BioSpectrum
the business of Bio & Health Sciences

FDA issues EUA for convalescent plasma therapy

24 August 2020 | News

For the treatment of COVID-19 in hospitalized patients as part of the agency's ongoing efforts to fight COVID-19

The U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients as part of the agency's ongoing efforts to fight COVID-19.

Based on scientific evidence available, the FDA concluded, as outlined in its decision memorandum, this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product.

This action follows the FDA's extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing.

The EUA authorizes the distribution of COVID-19 convalescent plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with COVID-19.

The EUA is not intended to replace randomized clinical trials and facilitating the enrollment of patients into any of the ongoing randomized clinical trials is critically important for the definitive demonstration of safety and efficacy of COVID-19 convalescent plasma.

The FDA continues to recommend that the designs of ongoing randomized clinical trials of COVID-19 convalescent plasma and other therapeutic agents remain unaltered, as COVID-19 convalescent plasma does not yet represent a new standard of care based on the current available evidence.