Center for Drug Evaluation and Research (CDER)
Emergency Use Authorization (EUA) Template:
Fact Sheet for Patients and Caregivers/Parents for
Unapproved Products and the Unapproved Use of Approved Products

Instructions:
The following template provides recommendations for information to include when developing an Emergency Use Authorization (EUA) **Fact Sheet for Patients and Parents/Caregivers** for a CDER-regulated product**.** This template is intended to help facilitate the preparation, submission, and authorization of the Patients and Caregivers/Parents Fact Sheet as part of an EUA, but is not required. Developers who intend to use alternative approaches should consider seeking CDER's feedback or recommendations.

Template Key:

- TEXT – Indicates a field that the user will replace.
- **TEXT** – Indicates instructions containing choices or options that will be deleted.
- **TEXT** – Indicates instructions that will be deleted and do NOT contain choices or options

FACT SHEET TEMPLATE BEGINS ON NEXT PAGE

OMB Control Number: 0910-XXXX; Expiration Date: TBD

Fact Sheet for Patients, PARENTS, AND CAREGIVERS Emergency Use Authorization (EUA) of DRUG-X for EMERGENCY CONDITION/DISEASE STATE-X

You are being given this fact sheet because your healthcare provider believes it is necessary to provide you with DRUG-X for AUTHORIZED USE. PROVIDE A SHORT SUMMARY OF THE AUTHORIZED USE IN PATIENT FRIENDLY LANGUAGE, WHILE ENSURING CONSISTENCY WITH THE AUTHORIZED USE IN THE LETTER OF AUTHORIZATION [LOA]. This fact sheet contains information to help you understand the risks and benefits of taking DRUG-X.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make DRUG-X available during the DESCRIBE EMERGENCY (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). DRUG-X is not **AN FDA-APPROVED MEDICINE, OR, ALTERNATIVELY, FOR APPROVED DRUGS THAT HAVE ADDITIONAL AUTHORIZED USES UNDER EUAS, STATE: "NOT FDA-APPROVED FOR THIS USE"** in the United States. Read this Fact Sheet for information about DRUG-X. Talk to your healthcare provider about your options or if you have any questions. It is your choice to take DRUG-X.

What is EMERGENCY CONDITION/DISEASE STATE?
INCLUDE A BRIEF DESCRIPTION OF THE CONDITION/DISEASE STATE AND COMMON SYMPTOMS. NO INFORMATION THAT IS OUTSIDE THE SCOPE OF THE DRUG'S AUTHORIZATION (E.G., AGE, SEVERITY OF DISEASE, SPECIFIC ENDPOINTS, ETC.) SHOULD BE INCLUDED BECAUSE OF THE PROMOTIONAL IMPLICATIONS FOR CONSUMER/PATIENT DIRECTED PROMOTIONAL MATERIALS.

What is DRUG-X?
INCLUDE A BRIEF DESCRIPTION OF THE DRUG AND ITS KNOWN OR POTENTIAL BENEFITS, AS DESCRIBED IN THE LOA.

The FDA has authorized the emergency use of DRUG-X for AUTHORIZED USE under an EUA. For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

What should I tell my healthcare provider before I take DRUG-X?
Tell your healthcare provider if you:

- Have any allergies
- Have kidney or liver disease OPTIONAL, DEPENDING ON THE DRUG
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any other medicines including prescription and over-the-counter, vitamins, or herbal products

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- In particular, notify your healthcare provider if you are taking NAME PRODUCTS THAT INTERACT WITH THE DRUG.

How do I take DRUG-X? / How will I receive DRUG-X?
INCLUDE ANY SPECIAL DOSING OR DETAILED ADMINISTRATION INSTRUCTIONS (e.g., ADULT VERSUS PEDIATRIC PATIENTS), IF APPROPRIATE.

Who should not take DRUG-X?
Do not take DRUG-X if**:**
INCLUDE THIS QUESTION AND RESPONSE IF THERE ARE CONTRAINDICATIONS FOR USE OF THE PRODUCT FOR THE AUTHORIZED USE.

What are the important possible side effects of DRUG-X?
INCLUDE IMPORTANT POSSIBLE SIDE EFFECTS, INCLUDING ANY BOX WARNINGS.

What other treatment choices are there?
INCLUDE LANGUAGE ASSURING PATIENTS WHO CHOOSE NOT TO RECEIVE DRUG-X THAT THEY SHOULD CONTINUE TO RECEIVE THE STANDARD OF CARE AS FOLLOWS:
It is your choice for **YOU OR YOUR CHILD** to be treated or not to be treated with DRUG-X. Should you decide not to receive it **OR FOR YOUR CHILD TO NOT RECEIVE IT**, it will not change your **OR YOUR CHILD'S** standard medical care.

What should I avoid while taking DRUG-X?
INCLUDE ANYTHING THAT SHOULD BE AVOIDED WHILE TAKING DRUG-X, SUCH AS "DON'T OPERATE HEAVY MACHINERY," OR "DON'T DRIVE."

What if I am pregnant or breastfeeding?

How do I report side effects with DRUG-X?
Contact your healthcare provider if you have any side effects that bother you or do not go away. Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088. IF APPLICABLE, INCLUDE STATEMENT "YOU MAY ALSO REPORT SIDE EFFECTS TO [SPONSOR NAME] BY CALLING [SPONSOR PHONE NUMBER]."

How should I store DRUG-X?
INCLUDE THIS QUESTION AND A RESPONSE IF THE PATIENT OR PARENT/CAREGIVER WILL NEED TO STORE THE DRUG.

How can I learn more about EMERGENCY CONDITION/DISEASE STATE?
- Ask your healthcare provider
- Visit CDC WEBSITE, IF AVAILABLE
- Contact your local or state public health department

What is an Emergency Use Authorization?

The United States FDA has made DRUG-X available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the DESCRIBE EMERGENCY.

DRUG-X for AUTHORIZED USE has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the DESCRIBE EMERGENCY, the FDA has determined, among other things, that based on the total amount of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing EMERGENCY CONDITION/DISEASE STATE, or a serious or life-threatening disease or condition caused by chemical, biological, radiological, or nuclear (CBRN); that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the DESCRIBE EMERGENCY. The EUA for DRUG-X is in effect for the duration of the DESCRIBE EMERGENCY declaration justifying emergency use of DRUG-X, unless terminated or revoked (after which DRUG-X may no longer be used under the EUA).

Manufacturer Information:

FOR DRUG AND BIOLOGICAL PRODUCTS INCLUDE:

- **MANUFACTURER NAME (E.G., "MANUFACTURED BY") (AND IF APPLICABLE ALSO INCLUDE PACKER AND DISTRIBUTOR, E.G., "PACKAGED BY", "DISTRIBUTED BY")**
- **LOCATION OF BUSINESS (STREET ADDRESS, CITY, STATE, AND ZIP CODE)**