

# **CDER Emergency Use Authorization (EUA) Template Fact Sheet for Healthcare Providers for Unapproved Products and the Unapproved Use of Approved Products**

## **Instructions:**

The following Emergency Use Authorization (EUA) **Fact Sheet for Healthcare Providers** template provides recommendations on developing three parts of this fact sheet:

- Highlights of Emergency Use Authorization,
- Table of Contents, and
- Full Fact Sheet for Healthcare Providers

## **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

**\*\*Remove this instruction page prior to finalization.\*\***

OMB Control No. 0910-0595

# FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR **DRUG-X**

## HIGHLIGHTS OF EMERGENCY USE AUTHORIZATION (EUA)

These highlights of the EUA do not include all the information needed to use **DRUG-X** under the EUA. See the FULL FACT SHEET FOR HEALTHCARE PROVIDERS for **DRUG-X**.

**DRUG-X** dosage form, route of administration

Original EUA Authorized Date: MM/YYYY

Fact Sheet Revised Date: MM/YYYY

### WARNING: TITLE OF WARNING

See Full Fact Sheet for Healthcare Providers for the complete boxed warning.

INCLUDE A BOXED WARNING FOR CONTRAINDICATIONS OR SERIOUS ADVERSE REACTIONS OR RISKS, PARTICULARLY THOSE THAT MAY LEAD TO DEATH OR SERIOUS INJURY.

### RECENT MAJOR CHANGES

Section Title, Subsection Title (XX)

M/YYYY

Section Title, Subsection Title (Xuxa)

M/YYYY

### EUA FOR **DRUG-X**

The U.S. Food and Drug Administration has issued an EUA for the emergency use of **DRUG-X** for **INCLUDE EUA AUTHORIZED USE**. However, **DRUG-X** is not approved for this use.

See Full Fact Sheet for Healthcare Providers for the justification for emergency use of drugs during the **EMERGENCY**, limitations of authorized use, information on available alternatives, and additional information on **EMERGENCY**.

### DOSAGE AND ADMINISTRATION

PROVIDE A SUMMARY OF THE ESSENTIAL DOSAGE, PREPARATION, AND ADMINISTRATION INSTRUCTIONS FOR THE AUTHORIZED USE.

### DOSAGE FORMS AND STRENGTHS

Dosage form(s): strength(s) (3)

### CONTRAINDICATIONS

IF NO CONTRAINDICATIONS HAVE BEEN IDENTIFIED INCLUDE THE FOLLOWING OR SIMILAR STATEMENT.

No contraindications have been identified based on the limited available data on the emergency use of **DRUG-X** authorized under this EUA. (4)

### WARNINGS AND PRECAUTIONS

- Text (5.x)
- Text (5.x)

### ADVERSE REACTIONS

Most common adverse reactions (incidence > x%) are **TEXT** (6.x)

You or your designee must report all **SERIOUS ADVERSE EVENTS** or **MEDICATION ERRORS** potentially related to **DRUG-X** (1) by submitting FDA Form 3500 **online**, (2) by **downloading** this form and then submitting by mail or fax, or (3) contacting the FDA at 1-800-FDA-1088 to request this form. Please also provide a copy of this form to **NAME OF FIRM THAT IS RESPONSIBLE FOR COLLECTING THESE REPORTS** at **TOLL-FREE PHONE # FOR FIRM** (6.4).

### DRUG INTERACTIONS

IF DRUG INTERACTIONS HAVE NOT BEEN IDENTIFIED, INCLUDE THE FOLLOWING OR SIMILAR STATEMENT.

No drug interactions have been identified based on the limited available data on the emergency use of **DRUG-X** authorized under this EUA. (7.x)

### USE IN SPECIFIC POPULATIONS

- Text (8.x)
- Text (8.x)

See FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS.

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## FULL FACT SHEET FOR HEALTHCARE PROVIDERS

### WARNING: TITLE OF WARNING

**INCLUDE A BOXED WARNING FOR CONTRAINDICATIONS OR SERIOUS ADVERSE REACTIONS OR RISKS, PARTICULARLY THOSE THAT MAY LEAD TO DEATH OR SERIOUS INJURY. HIGHLIGHT (1) ADVERSE REACTIONS THAT ARE SO SERIOUS IN PROPORTION TO THE POTENTIAL BENEFIT FROM THE PRODUCT THAT IT IS ESSENTIAL THAT IT BE CONSIDERED IS ASSESSING THE RISKS AND BENEFITS OF USING THE PRODUCT AND (2) SERIOUS ADVERSE REACTIONS THAT CAN BE PREVENTED OR REDUCED IN FREQUENCY OR SEVERITY BY APPROPRIATE USE OF THE PRODUCT. PROVIDE A BRIEF, CONCISE SUMMARY OF THIS INFORMATION IN BOLD FONT.**

### 1 EMERGENCY USE AUTHORIZATION FOR **DRUG-X**

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of **DRUG-X** for **EUA AUTHORIZED USE**. However, **DRUG-X** is not FDA approved for this use.

Justification for Emergency Use of Drugs During the **EMERGENCY**

**INCLUDE THE FOLLOWING INFORMATION ABOUT THE JUSTIFICATION FOR EMERGENCY USE OF DRUGS AND/OR BIOLOGICAL PRODUCTS DURING THE EMERGENCY, BACKGROUND ON EUAS, AND THE CRITERIA FOR EUAS.**

There is currently **DESCRIBE EMERGENCY OR THREAT OF EMERGENCY**. The Secretary of Health and Human Services (HHS) has declared that circumstances exist justifying the authorization of emergency use of **DRUGS AND/OR BIOLOGICAL PRODUCTS** during the **EMERGENCY** (**XX/XX/XXXX** declaration) based on **INSERT APPLICABLE 21 USC 564(b)(1) DETERMINATION LANGUAGE**.

An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances.

Criteria for issuing an EUA include:

- The chemical, biological, radiological, or nuclear agent(s) can cause a serious or life-threatening disease or condition;
- Based on the totality of the available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that
  - the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition; and
  - The known and potential benefits of the product - when used to diagnose, prevent, or treat such disease or condition - outweigh the known and potential risks of the product, taking into consideration the material threat posed by the biological agent(s);
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.

Information Regarding Approved or Authorized Available Alternatives for the EUA Authorized Use

INCLUDE INFORMATION REGARDING APPROVED OR AUTHORIZED AVAILABLE ALTERNATIVES FOR THE EUA AUTHORIZED USE INCLUDING THE BENEFITS AND RISKS OF THESE ALTERNATIVES. FOR EXAMPLE, IF THERE ARE OTHER PRODUCTS THAT MAY TREAT THE AUTHORIZED USE OF DRUG-X, CLARIFY WHY THEY ARE NOT ADEQUATE AND THE EUA FOR DRUG-X IS NEEDED (e.g., LIMITATIONS OF THE ALTERNATIVE THERAPIES AT REDUCING THE RISK OR TREATING THE AUTHORIZED USE). FURTHERMORE, INCLUDE THE FOLLOWING STATEMENT.

For information on clinical studies of DRUG-X and other therapies for the **INCLUDE THE APPROPRIATE TERM: TREATMENT/RISK REDUCTION** of **CONDITION OR DISEASE**, see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## 2 DOSAGE AND ADMINISTRATION

INCLUDE THE RECOMMENDED AUTHORIZED DOSAGE (e.g., RECOMMENDED STARTING DOSAGE, RECOMMENDED TITRATION SCHEDULE, MAXIMUM RECOMMENDED DOSAGE, MAXIMUM RECOMMENDED DURATION) AND ADMINISTRATION INSTRUCTIONS (e.g., RECOMMENDED INTRAVENOUS INFUSION RATE AND INFUSION DURATION, RECOMMENDED INJECTION SITES FOR DRUGS ADMINISTERED INTRAMUSCULARLY OR SUBCUTANEOUSLY. FOR EXAMPLE:

The recommended dosage for emergency use of DRUG-X authorized under this EUA is **INSERT RECOMMENDED DOSAGE AND ADMINISTRATION**.

**IN ADDITION, INCLUDE IF APPLICABLE:**

- **CRITICAL TESTS, PROCEDURES, AND/OR EVALUATIONS NEEDED PRIOR TO ADMINISTRATION**
- **REQUIRED AND/OR RECOMMENDED PRE-MEDICATION AND/OR CONCOMITANT THERAPIES TO ENHANCE SAFETY OR EFFICACY**
- **DOSAGE MODIFICATIONS DUE TO ADVERSE REACTIONS OR DUE TO DRUG INTERACTIONS**
- **DOSAGE IN SPECIFIC POPULATIONS (e.g., PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT)**
- **RECOMMENDATIONS FOR DISCONTINUATION**
- **PREPARATION INSTRUCTIONS (e.g., RECONSTITUTION OF A LYOPHILIZED POWDER, DILUTION)**
- **ADMINISTRATION INSTRUCTIONS**
- **STORAGE CONDITIONS NEEDED TO MAINTAIN THE STABILITY AND STERILITY OF THE RECONSTITUTED AND/OR DILUTED PRODUCT.**
- **DISPOSAL INSTRUCTIONS**

## 3 DOSAGE FORMS AND STRENGTHS

INCLUDE THE DOSAGE FORM(S), STRENGTH(S), AND THE IDENTIFYING CHARACTERISTICS OF THE DOSAGE FORM(S).

## 4 CONTRAINDICATIONS

MUST INCLUDE CONTRAINDICATIONS. CONTRAINDICATIONS ARE DEFINED AS SITUATIONS IN WHICH DRUG-X MUST NOT BE USED BECAUSE THE RISK OF USE CLEARLY OUTWEIGHS ANY POSSIBLE THERAPEUTIC BENEFIT. IF NO CONTRAINDICATIONS HAVE BEEN IDENTIFIED INCLUDE THE FOLLOWING OR SIMILAR STATEMENT.

No contraindications have been identified based on the limited available data on the emergency use of **DRUG-X** authorized under this EUA.

## 5 WARNINGS AND PRECAUTIONS

**DESCRIBE CLINICALLY SIGNIFICANT ADVERSE REACTIONS OR RISKS ASSOCIATED WITH THE USE OF DRUG-X, THE FREQUENCY/RATE OF OCCURRENCE OF THESE ADVERSE REACTIONS, LIMITATIONS OF USE IMPOSED BY THEM, AND STEPS TO TAKE TO PREVENT, MITIGATE, MONITOR FOR, OR MANAGE THESE CLINICALLY SIGNIFICANT ADVERSE REACTIONS OR RISKS. INCLUDE EACH CLINICALLY SIGNIFICANT REACTION OR RISK UNDER ITS OWN SUBSECTION (e.g., “5.1 HYPERSENSITIVITY REACTIONS”, “5.2 ELEVATED LIVER ENZYMES”). FOR EXAMPLE, POTENTIAL LANGUAGE MAY INCLUDE “*There are limited clinical data available for DRUG-X [in XX population, if applicable]. Serious and unexpected adverse events may occur that have not been previously reported with DRUG-X use.*”**

## 6 ADVERSE REACTIONS

**FOR THE PURPOSES OF EUAS, AN ADVERSE REACTION IS AN UNDESIRABLE EFFECT, REASONABLY ASSOCIATED WITH THE USE OF A DRUG THAT MAY OCCUR AS PART OF THE PHARMACOLOGICAL ACTION OF THE DRUG OR MAY BE UNPREDICTABLE IN ITS OCCURRENCE. THIS DEFINITION DOES NOT INCLUDE ALL ADVERSE EVENTS OBSERVED DURING USE OF A DRUG, ONLY THOSE FOR WHICH THERE IS SOME BASIS TO BELIEVE THERE IS A CAUSAL RELATIONSHIP BETWEEN THE DRUG AND THE OCCURRENCE OF THE ADVERSE EVENT. DO NOT INCLUDE ADVERSE EVENTS IN WHICH THERE IS NO BASIS TO BELIEVE THAT THERE IS A CAUSAL RELATIONSHIP BETWEEN DRUG-X AND THE OCCURRENCE OF THE EVENT.**

### 6.1 Adverse Reactions from Clinical Studies

**INCLUDE THE FOLLOWING STATEMENT OR SIMILAR STATEMENT BEFORE THE PRESENTATION OF THE ADVERSE REACTIONS IN THIS SUBSECTION.**

The following adverse reactions have been observed in the clinical studies of **DRUG-X** that supported EUA. The adverse reaction rates observed in these clinical studies cannot be directly compared to rates in the clinical studies of **INSERT IF DRUG-X IS ALSO FDA-APPROVED FOR AN INDICATION: “THE SAME DRUG FOR AN FDA-APPROVED INDICATION OR”** another drug and may not reflect the rates observed in clinical practice.

**INCLUDE A DESCRIPTION OF THE OVERALL CLINICAL TRIAL DATABASE FROM WHICH ADVERSE REACTION DATA HAVE BEEN DRAWN, INCLUDING A DISCUSSION OF OVERALL EXPOSURE (NUMBER OF PATIENTS, DOSAGE, DURATION), DEMOGRAPHICS OF THE EXPOSED POPULATION, DESIGNS OF THE TRIALS IN WHICH EXPOSURE OCCURRED (e.g., PLACEBO-CONTROLLED), AND ANY CRITICAL EXCLUSIONS FROM THE SAFETY DATABASE.**

**INCLUDE A TABLE OF THE ADVERSE REACTIONS IDENTIFIED FROM CLINICAL TRIALS THAT OCCURRED AT OR ABOVE A SPECIFIED RATE APPROPRIATE TO THE DATABASE (COMMON ADVERSE REACTIONS TABLE). WITHIN A LISTING, CATEGORIZE ADVERSE REACTIONS BY BODY SYSTEM, BY SEVERITY OF THE REACTION, OR IN ORDER OF DECREASING FREQUENCY, OR BY A COMBINATION OF THESE, AS APPROPRIATE. WITHIN A CATEGORY, LIST ADVERSE REACTIONS IN DECREASING ORDER OF FREQUENCY.**

**PRESENT THOSE CLINICALLY SIGNIFICANT ADVERSE REACTIONS THAT OCCURRED BELOW THE SPECIFIED RATE FOR INCLUSION IN THE COMMON ADVERSE REACTIONS TABLE, BUT FOR WHICH THERE IS SOME BASIS TO BELIEVE THERE IS A CAUSAL RELATIONSHIP BETWEEN THE DRUG AND THE EVENT (FOR PURPOSES OF THIS FACT SHEET, “LESS COMMON” ADVERSE REACTIONS).**

## **6.2 Adverse Reactions from Spontaneous Reports**

**INCLUDE THE FOLLOWING STATEMENT OR SIMILAR STATEMENT BEFORE THE PRESENTATION OF THE ADVERSE REACTIONS IN THIS SUBSECTION.**

The following spontaneous adverse reactions associated with the use of **DRUG-X** have been identified. Because these adverse reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**INCLUDE A LIST OF THE ADVERSE REACTIONS, THAT WERE IDENTIFIED FROM DOMESTIC AND FOREIGN SPONTANEOUS REPORTS.**

**SUBSECTION 6.4 SHOULD BE MODIFIED FOR THE SPECIFIC DRUG UNDER THE EUA (e.g., MAY CONSIDER ADDING REQUIRED REPORTING FOR ADVERSE EVENTS OF SPECIAL SIGNIFICANCE THAT ARE NOT SERIOUS).**

## **6.3 Required Reporting for Serious Adverse Events and Medication Errors**

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events\* and medication errors potentially related to **DRUG-X** within 7 calendar days from the healthcare provider's awareness of the event, using FDA Form 3500 (for information on how to access this form, see below). The FDA requires that such reports, using FDA Form 3500, include the following:

- Patient demographics and baseline characteristics (e.g., patient identifier, age or date of birth, gender, weight, ethnicity, and race)
- A statement "**DRUG-X** use for **EMERGENCY CONDITION/DISEASE STATE** under Emergency Use Authorization (EUA)" under the "**Describe Event, Problem, or Product Use/Medication Error**" heading
- Information about the serious adverse event or medication error (e.g., signs and symptoms, test/laboratory data, complications, timing of drug initiation in relation to the occurrence of the event, duration of the event, treatments required to mitigate the event, evidence of event improvement/disappearance after stopping or reducing the dosage, evidence of event reappearance after reintroduction, clinical outcomes).
- Patient's preexisting medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, NDC #).

Submit adverse event and medication error reports, using Form 3500, to FDA MedWatch using one of the following methods:

- Complete and submit the report online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Complete and submit a postage-paid FDA Form 3500 (<https://www.fda.gov/media/76299/download>) and return by:
  - o Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
  - o Fax to 1-800-FDA-0178, or

- Call 1-800-FDA-1088 to request a reporting form

In addition, please provide a copy of all FDA MedWatch forms to: **INCLUDE FIRM'S NAME AND CONTACT INFORMATION THAT WILL RECEIVE THE MEDWATCH FORMS.**

The prescribing healthcare provider and/or the provider's designee is/are responsible for responses (**INCLUDE MANDATORY RESPONSES IF INCLUDED IN THE EUA LOA.**) to requests from FDA for information about adverse events and medication errors following receipt of **DRUG-X**.

\*Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- Other important medical event, which may require a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

## 6.5 Other Reporting Requirements (if applicable)

**INCLUDE THIS SECTION IF INCLUDED IN THE LOA AS A CONDITION OF AUTHORIZATION**

Healthcare facilities and providers will report therapeutics information and utilization data as directed by the U.S. Department of Health and Human Services.

## 7 DRUG INTERACTIONS

**INCLUDE A DESCRIPTION OF CLINICALLY SIGNIFICANT DRUG INTERACTIONS (OBSERVED AND PREDICTED) WITH PRESCRIPTION DRUGS, NONPRESCRIPTION DRUGS, FOODS, BEVERAGES, AND/OR DIETARY SUPPLEMENTS. CONSIDER USING A TABULAR FORMAT. ALSO INCLUDE THE FOLLOWING:**

- **SPECIFIC PRACTICAL INSTRUCTIONS FOR PREVENTING OR MANAGING CLINICALLY SIGNIFICANT DRUG INTERACTIONS**
- **MECHANISM OF THE CLINICALLY SIGNIFICANT DRUG INTERACTIONS IF KNOWN**
- **CLINICAL EFFECT(S) OF CLINICALLY SIGNIFICANT DRUG INTERACTIONS**

**IF DRUG INTERACTIONS HAVE NOT BEEN IDENTIFIED, INCLUDE ONE OF THE FOLLOWING STATEMENTS: "No drug interactions have been identified based on the limited available data on the emergency use of DRUG-X authorized under this EUA" or "No clinical drug-drug interaction trials of DRUG-X with concomitant medications, including other treatments for EUA AUTHORIZED DISEASE/CONDITION, have been conducted [see Clinical Pharmacology]"**



**IF DRUG INTERACTION INFORMATION IS AVAILABLE, INCLUDE THE FOLLOWING SUBSECTIONS, AS APPROPRIATE.**

#### **7.1 Effect of Other Drugs on **DRUG-X****

#### **7.2 Effect of **DRUG-X** on Other Drugs**

### **8 USE IN SPECIFIC POPULATIONS**

#### **8.1 Pregnancy**

##### **Risk Summary**

**INCLUDE RISK SUMMARY STATEMENT(S) THAT DESCRIBE, FOR THE DRUG, THE RISK OF ADVERSE DEVELOPMENTAL OUTCOMES BASED ON ALL RELEVANT HUMAN DATA, ANIMAL DATA, AND/OR THE DRUG'S PHARMACOLOGY, UNDER THIS HEADING. IF SUCH ANIMAL AND/OR HUMAN DATA ARE UNAVAILABLE OR INSUFFICIENT, INCLUDE A STATEMENT NOTING THIS. INCLUDE PREGNANCY REGISTRY INFORMATION, IF APPLICABLE.**

##### **Data**

**WHEN APPLICABLE, SUMMARIZE THE HUMAN AND/OR ANIMAL DATA THAT SUPPORT THE RISK SUMMARY STATEMENTS.**

#### **8.2 Lactation**

##### **Risk Summary**

**SUMMARIZE INFORMATION ON THE PRESENCE OF A DRUG AND/OR ITS ACTIVE METABOLITE(S) IN HUMAN MILK, THE EFFECTS OF A DRUG AND/OR ITS ACTIVE METABOLITE(S) ON THE BREASTFED CHILD, AND THE EFFECTS OF A DRUG AND/OR ITS ACTIVE METABOLITE(S) ON MILK PRODUCTION. IF THIS INFORMATION IS UNKNOWN, INCLUDE A STATEMENT NOTING THIS.**

**IF ONLY ANIMAL LACTATION DATA ARE AVAILABLE, STATE WHETHER OR NOT THE DRUG AND/OR ITS ACTIVE METABOLITE(S) WERE DETECTED IN ANIMAL MILK. INCLUDE ANY RECOMMENDATIONS CONCERNING DRUG USE AND BREASTFEEDING.**

##### **Data**

**WHEN APPLICABLE, DESCRIBE THE HUMAN AND/OR ANIMAL DATA ON WHICH THE LABELING UNDER THE RISK SUMMARY IS BASED. WHEN THE INFORMATION UNDER THE RISK SUMMARY HEADING IS BASED ON HUMAN DATA, ANIMAL DATA MUST NOT BE INCLUDED UNLESS THE ANIMAL MODEL IS SPECIFICALLY KNOWN TO BE PREDICTIVE FOR HUMANS.**

#### **8.3 Females and Males of Reproductive Potential**

**IF APPLICABLE, INCLUDE THIS SUBSECTION IF THERE ARE RECOMMENDATIONS FOR PREGNANCY TESTING AND/OR CONTRACEPTION BEFORE, DURING, OR AFTER DRUG THERAPY, AND/OR (2) THERE ARE HUMAN AND/OR ANIMAL DATA SUGGESTING DRUG-ASSOCIATED EFFECTS ON FERTILITY AND/OR PRE-IMPLANTATION LOSS EFFECTS. INCLUDE THE INFORMATION UNDER THE FOLLOWING HEADINGS, WHEN APPLICABLE.**

Pregnancy Testing

Contraception

*Females*

*Males*

Infertility

*Females*

*Males*

#### **8.4 Pediatric Use**

CLEARLY STATE IF AN EUA WAS GRANTED OR NOT GRANTED IN ALL PEDIATRIC AGE GROUPS.

IF AN EUA WAS GRANTED IN A PEDIATRIC SUBPOPULATION, INCLUDE THE FOLLOWING STATEMENT OR SIMILAR STATEMENT:

The FDA has issued an EUA for the emergency use of **DRUG-X** for **EUA AUTHORIZED USE** in **INCLUDE AUTHORIZED PEDIATRIC POPULATION**. However, **DRUG-X** is not approved for this use.

IF AN EUA WAS NOT GRANTED IN A PEDIATRIC SUBPOPULATION, INCLUDE THE FOLLOWING STATEMENT OR SIMILAR STATEMENT:

**DRUG-X** is not authorized or approved for the emergency use for **INCLUDE EUA AUTHORIZED DISEASE/CONDITION** in **INCLUDE UNAUTHORIZED PEDIATRIC SUBPOPULATION**.

INCLUDE SPECIFIC RISKS OR SAFETY CONCERNS IN PEDIATRIC PATIENTS AND/OR NEED FOR SPECIFIC MONITORING, ANY LIMITATIONS ON PEDIATRIC AUTHORIZED USE, AND ANY DIFFERENCES BETWEEN THE EFFECTIVENESS AND SAFETY OF DRUG-X IN PEDIATRIC AND ADULT PATIENTS.

#### **8.5 Geriatric Use**

INCLUDE THE NUMBER AND PERCENTAGE OF DRUG-X-TREATED AND CONTROL-TREATED GERIATRIC PATIENTS (PATIENTS 65 YEARS OF AGE AND OLDER) IN THE CLINICAL STUDIES. IF DATA IS AVAILABLE, INCLUDE ADDITIONAL EXPOSURE DATA IN GERIATRIC SUBPOPULATIONS (e.g., 65 TO 74 YEARS OF AGE, 75 TO 84 YEARS OF AGE, AND 85 YEARS OF AGE AND OLDER) IF APPROPRIATE.

- IF THERE IS INSUFFICIENT DATA TO DETECT DIFFERENCES IN SAFETY AND/OR EFFECTIVENESS BETWEEN GERIATRIC PATIENTS AND YOUNGER ADULT PATIENTS, THEN STATE: "CLINICAL STUDIES OF DRUG-X DID NOT INCLUDE SUFFICIENT NUMBERS OF PATIENTS 65 YEARS OF AGE AND OLDER TO DETERMINE WHETHER THEY RESPOND DIFFERENTLY FROM YOUNGER ADULT PATIENTS." INCLUDE SPECIFIC RISKS OR SAFETY CONCERNS ASSOCIATED WITH THE USE OF DRUG-X IN GERIATRIC PATIENTS AND SPECIFIC RISK MITIGATION IN GERIATRIC PATIENTS.

- IF THERE IS SUFFICIENT DATA TO DETECT DIFFERENCES IN SAFETY AND/OR EFFECTIVENESS BETWEEN GERIATRIC PATIENTS AND YOUNGER ADULT PATIENTS, BUT NO OVERALL DIFFERENCES WERE OBSERVED, THEN STATE: "NO OVERALL DIFFERENCES IN SAFETY OR EFFECTIVENESS OF DRUG-X HAVE BEEN OBSERVED BETWEEN PATIENTS 65 YEARS OF AGE AND OLDER AND YOUNGER ADULT PATIENTS."
- IF THERE IS SUFFICIENT DATA TO DETECT DIFFERENCES IN SAFETY AND/OR EFFECTIVENESS BETWEEN GERIATRIC PATIENTS AND YOUNGER ADULT PATIENTS, THEN DESCRIBE THESE DIFFERENCES AND PROVIDE INFORMATION ON RISK MITIGATION IN GERIATRIC PATIENTS.

## 8.6 Subpopulation X

INCLUDE ADDITIONAL SUBSECTIONS (AFTER SUBSECTION 8.5 GERIATRIC USE) IF SUFFICIENT DATA ARE AVAILABLE CONCERNING USE OF DRUG IN OTHER SPECIFIED SUBPOPULATIONS (e.g., 8.6 RENAL IMPAIRMENT, 8.7 HEPATIC IMPAIRMENT).

## 9 DRUG ABUSE AND DEPENDENCE

### 9.1 Controlled Substance

IN ADDITION TO THE EUA USE, IF THE DRUG IS APPROVED FOR A USE AND IS SCHEDULED UNDER THE CONTROLLED SUBSTANCES ACT, STATE THAT THE DRUG IS A CONTROLLED SUBSTANCE AND IDENTIFY THE SCHEDULE UNDER WHICH THE DRUG IS CONTROLLED.

### 9.2 Abuse

INCLUDE, AS APPROPRIATE, INFORMATION ABOUT THE DRUG RELATED TO ABUSE, MISUSE, AND ADDICTION THAT IS IMPORTANT FOR HEALTHCARE PRACTITIONERS TO CONSIDER.

### 9.3 Dependence

INCLUDE INFORMATION ABOUT THE DRUG RELATED TO PHYSICAL DEPENDENCE, WITHDRAWAL, AND TOLERANCE. SUMMARIZE SIGNS AND SYMPTOMS OF WITHDRAWAL AFTER CHRONIC USE OR ABUSE OF THE DRUG IN THE DEPENDENCE SUBSECTION, WHEREAS DISCUSS ABUSE-RELATED ADVERSE REACTIONS IN THE ABUSE SUBSECTION.

## 10 OVERDOSAGE

IF APPLICABLE, DESCRIBE SIGNS, SYMPTOMS, AND LABORATORY FINDINGS OF OVERDOSAGE, COMPLICATIONS THAT CAN OCCUR WITH OVERDOSAGE (e.g., ORGAN TOXICITY), THE AMOUNT OF DRUG IN A SINGLE DOSE THAT IS ASSOCIATED WITH SYMPTOMS OF OVERDOSAGE, THE AMOUNT OF DRUG IN A SINGLE DOSE THAT IS LIKELY TO BE LIFE-THREATENING, AND GENERAL TREATMENT PROCEDURES AND SPECIFIC MEASURES FOR SUPPORT OF VITAL FUNCTIONS DURING AN OVERDOSAGE.

## 11 DESCRIPTION

INCLUDE THE DRUG NAME(S), DOSAGE FORM(S), ROUTE(S) OF ADMINISTRATION, PHARMACOLOGIC OR THERAPEUTIC CLASS, QUALITATIVE AND QUANTITATIVE INGREDIENT INFORMATION. ADDITIONALLY, FOR DRUG PRODUCTS, INCLUDE THE CHEMICAL NAME AND STRUCTURAL FORMULA.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

SUMMARIZE WHAT IS KNOWN ABOUT THE MECHANISM(S) OF ACTION OF THE DRUG (1) FOR THE EUA AUTHORIZED USE AND (2) FOR THE CLINICALLY SIGNIFICANT ADVERSE REACTIONS ASSOCIATED WITH THE DRUG. IF THE MECHANISM OF ACTION FOR THE AUTHORIZED USE IS UNKNOWN, INCLUDE A STATEMENT ABOUT THE LACK OF THIS INFORMATION. PROMOTIONAL LANGUAGE SHOULD BE AVOIDED.

### 12.2 Pharmacodynamics

DESCRIBE THE BIOCHEMICAL OR PHYSIOLOGIC PHARMACOLOGIC EFFECTS OF THE DRUG AND/OR ACTIVE METABOLITES RELATED TO THE DRUG'S AUTHORIZED USE OR RELATED TO THE CLINICALLY SIGNIFICANT ADVERSE REACTIONS ASSOCIATED WITH THE USE OF THE DRUG.

### 12.3 Pharmacokinetics

AT THE BEGINNING OF THIS SUBSECTION, PROVIDE A BRIEF INTRODUCTION THAT DESCRIBES THE GENERAL, CLINICALLY SIGNIFICANT PHARMACOKINETIC PROPERTIES OF THE PARENT DRUG AND ITS RELEVANT METABOLITES, AND ANY UNIQUE DRUG CHARACTERISTICS. INCLUDE THE FOLLOWING HEADINGS AND SUBHEADINGS, IF RELEVANT.

#### Absorption

*Effect of Food*

#### Distribution

#### Elimination

*Metabolism*

*Excretion*

#### Specific Populations

*Geriatric Patients*

*Pediatric Patients*

*Male and Female Patients*

*Racial or Ethnic Groups*

*Patients with Renal Impairment*

*Patients with Hepatic Impairment*

*Pregnant Women*

#### Drug Interaction Studies

*Drug A*

*Drug B*

## 12.4 Microbiology

INCLUDE INFORMATION RELEVANT TO THE MICROBIOLOGY CHARACTERISTICS OF THE DRUG.

## 12.5 Pharmacogenomics

INCLUDE CLINICALLY RELEVANT DATA OR INFORMATION ON THE EFFECT OF GENETIC VARIATIONS AFFECTING DRUG THERAPY.

## 12.6 Immunogenicity

INCLUDE THIS SUBSECTION IF THE DRUG HAS HAD AN IMMUNOGENICITY ASSESSMENT.

IF THE METHODOLOGY FOR THE SUBMITTED IMMUNOGENICITY EVALUATION IS ADEQUATE SUCH THAT IT ALLOWS FOR AN ASSESSMENT OF ANTI-DRUG-ANTIBODY (ADA) INCIDENCE INCLUDE THE FOLLOWING:

- INCLUDE THE FOLLOWING PARAGRAPH AT THE BEGINNING OF THIS SUBSECTION, PRECEDING THE IMMUNOGENICITY DATA:

"THE OBSERVED INCIDENCE OF ANTI-DRUG ANTIBODIES IS HIGHLY DEPENDENT ON THE SENSITIVITY AND SPECIFICITY OF THE ASSAY. DIFFERENCES IN ASSAY METHODS PRECLUDE MEANINGFUL COMPARISONS OF THE INCIDENCE OF ANTI-DRUG ANTIBODIES IN THE STUDIES DESCRIBED BELOW WITH THE INCIDENCE OF ANTI-DRUG ANTIBODIES IN OTHER STUDIES, INCLUDING THOSE OF [INSERT PROPER NAME, ACTIVE MOIETY NAME, OR ACTIVE INGREDIENT NAME] OR OF OTHER [INSERT CORE NAME, ACTIVE MOIETY NAME, OR ACTIVE INGREDIENT NAME] PRODUCTS."

- REPORT THE INCIDENCE OF ADA, INCLUDING NEUTRALIZING ANTIBODIES, ALONG WITH DURATION OF EXPOSURE TO THE DRUG AND TIME PERIOD OVER WHICH SAMPLING FOR ADA WAS CONDUCTED.
- SUMMARIZE THE KNOWN EFFECT(S) OF ADA ON THE PHARMACOKINETICS AND PHARMACODYNAMICS UNDER THE HEADINGS ANTI-DRUG ANTIBODY EFFECTS ON PHARMACOKINETICS AND ANTI-DRUG ANTIBODY EFFECTS ON PHARMACODYNAMICS, RESPECTIVELY.

IF THE METHODOLOGY FOR THE SUBMITTED IMMUNOGENICITY EVALUATION IS INADEQUATE, SUCH THAT IT PRECLUDES AN ASSESSMENT OF THE INCIDENCE OF ADA, INCLUDE THE FOLLOWING OR SIMILAR STATEMENT IN THIS SUBSECTION:

"THERE IS INSUFFICIENT INFORMATION TO CHARACTERIZE THE ANTI-DRUG ANTIBODY RESPONSE OF [INSERT PROPER NAME, ACTIVE MOIETY NAME, OR ACTIVE INGREDIENT NAME] AND THE EFFECTS OF ANTI-DRUG ANTIBODIES ON PHARMACOKINETICS, PHARMACODYNAMICS, SAFETY, OR EFFECTIVENESS OF OTHER [INSERT CORE NAME, ACTIVE MOIETY NAME, OR ACTIVE INGREDIENT NAME] PRODUCTS."

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

INCLUDE INFORMATION ON ANIMAL STUDIES/MODELS ABOUT THE CARCINOGENIC POTENTIAL, MUTAGENESIS, AND IMPAIRMENT OF FERTILITY OF THE DRUG.

### 13.2 Animal Toxicology and/or Pharmacology

INCLUDE INFORMATION ABOUT SIGNIFICANT ANIMAL DATA THAT IS NOT INCORPORATED IN OTHER SECTIONS OF THIS FACT SHEET.

## 14 CLINICAL STUDIES

DISCUSS THE CLINICAL STUDIES THAT ARE IMPORTANT TO A HEALTHCARE PRACTITIONER'S UNDERSTANDING OF THE EMERGENCY USE OF DRUG-X FOR THE AUTHORIZED USE. TYPICALLY, THIS SECTION SHOULD INCLUDE A DESCRIPTION AND RESULTS OF THE CLINICAL STUDIES THAT PROVIDED THE PRIMARY SUPPORT FOR THE AUTHORIZATION. INCLUDE INFORMATION ABOUT CLINICAL STUDIES THAT SUGGEST A LACK OF SUPPORT AND REASONING FOR LACK OF SUPPORT OF AN EFFECT IN A CLINICAL SITUATION OR LACK OF EFFECT ON AN ENDPOINT.

INCLUDE STUDY DESIGN CHARACTERISTICS, INCLUDING:

- MAJOR DESIGN CHARACTERISTICS
- STUDY TREATMENT ARMS, INCLUDING DOSING REGIMENS AND TITRATIONS
- IMPORTANT ELIGIBILITY CRITERIA FOR UNDERSTANDING THE TREATMENT EFFECT
- IMPORTANT CONCOMITANT THERAPY THAT HELPS UNDERSTAND THE EFFECTS OF THE DRUG
- ENDPOINTS CRITICAL TO ESTABLISH THE AUTHORIZED USE, AND IMPORTANT LIMITATIONS OF THE STUDIES

WHEN SUMMARIZING STUDY FINDINGS INCLUDE:

- NUMBER ENROLLED
- IMPORTANT BASELINE DISEASE CHARACTERISTICS AND DEMOGRAPHICS IMPORTANT FOR UNDERSTANDING THE TREATMENT EFFECT OR FOR UNDERSTANDING IF THE RESULTS CAN BE GENERALIZED
- ENDPOINT RESULTS THAT ARE FOUND TO BE BOTH STATISTICALLY AND CLINICALLY SIGNIFICANT OR SUGGESTED A LACK OF SUPPORT OF AN EFFECT
- CONFIDENCE INTERVALS EVEN IF P-VALUES ARE PRESENTED
- SUMMARY STATEMENT ABOUT EFFECTS IN DEMOGRAPHIC SUBGROUPS (E.G., AGE, GENDER, RACIAL SUBGROUPS) OR IMPORTANT BASELINE DISEASE CHARACTERISTICS (E.G., GENETIC DIFFERENCES) WHEN THE SUBGROUP WAS APPROPRIATELY PRE-SPECIFIED AND THE SUBGROUP SAMPLE SIZE HAD A REASONABLE ABILITY TO DETECT SUBGROUP DIFFERENCES. INCLUDE LIMITATIONS OF SUBGROUP ANALYSES, E.G., "HOWEVER, THESE SUBGROUP EXPLORATORY ANALYSES WERE NOT CONTROLLED FOR MULTIPLE COMPARISONS." STATE WHEN SUBGROUP ANALYSES ARE INADEQUATE FOR ASSESSING THE EFFECTS IN PARTICULAR SUBGROUPS.

DO NOT INCLUDE ANY INFORMATION THAT IMPLIES OR SUGGESTS EUA USES OR DOSAGES THAT ARE NOT AUTHORIZED IN SECTIONS 1 OR 2 OF THIS FACT SHEET, RESPECTIVELY.

## 15 REFERENCES

**THIS SECTION IS USUALLY OMITTED, UNLESS THERE ARE AUTHORITATIVE REFERENCES IMPORTANT TO PRESCRIBING DECISIONS THAT ARE MENTIONED IN ANOTHER SECTION OF THIS FACT SHEET BUT CANNOT READILY BE SUMMARIZED.**

## 16 HOW SUPPLIED/STORAGE AND HANDLING

**INCLUDE INFORMATION ABOUT THE DOSAGE FORM(S), STRENGTH(S), UNITS IN WHICH THE DOSAGE FORM IS ORDINARY AVAILABLE (e.g., BOTTLES OF 100), IDENTIFYING CHARACTERISTICS OF THE DOSAGE FORM(S), SPECIAL HANDLING, AND STORAGE CONDITIONS OF THE SUPPLIED PRODUCT (e.g., REFRIGERATE, DO NOT FREEZE).**

## 17 PATIENT COUNSELING INFORMATION

As a healthcare practitioner, you must provide a copy of the “FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS” and communicate to the patient and/or caregiver information consistent with the fact sheet prior to administration of **DRUG-X**. **OPTIONAL STATEMENT FOR PRODUCT USE IN LIFE-THREATENING SITUATIONS:** However, if providing this information will delay the administration of **DRUG-X** to a degree that would endanger the life of a patient, the information must be provided to the parent and/or caregiver as soon as feasible after **DRUG-X** administration.

## 18 MANUFACTURER INFORMATION

**FOR DRUG 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)**