Emergency IND Application Timeline

Emergency IND Application: Initial Submission

Time	Action	Supportive Documentation
Day 0-1	Contact Investigational New Drug (IND) supplier (e.g., product's manufacturer) to obtain their agreement to provide the IND for emergency use	Authorization from IND supplier (e.g., product's manufacturer) granting the right of reference to the information contained in the supplier's existing IND application[1] A Letter of Authorization to be sent to FDA at the time of full IND application submission by Day 15
Day 1	Call FDA to request opening an Emergency IND application and obtain FDA authorization for the investigational treatment	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 their legally authorized representative prior to administering treatment	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	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 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 to include: i) Rationale for intended use of the investigational drug including a list of available therapeutic options tried before resorting to the emergency IND treatment; ii) Description of the patient's disease or condition, including recent medical history and previous treatments; iii) Proposed method of administration of the drug, dose, and duration of therapy; iv) Description of clinical procedures, laboratory tests, or monitoring necessary to evaluate the effects of the drug and to minimize its risks. 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.

Emergency IND Application: Subsequent Submissions

Submission / Time	Action	Supportive Documentation
Mandatory Safety Reports - Fatal or Life-Threatening Events: As soon as possible but no later than within 7 Days of occurrence	Report unexpected fatal or life-threatening suspected adverse reactions[3]	1. FDA form 1571 (check initial or follow up IND Safety Report in Section 11) 2. FDA form 3500A
Mandatory Safety Reports-Other: As soon as possible but no later than within 15 days of occurrence	Report serious and unexpected suspected adverse reactions[3]	1. FDA form 1571 (check initial or follow up IND Safety Report in Section 11) 2. FDA form 3500A
IND Application Amendments: At any time during the IND application life cycle	Submit an Amendment to the Emergency IND application if there are any changes to the information sent in the initial Emergency IND application submission	1. FDA form 1571 (check Section 11 for all amendments that apply) 2. Application's Amendment with explanation of the changes to the application and additional data, when relevant 3. FDA form 1572 (required only if a new investigator is added)
Emergency IND Treatment Results Summary: Following completion of the emergency IND treatment	Provide FDA with a written summary of the results of the emergently used investigational treatment	1. FDA form 1571 2. Cover letter referring to the written summary report 3. Written report of the results of treatment, patient response, all adverse effects, and drug disposition A request to close the Emergency IND application may be sent to FDA at this time and should be included in the cover letter
IND Application Annual Reports: After 1 year* and within 60 days of FDA's original authorization date *if Emergency IND application remains active	Submit Emergency IND application Annual Report to the Review Division in CDER	1. FDA form 1571 (check Annual Report in Section 11) 2. An update for all information sent in the initial submission for the Emergency IND application to include: (1) summary of treatment results, (2) safety findings, (3) drug disposition, and (4) any other changes including non-clinical or clinical information, as relevant

[3]Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA&BE Studies; December 2012
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf