**DRUG FORMULARY COMMISSION**

**Drugs for Formulary Inclusion Consideration:**

**Evaluation and Review Form**

**November 5, 2015**

1. **Introduction**

Generic name:

Trade name:

Dosage form

National Drug Code (NDC) #

Manufacturer:

Classification: (see below)

**ADF Product Classification** – Check all that apply

☐ Physical / Chemical barrier

☐ Agonist / Antagonist combination

☐ Aversion

☐ Delivery System

☐ New Molecular entity or Prodrug

☐ Combination

☐ Novel Approach

1. **Preliminary Review**

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Preliminary Review of Individual Drug Product* |  |  |
| **Question** |  | **Result** | **Result** |
| 1 | *Does the drug have FDA abuse deterrent labeling or an abuse deterrent property?* | YES | NO |

* If the answer is yes, the drug will be fully evaluated.
* If the answer is no, the drug will not be further evaluated.

1. **Executive Summary**

Summary of analysis for consideration, including:

* + Reason and purpose of the evaluation:
    - New ADF into the market place
    - Therapeutic substitution of an ADF drug for a Non-ADF drug designated as having a heightened public health risk.
  + Summary of in-depth literature review and product evaluation
  + Summary of key data review.
  + Summary of how the proposed therapeutic substitute compared to the drug product in key Monograph content areas.
  + Strengths
  + Weaknesses

**IV. Monograph Content**

Every item will be addressed, even if no information is available or is not applicable.

1. **Reference Data**

* Mechanism of action
* Relevant Pharmacokinetic parameters drug
* data
* Pharmacologic class / Therapeutic Category
* Identification of similar drugs
* How properties compare to other similar medications

1. **Therapeutic indications/efficacy**

* Efficacy of ADF compared to non-ADF
* FDA approved versus non-FDA approved indications supported by the literature review.
* Drug studies, reference where applicable
* Post-marketing data where applicable

# Pharmacokinetics / Pharmacogenomics

* Absorption, bioavailability, extent and rate of absorption, factors affecting rate or extent of absorption
* Distribution, protein binding, volume of distribution, cross blood-brain barrier
* Metabolism, sites, extent, activity of metabolites
* Excretion, routes of elimination
* Special populations, pediatrics, renal or hepatic insufficiency, geriatrics
* Gender, Race

1. **Dosage forms**

* Forms and strengths
* Special handling or storage

1. **Dosage range**

* Adults
* Elderly
* Pediatrics
* Renal or hepatic insufficiency
* Special administration requirements—time of day, with regard to meals or other medications
* Gender

# Adverse effects

* List most frequent, most serious and distinguishing adverse reactions (addiction, overdose)
* Prevention of adverse effects

# Contraindications

* Special warnings and precautions

1. **Toxicities**

* Pregnancy
* Lactation
* Use with impaired liver function, Hep C

# Drug interactions

* Drug-drug
* Drug-food
* Include reported and theoretical, rating

1. **Patient monitoring guidelines**

* Effectiveness
* Compliance

1. **Cost Effectiveness**

* Compare to other therapies
* Cost impact
* Accessibility

**12) Utilization Data**

* Prescriptions written / dispensed
* Solid dose quantity dispensed
* Average days supply dispensed
* High Prescriber Utilizers
* Multiple Prescriber Episodes
* Pharmacy with high number of MPE episodes

**V. References**

Listed in the order they are cited.