APPENDIX A

Proposed Amendments to form CDC 54.1 (Malaria Case Surveillance Report)

As a part of the montoring of the new treatment drug for use in the U.S., Artemether/lumefantrine, these questions have been added or updated to comply with the FDA protocol.

***Changes are in **Bold** font

Current Form (Field Names)	Current Value Set	Proposed Form (Field Names)	Proposed Value Set	Justification
PART I				
NEW FIELD		**Height**	____ ft. and _____in.	available
NEW FIELD		**Weight**	____lbs/kg (circle units)	available
Therapy for this attack (check all that apply)	Chloroquine, Tetracycline, Doxycycline, Mefloquine, Exchange transfusion, Unknown, Primaquine, Quinine, Quinidine, Clindamyacin, Atovaquone/proguanil, Artesunate, Other (specify)	Therapy for this attack (check all that apply)	Chloroquine, Tetracycline, Doxycycline, Mefloquine, Exchange transfusion, Unknown, Primaquine, Quinine, Quinidine, Clindamyacin, Atovaquone/proguanil, Artesunate, **Artemether/lumefantrine**, Other (specify)	Updated value set to capture the drug Artemether/lumefantrine available for treatment
PART II	**NOTE: The expectation for PART II is that CDC staff will be completing this section, therefore the PRA change worksheet will not change (no additional Cost/Burden hours are added). States are allowed to complete section if desired, however are not obligated.**			
NEW FIELD		Please list all prescription and over the counter medicines the patient had taken during the 2 weeks before starting their treatment for malaria.		

NEW FIELD	Please list all prescription and over the counter medicines the patient had taken during the 4 weeks after starting their treatment for malaria.	
NEW FIELD	Was the medicine for malaria treatment taken as prescribed?	No, doses missed/Yes, no doses missed/Unknown
NEW FIELD	Did all signs or symptoms of malaria resolve without any additional malaria treatment within 7 days after treatment start?	No/Yes/Unknown
NEW FIELD	If yes, did the patient experience a recurrence of signs or symptoms of malaria during the 4 weeks after starting malaria treatment?	No/Yes/Unknown
NEW FIELD	Did the patient experience any adverse events within 4 weeks after receiving the malaria treatment?	No/Yes/Unknown
NEW FIELD	(If Yes): Event description	Relationship to treatment suspected*/Time to onset since treatment start/Fatal?/Life-threatening?/Other seriousness? **

* Suspected means that a causal relationship between the treatment and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

** A *serious* adverse event is defined as an event which is fatal or life-threatening, results in persistent or significant disability/incapacity, constitutes a congenital anomaly/birth defect, is medically significant (i.e., jeopardizes the patient or may require medical or surgical intervention), or requires inpatient hospitalization or prolongation of existing hospitalization