FDA is alerting compounders and patients about a voluntary recall of two lots – DR4654A and DL4654A – of quinacrine dihydrochloride active pharmaceutical ingredients (API) from Darmerica LLC of Casselbury, Florida. According to the company, this drug is being recalled due to a label error. The API, which was labeled as quinacrine HCl and was shipped to compounding pharmacies nationwide, was tested and identified as artemisinin API.

Using artemisinin instead of the prescribed quinacrine places patients at risk because their symptoms or condition could become worse. Exposure to artemisinin can also seriously affect a patient’s brain, heart, liver, kidney, immune system and reproductive system and may require medical attention.

FDA recommends repackagers, relabelers and distributors who have quinacrine arrange for identity testing prior to distribution or use in producing drugs for patient use.

See FDA to Compounders: Know Your Bulks Supplier for more information.

For more information, please visit FDA’s Human Drug Compounding web site.