****IV ARTESUNATE IS AN INVESTIGATIONAL PRODUCT. THEREFORE, INFORMED CONSENT MUST BE OBTAINED (APPENDIX I)****

Reminder Checklist --GUILIN (FOSUN)

The following checklist outlines the required steps that must be completed in using IV artesunate (IV AS) under this IND for your patient. Please use this checklist to help your hospital ensure compliance with federal requirements for use of IV AS.

Pharmacist Responsibility		**Check (X) when complete**
1*.	Read IV AS protocol Section 8.2 ("Reconstitution, dilution and administration of IV artesunate") on how to prepare IV artesunate.#^	
2*.	Provide IV AS protocol and remaining report forms (Appendix I, II, III, IV, V) to treating physician before IV AS is administered.	
3.	Complete and return Investigational Drug Accountability and Return Form (Appendix VI) to CDC by fax at 404-639-3717 within 14 days of receipt of IV AS by pharmacy. If IV AS is not administered to the patient, unopened and unused product should be returned. **Use 6-digit QARS# for Participant ID**.	

 # Actual body weight should be used for dosing (not ideal body weight) ^No filter required for this formulation

Treating Physician Responsibility		**Check (X) when complete**
1*.	Read IV AS Protocol	
2*.	Complete Appendix I (Informed Consent/Parental Permission Form) **and** FDA Form 1572 **BEFORE** IV AS administration and fax to CDC within 48 hours • Appendix I: Informed Consent/Parental Permission Form. Informed consent **must** be obtained from patient, legal guardian or other legally authorized representative, and witnessed by the physician or other healthcare provider before administering IV AS.	
3.	Complete IV AS IND case report form **BEFORE, DURING, AND AFTER** artesunate administration (**Use 6-digit QARS# for Participant ID**): • Appendix II (Eligibility), Appendix III (Demographics), IV (Treatment Plan), V (Adverse Events Form)	
4.	Monitor for post-artesunate delayed hemolysis† starting one week after initial dose for up to 4 weeks. Weekly lab evaluation should include hemoglobin, reticulocyte count, haptoglobin, lactate dehydrogenase (LDH), and total bilirubin.	
5.	Malaria is a nationally notifiable disease, please **REPORT** the malaria case to local and state health departments according to your state regulations.	

Appendices I, FDA Form 1572, and treating physician's CV must be completed and returned to CDC within 48 hours of IV AS administration. Appendices II, III, IV and V should be returned within 14 days of IV AS administration.

Fax these report forms directly to CDC at 678-530-1153. ***Please include QARS#/Participant ID on coversheet of fax.*** QARS# is found on lower right-hand corner of packing slip.

*Please note that these tasks should be completed immediately.

†Post-artesunate delayed hemolysis is a nonrecurring event characterized by a 10% or greater decrease in hemoglobin levels in the setting of a haptoglobin level <0.1 g/L and an increase of LDH levels to >390 U/L, or an increase of ≥10%over baseline at least 7 days after initiation of parenteral artesunate treatment.