DRUG FORMULARY COMMISSION
Drugs for Formulary Inclusion:
DRAFT Evaluation and Review
October 15, 2015

I. Introduction

Generic name:
Trade name:
Manufacturer:
Classification[i]:

II. Preliminary Review

a. Section 1:

	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 evaluated in Section 2.
- If the answer is no, the drug will not be further evaluated.

b. Section 2:

	Preliminary Review of Individual Drug Product		
Question		**Result**	**Result**
2	*Does the dosage form have significant utilization of prescriptions written and dosage units dispensed (defined as >25,000 prescriptions written and 1,000,000 dosage units dispensed)?*	YES	NO

- If the answer is yes, the drug will be fully evaluated and all of the factors in the monograph will be applied.
- If the answer is no, the drug will not be further evaluated.

III. Executive Summary

- Summary of analysis for consideration, including:
  - 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 key literature review.

- Summary of key data review.
- Summary of how the proposed therapeutic substitute compared to the drug product in key Monograph content areas.

IV. Monograph Content

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

1) Reference Data

- Mechanism of action
- Pharmacokinetic data
- Pharmacologic class
- Identification of similar drugs
- How properties compare to other similar medications

2) 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

3) Pharmacokinetics

- 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

4) Dosage forms

- Forms and strengths
- Special handling or storage

5) Dosage range

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

6) Adverse effects

- List most frequent, most serious and distinguishing adverse reactions
- Prevention

7) Contraindications

- Special warnings and precautions

8) Toxicities

- Pregnancy
- Lactation

9) Drug interactions

- Drug-drug
- Drug-food
- Include reported and theoretical

10) Patient monitoring guidelines

- Effectiveness
- Adverse effects
- Compliance

11) Cost Effectiveness

- Compare to other therapies
- Cost impact
- Accessibility

12) 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.

[i] This is the table that corresponds to the "Classification" designation contained within this section.

Classification System	
By Chemical Type	
Type	**Definition**
1	New molecular entity not marketed in U.S.
2	New salt, ester, or other derivative of another drug marketed in the U.S.
3	New ADF formulation of a drug marketed in U.S.
4	Type of ADF technology
5	Manufacturer Post-Marketing data if available
6	Additional references