WHAT'S NEW: Reporting of EUA use revised to confirm no IRB reporting required

What is an Emergency Use Authorization?

The Emergency Use Authorization (EUA) authority allows the FDA to help strengthen the nation’s public health protections by facilitating the availability and use of medical countermeasures (MCM) needed during public health emergencies. Note that MCM can include drugs, biological products and devices.

Under section 564 of the Federal Food, Drug, and Cosmetic Act, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

The FDA video link below provides an overview of what an EUA is:
https://www.youtube.com/watch?v=iGkwaESsGBQ&feature=youtu.be

The FDA has issued guidance on "Emergency Use Authorization of Medical Products and Related Authorities", which can be accessed using the link below.

Where can I find current information on FDA approved EUA's for COVID-19?

The FDA maintains a website listing of all medical products granted an EUA for COVID-19 treatment, including FDA approval letters, "Fact Sheets" for health care professional and patients, and device "Instructions for Use" (IFU's). This list is updated frequently and can be accessed using the link below.

Are there any special considerations to be aware of in using a product to treat patients under an EUA?

A treating physician would need to determine when, and if, EUA use of any medical product is medically appropriate.

If medically appropriate, the treating physician should ensure the FDA website is used to obtain the EUA "Fact Sheet" for health care professionals and for patients. Product specific "Instructions for Use" (IFU), Operator's Manual, or other similar instructions for product use, are also available from the FDA website. The Fact sheet contains information that FDA requires to be shared with the patient on risks/benefits, and other available treatments. Sharing of the Patient "Fact Sheet" should be documented in the medical record. Informed consent for any procedure should be obtained per practice standards.

How do I report the use of a product under an EUA?

EUA use of a product is not considered research. Reporting to an Institutional Review Board (IRB) is not required.

Refer to the FDA's EUA letter for specific requirements for safety reporting. This may include submission of events using the FDA's MedWatch Adverse Event Reporting program.