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FDA Bhawan, Kotla Road, New Delhi-110002 Dated: ¶ 4 MAY 2021

Information on Convalescent Plasma in COVID-19

This is with reference to the public notice dated 01-07-2020 issued by CDSCO w.r.t. information on convalescent plasma in COVID-19 wherein CLINICAL MANAGEMENT PROTOCOL: COVID-19 issued by the Government of India, Ministry of Health and Family Welfare, Directorate General of Health Services has indicated certain therapies for use as investigational therapies, in which convalescent plasma was indicated as "off label" in COVID-19 patients.

In this regard, it is to inform that AIIMS/ICMR-COVID-19 National Task Force/ Joint Monitoring Group (Dte.GHS), Ministry of Health & Family Welfare, Government of India has revised and issued a clinical guidance for management of Adult COVID-19 patients on 19.05.2021 where in "Convalescent plasma" (off label) as investigational therapy has been taken out of the clinical management protocol.

This is for disseminating information in public interest in light of COVID-19 situation. The said Clinical guidance is available in MoHFW website as "Revised COVID-19 Clinical Management protocol Algorithm" dated 19.05.2021. (https://www.mohfw.gov.in).