

## Target Product Profile: Drug Name

(May be modified for use with devices)

Milestone (meeting/submission)	Date	TPP Submitted? Y/N	TPP Version Date	TPP Discussed? Y/N
Pre-IND				
IND Submission				
EOP1				
EOP2A				
EOP2/Pre-Phase 3				
Pre-NDA/BLA				
Other (specify)				
Pre-IDE				
IDE Submission				
510(k) or PMA				
Other (specify)				

Target	Annotations
<p><i>A statement that the drug is indicated in the treatment, prevention, or diagnosis of a recognized disease or condition,</i> OR</p> <p><i>A statement that the drug is indicated for the treatment, prevention, or diagnosis of an important manifestation of a disease or condition,</i> OR</p> <p><i>A statement that the drug is indicated for the relief of symptoms associated with a disease or syndrome,</i> OR</p> <p><i>A statement that the drug is indicated for a particular indication only in conjunction with a primary mode of therapy</i></p>	<p><i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date</i> When listing studies, consider:</p> <ul style="list-style-type: none"> <li>• <i>The intent to develop evidence to support safety and efficacy in selected subgroups (i.e., limitations of use)</i></li> <li>• <i>Tests needed for selection or monitoring of patients (i.e., susceptibility tests)</i></li> <li>• <i>Whether safety considerations require the drug to be reserved for certain situations (i.e., in refractory patients)</i></li> <li>• <i>Whether the drug is to be used on a chronic basis</i></li> <li>• <i>What evidence will be developed to support comparator statements regarding safety or effectiveness</i></li> </ul>

## 1 Indications and Usage

Target	Annotations
<p><i>A statement that the drug is indicated in the treatment, prevention, or diagnosis of a recognized disease or condition, OR</i></p> <p><i>A statement that the drug is indicated for the treatment, prevention, or diagnosis of an important manifestation of a disease or condition, OR</i></p> <p><i>A statement that the drug is indicated for the relief of symptoms associated with a disease or syndrome, OR</i></p> <p><i>A statement that the drug is indicated for a particular indication only in conjunction with a primary mode of therapy</i></p>	<p><i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date</i></p> <p><i>When listing studies, consider:</i></p> <p><i>The intent to develop evidence to support safety and efficacy in selected subgroups (i.e., limitations of use)</i></p> <p><i>Tests needed for selection or monitoring of patients (i.e., susceptibility tests)</i></p> <p><i>Whether safety considerations require the drug to be reserved for certain situations (i.e., in refractory patients)</i></p> <p><i>Whether the drug is to be used on a chronic basis</i></p> <p><i>What evidence will be developed to support comparator statements regarding safety or effectiveness</i></p>

Comments:

## 2 Dosage and Administration

Target	Annotations
<p><i>For each indication, state the following:</i></p> <ul style="list-style-type: none"><li><i>• Route of administration Recommended usual dose</i></li><li><i>• Dose range shown to be safe and effective Exposure (dose- or blood level-response relationship, if any)</i></li><li><i>• Dosage intervals or titration schedule Usual duration of treatment course when treatment is not chronic</i></li><li><i>• Dosage adjustments (e.g., in specific genotypes, pediatric patients, geriatric patients, or patients with renal or hepatic disease)</i></li><li><i>• Tests for guiding dosing (e.g., target plasma drug levels, therapeutic range, response biomarkers)</i></li></ul>	<p><i>Summary information regarding completed or planned studies to support the safety and effectiveness of the proposed dosage and route of administration:</i></p> <p><i>Protocol #, Serial #, Submission date</i></p>

Comments:

### 3 Dosage Forms and Strengths

Target	Annotations
<i>Include information on the available dosage forms, including strength or potency of dosage form in metric system and a description of identifying characteristics of dosage forms</i>	<i>Summary information regarding completed or planned studies to support the dosage forms and strengths: Protocol #, Serial #, Submission date</i>

Comments:

### 4 Contraindications

Target	Annotations
<i>List situations in which the drug might be contraindicated, including: Increased risk of harm because of age, sex, concomitant therapy, disease state Adverse reactions which would limit use Known, not theoretical, hazards</i>	<i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date Or, literature references describing contraindication for drug class.</i>

Comments:

## 5 Warnings and Precautions

Target	Annotations
<p><i>Include a description of clinically significant adverse reactions and potential safety hazards and limitations of use because of safety considerations, as reasonable evidence of these issues is established or suspected during the drug development program. A causal relationship need not be demonstrated. Include information regarding any special care to be exercised for safe use, including precautions that are not required under any other section of the label. Identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions.</i></p>	<p><i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date Or, literature references describing significant adverse reactions shared by the drug class of the new drug.</i></p>

**Comments:**

## 6 Adverse Reactions

Target	Annotations
<p><i>Describe overall adverse reaction profile of the drug based on entire safety database. List adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable. Within a listing, adverse reactions should be categorized by body system, severity of the reaction, or in order of decreasing frequency, or by a combination of these, as appropriate. Within a category, adverse reactions should be listed in decreasing order of frequency.</i></p> <p><i>Include the studies in the development program that will address adverse reactions associated with a particular drug class.</i></p>	<p><i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date</i></p>

**Comments:**

## 7 Drug Interactions

Target	Annotations
<i>Describe clinically significant interactions, either observed or predicted (i.e., other prescription drugs or over-the-counter drugs, class of drugs, or foods such as grapefruit juice or dietary supplements); practical advice on how to prevent drug-drug interactions; (description of results from studies conducted or observations from the integrated safety summary); drug-laboratory test interactions (known interference of drug with lab test outcome).</i>	<i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date</i>

Comments:

## 8 Use in Specific Populations

Target	Annotations
<i>Consider the following: Limitations, need for monitoring, specific hazards, differences in response, or other information pertinent to the population.</i>	<i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date If there are no plans to study the drug in a specific population, include rationale.</i>

Comments:

**8.1 Pregnancy** (This subsection can be omitted if the drug is not absorbed systemically):

- *Teratogenic effects: Pregnancy Categories: A, B, C, D, X*
- *Non-teratogenic effects: Other effects on reproduction, the fetus, or newborn.*

**8.2 Labor and Delivery:** *Use during labor or delivery, effects on mother, fetus, duration of labor, delivery, and effects on later growth of newborn.*

**8.3 Nursing Mothers:** *If the drug is absorbed systemically, information about excretion of drug in human milk and effects on the nursing infant. Describe pertinent adverse events in animal offspring or tumorigenicity potential if it is detected or suspected.*

**8.4 Pediatric Use:** *Statements relevant to the use of the drug product in the pediatric population (birth to 16 years of age). Cite any limitations, need for monitoring, specific hazards, differences in response, or other information pertinent to the pediatric population.*

**8.5 Geriatric Use:** Statements relevant to the use of the drug product in the geriatric population (age 65 and older). Cite any limitations, need for monitoring, specific hazards, differences in response, or other information pertinent to the referenced population.

**8.6 Additional Subsections:** Use of drug in other specified populations (e.g., those with renal or hepatic impairment).

## 9 Drug Abuse and Dependence

Target	Annotations
<i>Include the following subsections, as appropriate for the drug:</i>	<i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date</i>

### Comments:

**9.1 Controlled Substance:** Anticipated DEA schedule.

**9.2 Abuse:** Identify types of abuse and adverse reactions pertinent to them. Identify particularly susceptible patient populations.

**9.3 Dependence:** Discuss potential for dependence and describe the characteristic effects resulting from psychological or physical dependence.

## 10 Over dosage

Target	Annotations
<p><i>Provide specific information about:</i></p> <ul style="list-style-type: none"><li>• <i>Signs, symptoms, and lab findings associated with an over dosage of the drug</i></li><li>• <i>Complications that can occur with overdose of the drug (e.g., organ toxicity)</i></li><li>• <i>Concentrations of the drug in biofluids associated with toxicity or death</i></li><li>• <i>The amount of the drug in a single overdose that is ordinarily associated with symptoms, and the amount of the drug in a single overdose that is likely to be life-threatening</i></li><li>• <i>Whether the drug is dialyzable</i></li><li>• <i>Recommended general treatment procedures</i></li></ul>	<p><i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date. Update with human data, if available.</i></p>

**Comments:**

## 11 Description

Target	Annotations
<p><i>Include the proprietary name and established name, dosage form and route of administration, qualitative and quantitative ingredients, pharmacologic or therapeutic class, and any other important physical and chemical characteristics.</i></p>	<p><i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date.</i></p>

**Comments:**

## 12 Clinical Pharmacology

Target	Annotations
<i>Include a concise factual summary of the clinical pharmacology and actions of the drug in humans. Data that describe the drug's pharmacologic activity can be included in this section, including biochemical or physiological mechanism of action, pharmacokinetic information, degree of absorption, pathway for biotransformation, percent dose unchanged, metabolites, rate of half-lives including elimination concentration in body fluids at therapeutic and toxic levels, degree of binding to plasma, degree of uptake by a particular organ or fetus, and passage across the blood-brain barrier. Include the following subsections:</i>	<i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date.  If applicable, a subsection (e.g., 12.4 Microbiology) can be created under this section heading and all of the microbiology information for antimicrobial products consolidated into that subsection.</i>

### Comments:

**12.1 Mechanism of Action:** Summarize established mechanisms of action in humans at various levels (e.g., receptor membrane, tissue, organ, whole body). Do not include theorized mechanisms of action.

**12.2 Pharmacodynamics:** Include a description of any biochemical or physiologic pharmacologic effects of the drug or active metabolites related to the drug's clinical effect or those related to adverse effects or toxicity. Include data on exposure-response relationship and time course of pharmacodynamic response.

**12.3 Pharmacokinetics:** Describe clinically significant pharmacokinetics of a drug or active metabolites (i.e., pertinent absorption, distribution, metabolism, excretion parameters). Include results of pharmacokinetic studies that establish the absence of an effect, including pertinent human studies and in vitro data.



### 13 Nonclinical Toxicology

Target	Annotations
<i>Include the following subsections, as appropriate:</i>	<i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date</i>

#### Comments:

#### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility:**

*Results of long-term carcinogenicity studies — species identified*

*Mutagenesis results*

*Reproduction study results*

**13.2 Animal Toxicology and/or Pharmacology:** *Ordinarily, significant animal data necessary for safe and effective use of the drug in humans should be included in other sections of the labeling, as appropriate. If the pertinent animal data cannot be appropriately incorporated into other sections of the labeling, this subsection can be used.*

### 14 Clinical Studies

Target	Annotations
<i>Provide a description of studies that support statements about the efficacy or safety benefits. Consider including a description of supporting tables and graphs.</i>	<i>Summary information about completed or planned studies regarding the intent to develop evidence to support benefits of treatment (i.e., safety or efficacy benefits of primary or secondary endpoints in the selected population): Protocol #, Serial #, Submission date, Measurement instruments (e.g., patient reported outcomes instrument), and references to supporting development and validation documentation.</i>  <i>Also consider including where the studies will be (or have been) run (i.e., geographical area).</i>

#### Comments:

- 15 References** — Can include when labeling must summarize or otherwise rely on recommendation by authoritative scientific body, or a standardized methodology, scale, or technique, because information is necessary for safe and effective use.

**16 How Supplied/Storage and Handling**

Target	Annotations
<p><i>Include information about the available dosage forms to which the labeling will apply and for which the manufacturer or distributor will be responsible. For example:</i></p> <ul style="list-style-type: none"> <li>• <i>Strength of the dosage form</i></li> <li>• <i>Units in which the dosage form ordinarily is available</i></li> <li>• <i>Information to facilitate identification of dosage forms</i></li> <li>• <i>Special handling and storage conditions</i></li> </ul>	<p><i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date</i></p>

**Comments:**

**17 Patient Counseling Information**

Target	Annotations
<p><i>Include information for prescribers to convey to patients to use the drug safely and effectively. For example:</i></p> <ul style="list-style-type: none"> <li>• <i>Precautions concerning driving</i></li> <li>• <i>Concomitant use of other substances that may have harmful additive effects</i></li> <li>• <i>Proper use and disposal of syringes and needles Adverse reactions reasonably associated with use of the drug</i></li> <li>• <i>Lab tests and monitoring required</i></li> <li>• <i>Indicate whether a Patient Package Insert or MedGuide are planned.</i></li> </ul>	<p><i>Summary information regarding completed or planned studies to support the target: Protocol #, Serial #, Submission date</i></p>

1. This guidance has been prepared by the Office of New Drugs in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.
2. For the purposes of this guidance, all “*drug*” references *include* both human drugs and therapeutic biological products unless otherwise noted. All references to another product including *in vitro diagnostic* and other devices.
3. We update guidance periodically. To make sure you have the most recent version of a guidance, check the following web pages at:
  - [FDA About the Center for Drug Evaluation and Research](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm)  
(<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm>)
  - [FDA Device Advice: Comprehensive Regulatory Assistance](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)  
(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>).
  - [FDA Medical Devices](http://www.fda.gov/MedicalDevices/default.htm) (<http://www.fda.gov/MedicalDevices/default.htm>)
4. See the guidance for industry *Fast Track Drug Development Programs — Designation, Development, and Application Review*
5. A clean copy of the [Target Product Profile Template](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080593.pdf) can be found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080593.pdf>
6. [Critical Path Initiative](http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm):  
<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>