood product categories for red blood cells, platelets, plasma, and cryoprecipitate (In the crosswalk below, new fields are highlighted).

Table 3 is a new table. Data collected in table 3 includes a breakdown of pathogen reduced apheresis platelets in plasma and in platelet additive solution.

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Current Question

Table 2

Products		Unites Transfused	Aliquots Transfused	Total Discards
Platelets	Whole blood derived Psoralen-treated			
	Apheresis Psoralen-treated			
Plasma (all types)	Whole blood derived Psoralen-treated			
	Apheresis Psoralen-treated			

Requested Change

Table 2

Products			Unites Transfused	Aliquots Transfused	Total Discards
Red blood cells	Whole blood derived	TOTAL			
		S-303-treated			
		Riboflavin-treated			
	Apheresis	TOTAL			
		S-303-treated			
		Riboflavin-treated			
Platelets	Whole blood derived	TOTAL			
		Psoralen-treated			
		Riboflavin-treated			
	Apheresis	TOTAL			
		Psoralen-treated			
		Riboflavin-treated			
Plasma (all types)	Whole blood derived	TOTAL			
		Psoralen-treated			
		Riboflavin-treated			
	Apheresis	TOTAL			
		Psoralen-treated			
		Riboflavin-treated			
Cryoprecipitate		TOTAL			
		Riboflavin-treated			

N/A

Table 3

Products			Units Transfused	Aliquots Transfused	Total Discards
Platelets	Apheresis	Psoralen-treated			
		Psoralen-treated and in Plasma			
		Psoralen-treated and in Platelet additive solution			
		Riboflavin-treated			
		Riboflavin-treated and in Plasma			
		Riboflavin-treated and in Platelet additive solution			