Timeline for Emergency IND Application Initial Submission

TIME	ACTION	SUPPORTING DOCUMENTATION
Day 0-1	Contact the drug manufacturing company to obtain agreement to provide access to the drug (Investigational New Drug (IND) for emergency use)	Authorization from IND supplier (drug manufacturer) granting the right of reference to the information contained in the supplier's existing IND application to FDA[1] A Letter of Authorization to be sent to FDA at the time of full IND application submission by Day 15
Day 1	If the drug manufacturer agrees to provide the drug, call FDA to request opening an Emergency IND application and obtain FDA authorization for the investigational treatment (IND number)	Information listed on the Physician's Checklist for Emergency IND application The necessary information or the completed checklist for Emergency IND application may be faxed or e-mailed to FDA
Day 1	Obtain Informed Consent from patient or his/her legally authorized representative prior to administering treatment. Notify IRB of the planned emergency treatment if there is no time to obtain IRB approval.	Informed Consent Form from your institution (to be sent to FDA at the time of full IND application submission by Day 15) Exceptions from informed consent requirements in emergency situations
Post-treatment by Day 5	Notify IRB of the emergency IND treatment and apply for approval	Supporting documentation as required by the respective Institutional Review Board (IRB)
By Day 15	1. Submit the full Emergency IND application to the appropriate Review Division in the Center for Drug Evaluation and Research (CDER) at FDA 2. Identify submission as "Expanded Access Submission: Emergency Treatment for an Individual Patient"	1. IND application cover letter 2. Completed FDA Form 3926 (old forms 1571 and 1572) 3. Letter of Authorization[2] from the IND product's supplier for the right of reference to the information contained in their existing IND application[1] 4. Clinical protocol for emergency treatment of a single patient (the information in Form 3926) 5. Copy of the Informed Consent 6. Copy of the Investigator's Brochure (optional)

[1] *May also apply to other relevant information such as information contained in the respective Drug Master File*

[2] *In the absence of a Letter of Authorization from the IND Supplier (product's manufacturer), the emergency IND application's sponsor is responsible for providing the following in the IND application submission: (a) Description of the facility where the investigational new drug product is manufactured; (b) Chemistry, manufacturing, and controls information adequate to ensure the proper identification, quality, purity, and strength of the investigational drug product; (c) Pharmacology and toxicology information adequate to conclude that the drug is reasonably safe at the dose and duration proposed for this emergency use.*