



# **P.E.P. Regulation**

**A Framework for Analysis**

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# **P.E.P. Regulation**

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- **What Kinds of Products?**
- **Performing What Functions?**
- **Used By Whom?**
- **Used When?**
- **Regulated As What?**

# What Kind of Products?

- **What are the key ingredients?**
  - **Protein?**
  - **Vitamins/minerals?**
  - **Electrolytes?**
  - **Creatine?**
  - **Pyruvate?**
  - **DHEA?**
  - **Ephedra?**
  - **Andro/"Pro-hormones"?**



# What Kind of Products?

- **What are the product forms?**
  - **Drinks?**
  - **Powders?**
  - **Bars?**
  - **Tablets?**
  - **Capsules?**
  - **Other?**



# What Functions?

- **General nutrition?**
- **Energy?**
  - Immediate?
  - Sustained?
- **Muscle building?**
- **Alertness?**
- **Pre/During/Post Performance?**

# Used by Whom?

- **Gender specific or unisex?**
- **Age specific?**
  - Adult?
  - Teens?
  - Children?
- **Performance Level?**
  - Professional?
  - Dedicated?
  - Casual?

# Used When?

- **Sustained performance?**
  - Team sports?
  - Individual efforts?
- **Episodic use?**
  - By type of activity?
  - By performance goals?
  - By peer pressure?

# Regulated as What?

- **Integrates answers to prior questions**
- **Options:**
  - **Conventional Food**
  - **Special Dietary Food**
  - **Dietary Supplement**
  - **Drug**



# Regulated as What?

- **Conventional Food**
  - **Safety:**
    - “adulteration”
    - food additives
  - **Claims:**
    - “structure/function”
    - Performance
  - **Warnings: “failure to disclose”**

# Regulated as What?

- **Special Dietary Food**
  - **Safety:**
    - “adulteration”
    - food additives
  - **Claims:**
    - Weight gain/loss
    - Supplementing the diet
  - **Warnings: “failure to disclose”**

# Regulated as What?

- **Dietary Supplements**
  - **Safety:**
    - “adulteration”
    - Grandfathering and notification
  - **Claims:**
    - Nutrient based
    - Section 403(r)(6)
  - **Warnings: as needed**

# Regulated as What?

- **Drug**
  - **Safety:**
    - **Benefit/Risk standard**
    - **cGMPs**
  - **Claims:**
    - **“Substantial Evidence” standard**
  - **Warnings: statutory mandate**



# Ingredient Examples

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- **Caffeine –**
  - **Food: in coffee, tea and soft drinks**
  - **Dietary Supplement: for alertness**
  - **Drug: in OTC migraine products**



# **Ingredient Examples**

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- **Ascorbic Acid**
  - **Food: as a nutrient supplement and preservative**
  - **Dietary Supplement: as a nutrient**
  - **Drug: as a treatment**



# Product Examples

- **Food:**
  - **Electrolyte drinks**
  - **Protein products**
    - **Powders**
    - **Bars**
  - **Carbohydrate products**
    - **Immediate Energy**
    - **Sustained Energy**



# Product Examples

- **Dietary Supplements:**
  - Ephedra
  - Ginseng
  - Caffeine
  - Andro
  - DHEA
  - Vitamin-Minerals
  - Creatine





# Framework Summary

1. Determine the Product Form
2. Determine the Product Claims
3. Determine the Product Uses

These give you the product Category

Then you can determine the  
Form of Regulation