

Creating a Future Vision

A Regulatory Continuum for Supplements

The Regulatory Continuum



The Regulatory Continuum



The Regulatory Continuum

**Nutrient Content
Claims**

**Statements of
Nutritional Support**

**Health
Claims**

**Drug
Claims**

Foods

**Dietary
Supplements**

OTCs

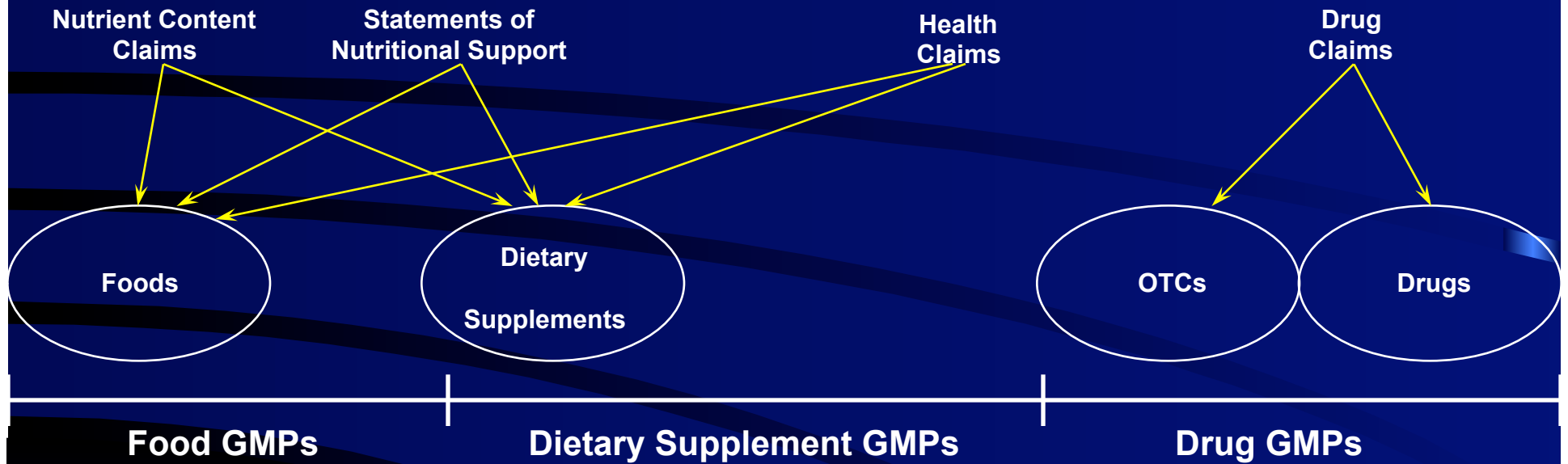
Drugs

Food GMPs

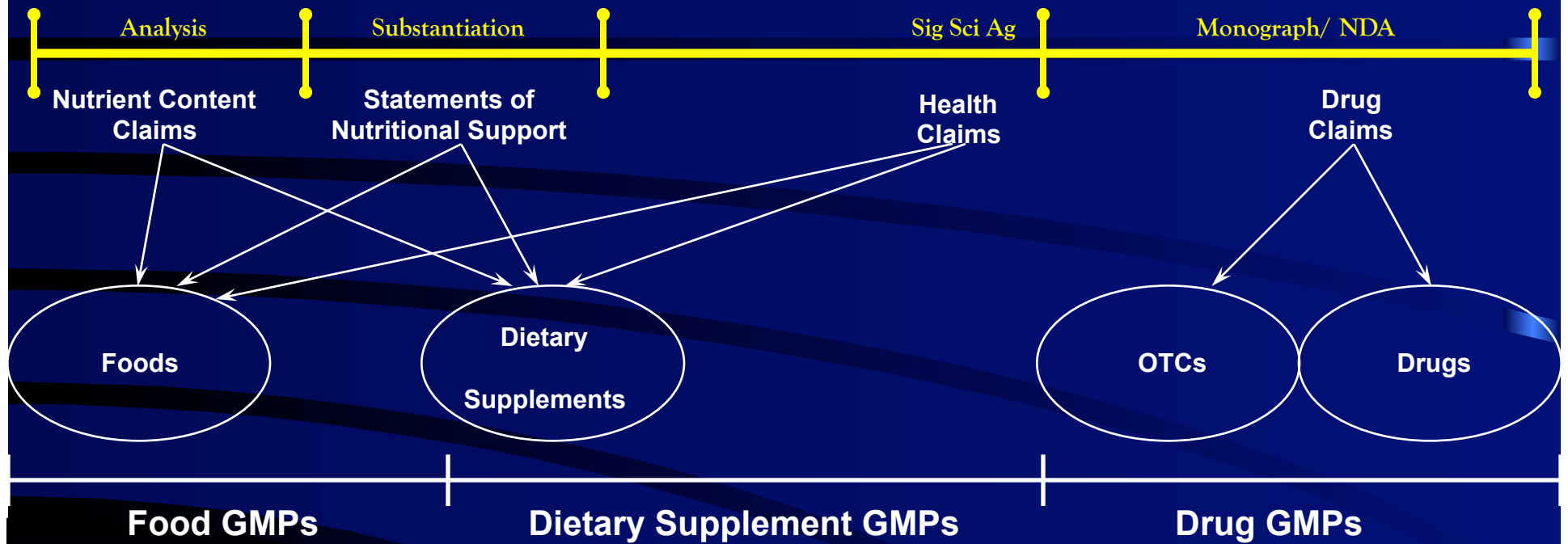
Dietary Supplement GMPs

Drug GMPs

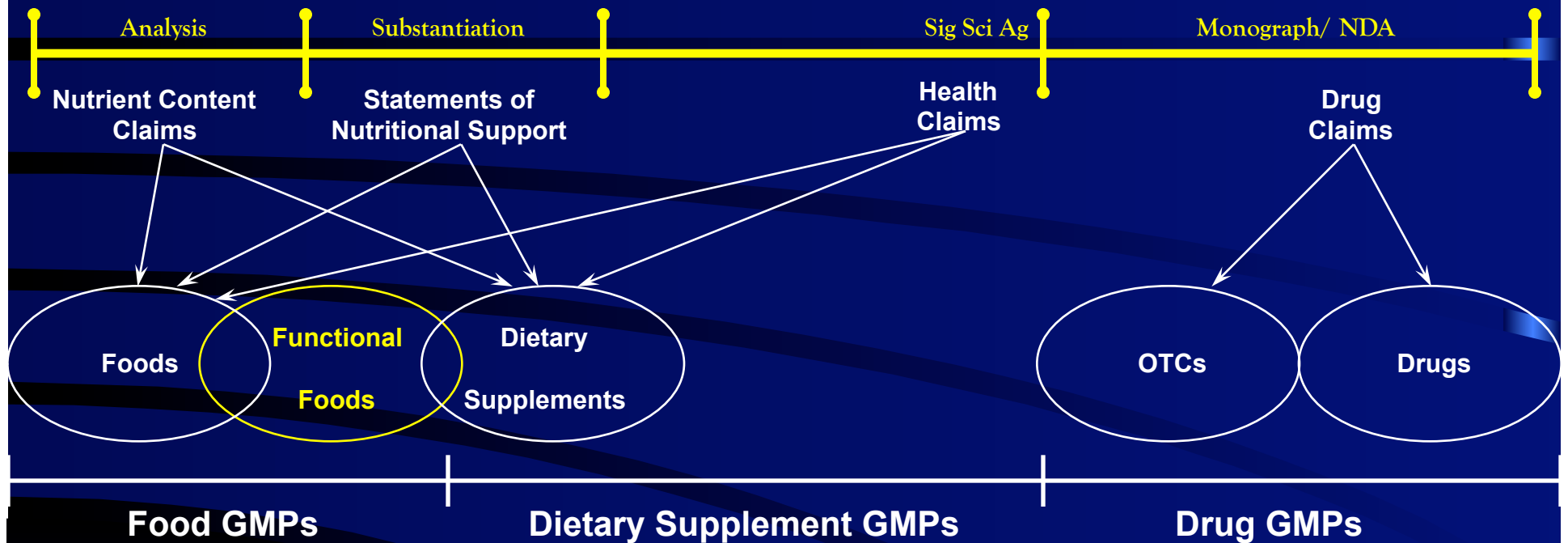
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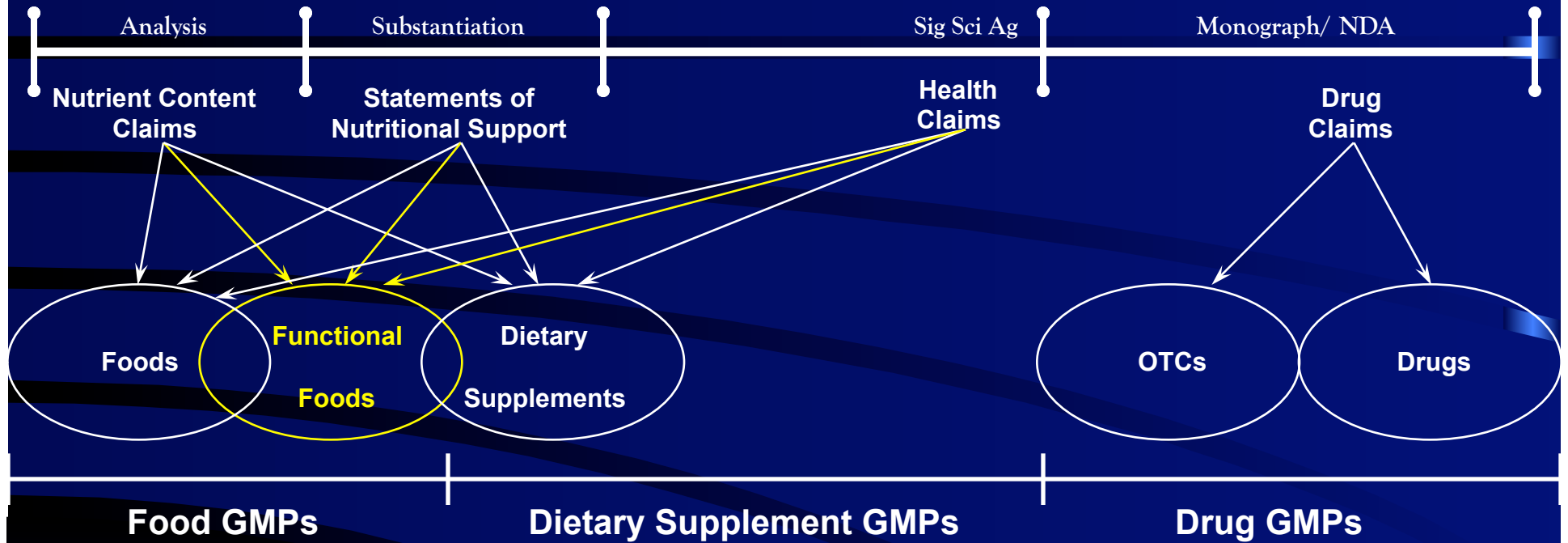
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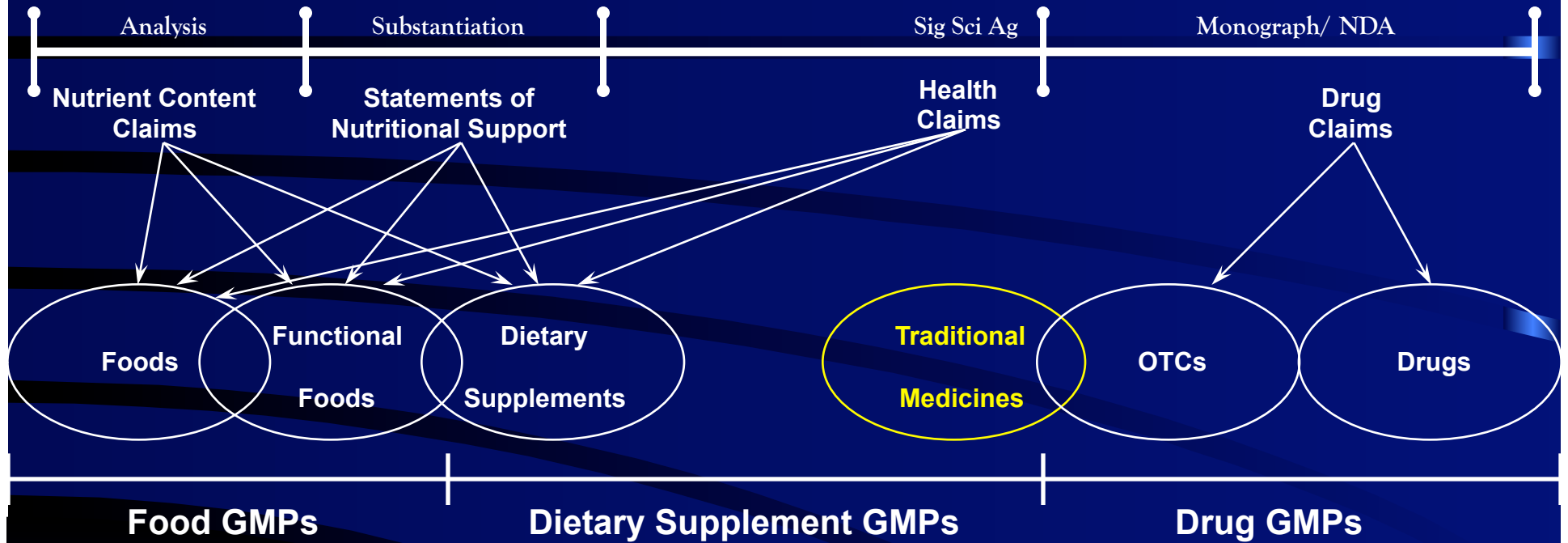
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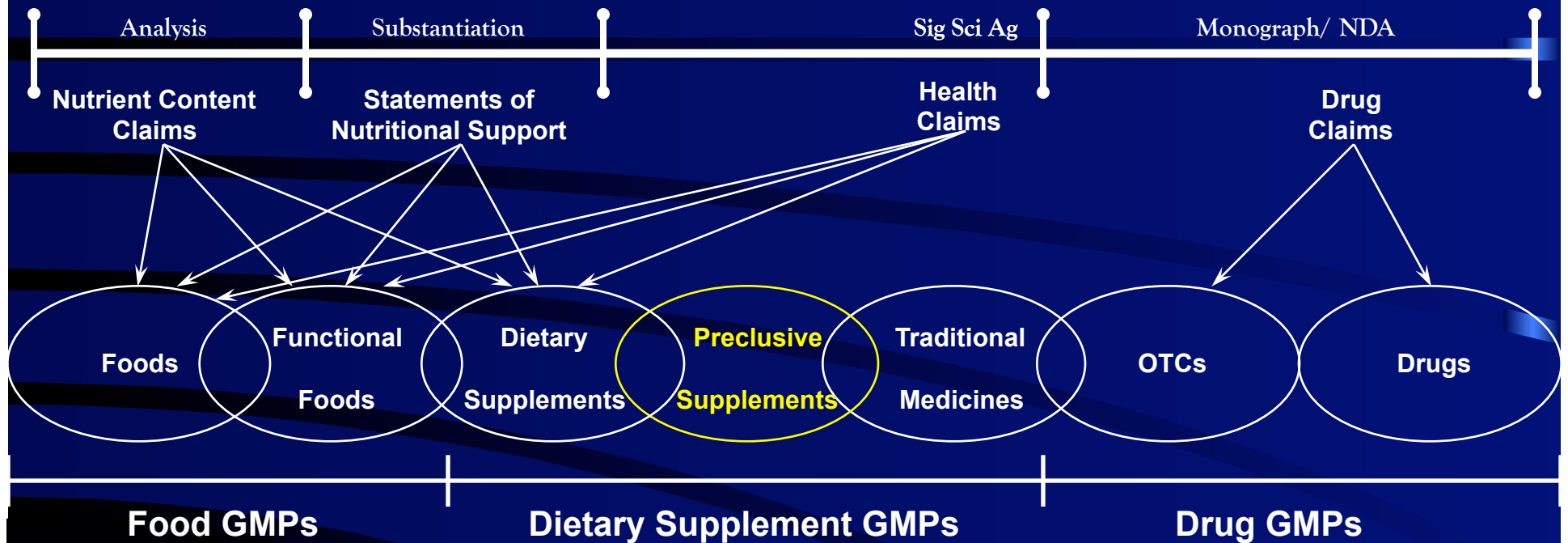
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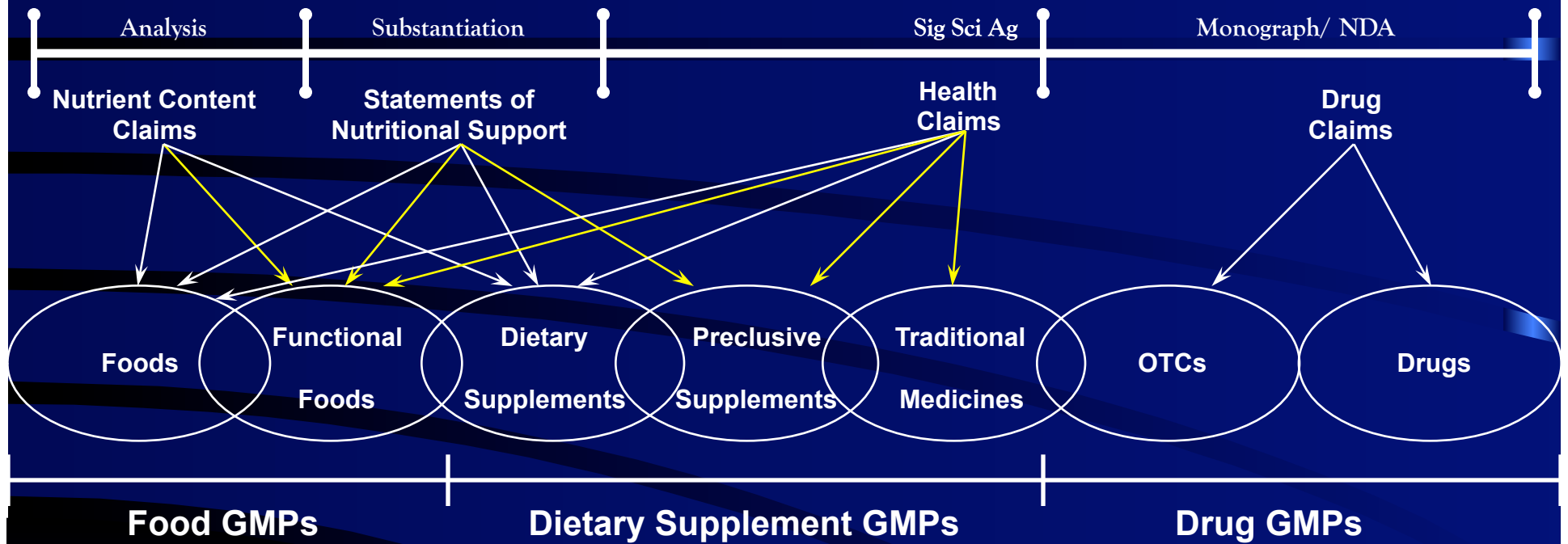
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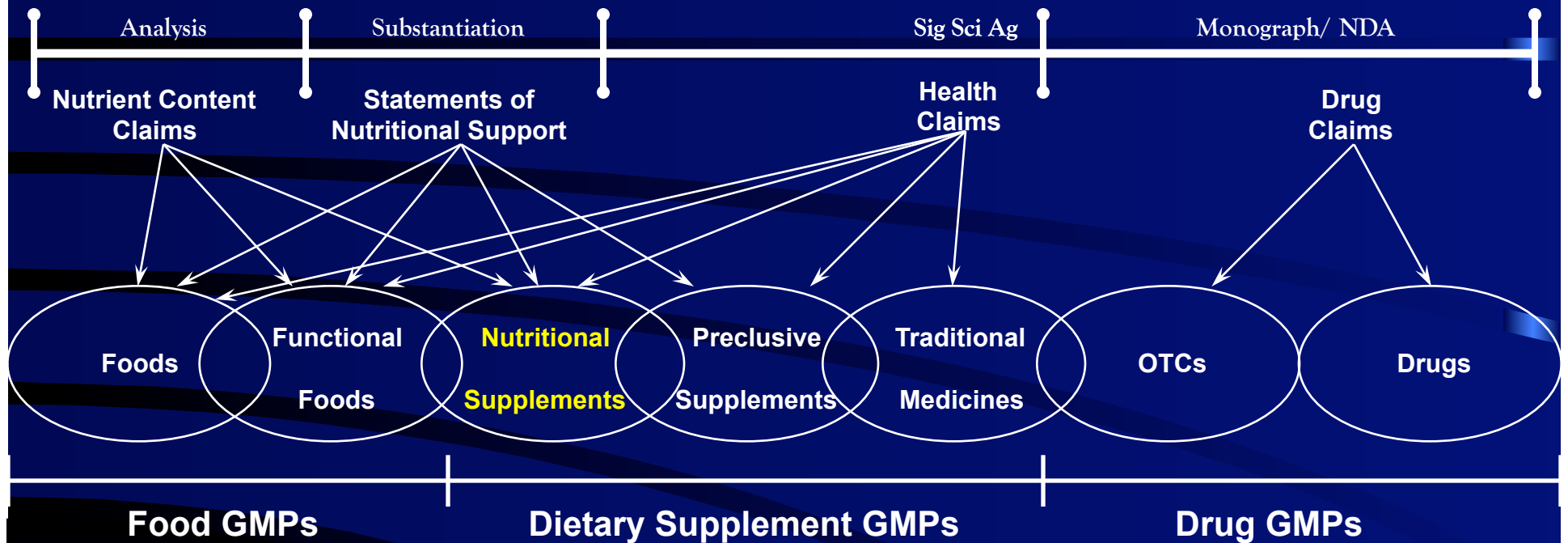
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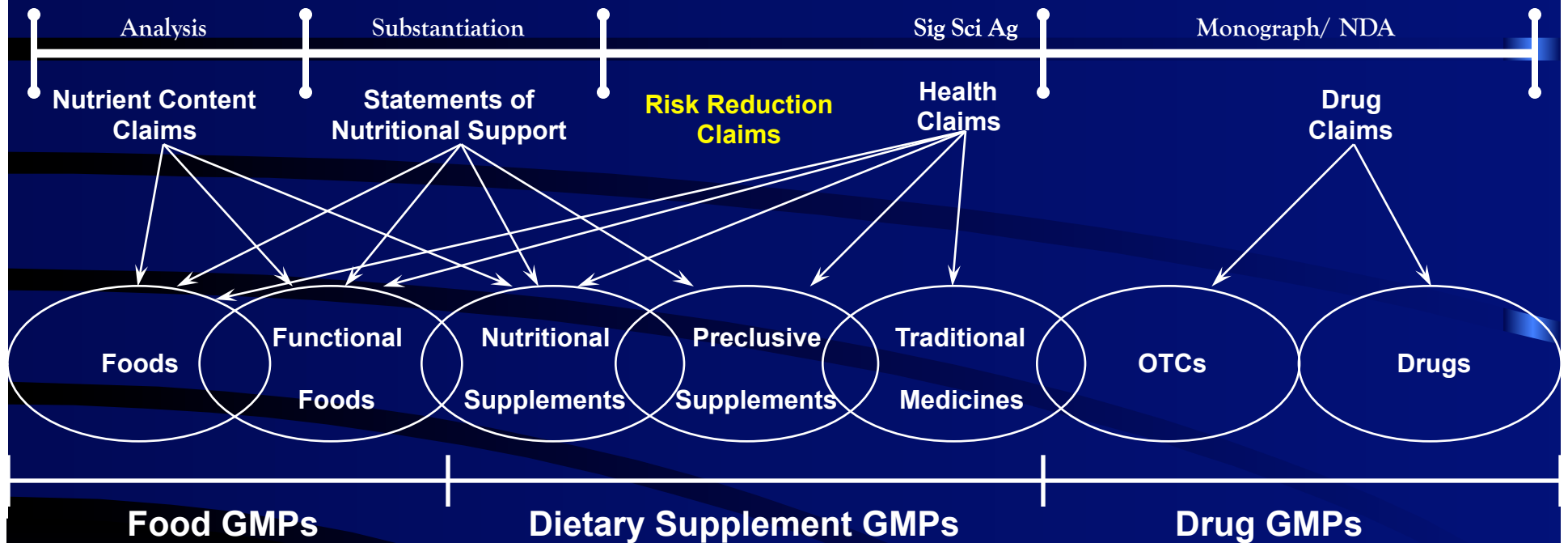
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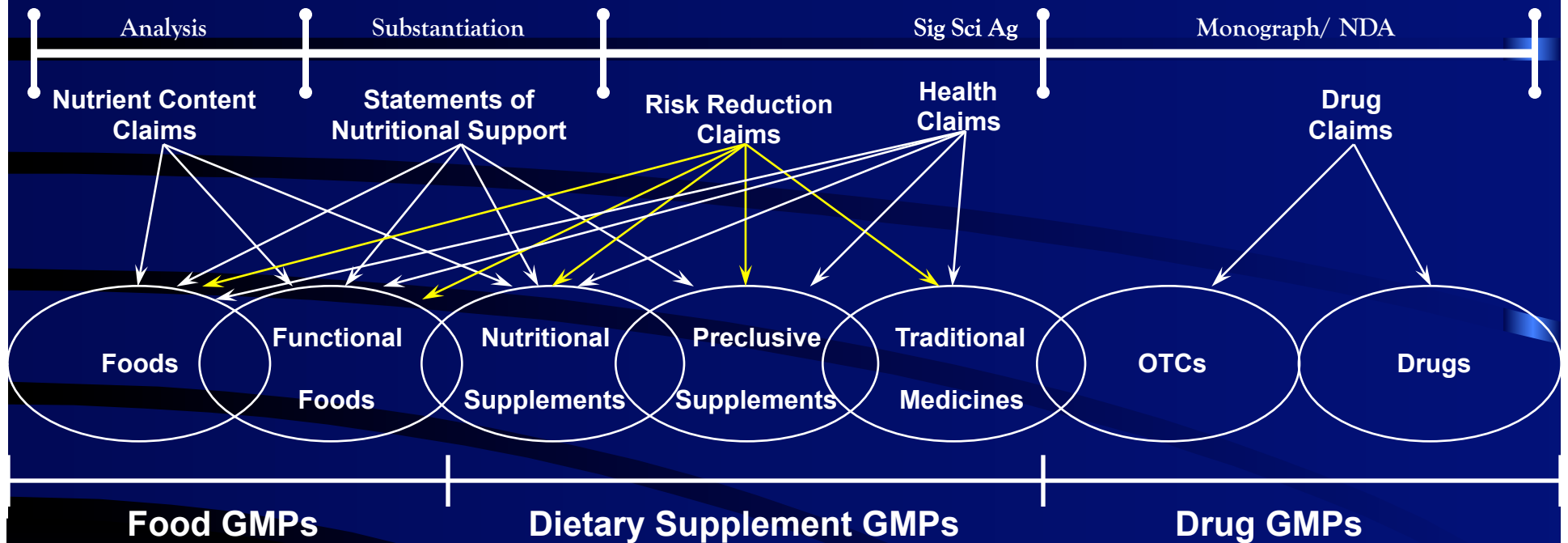
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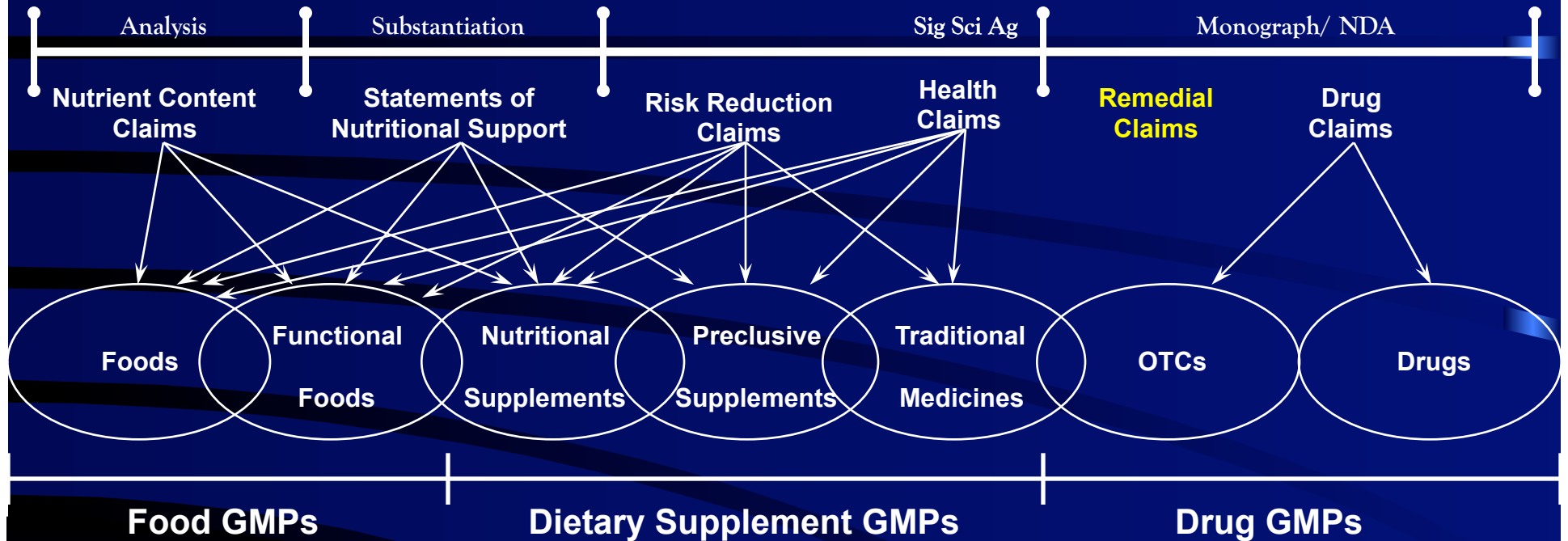
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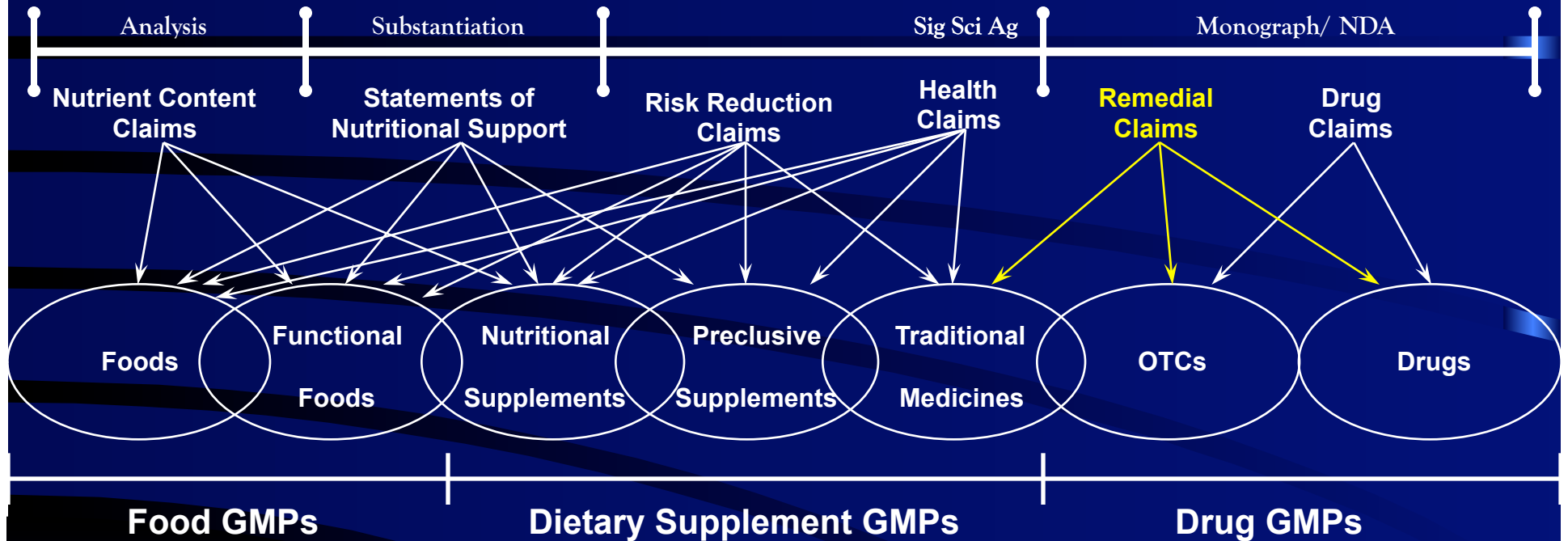
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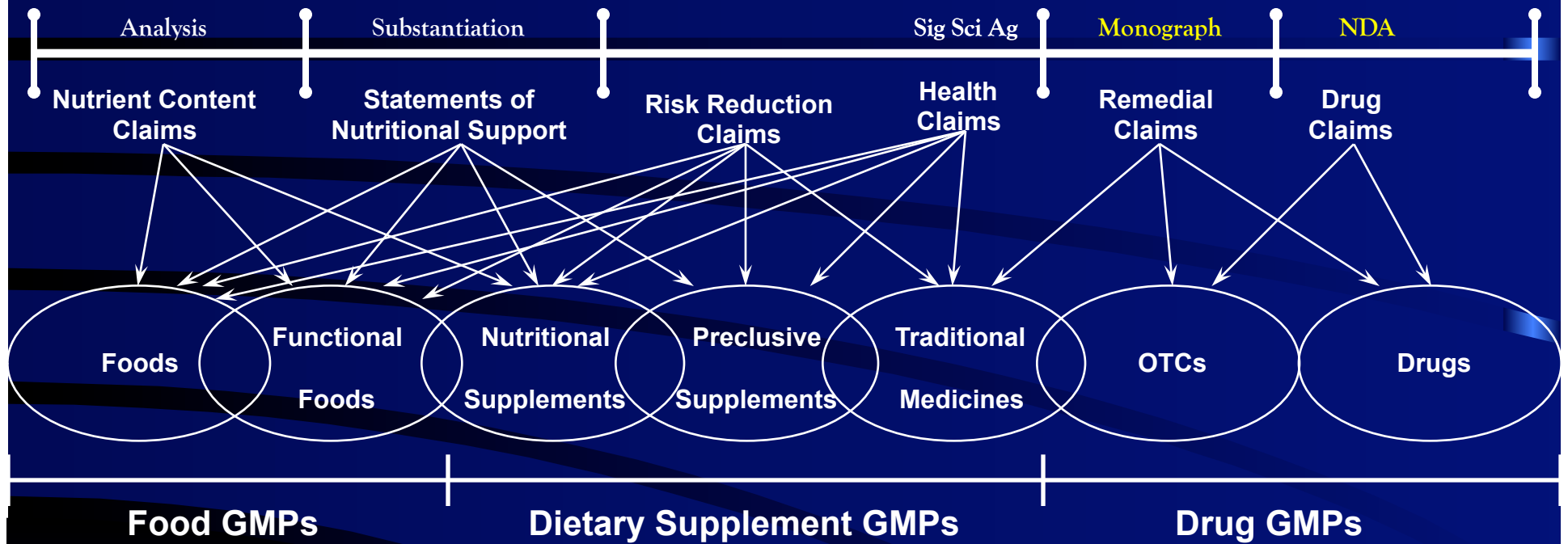
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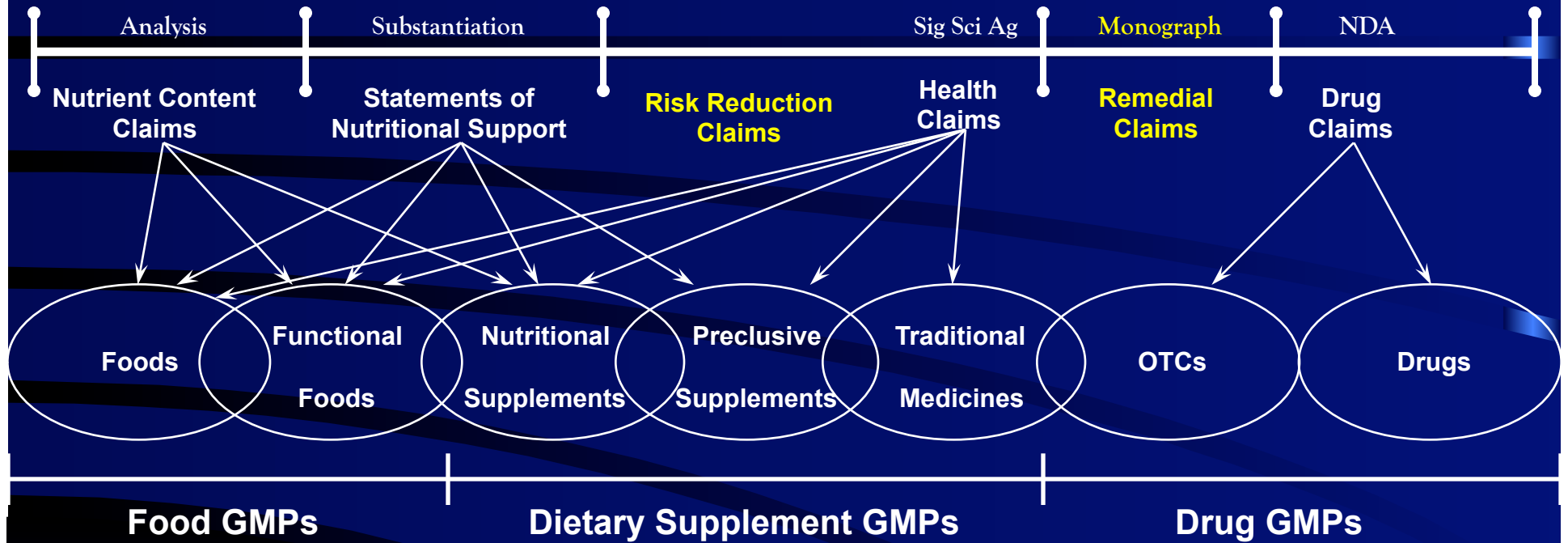
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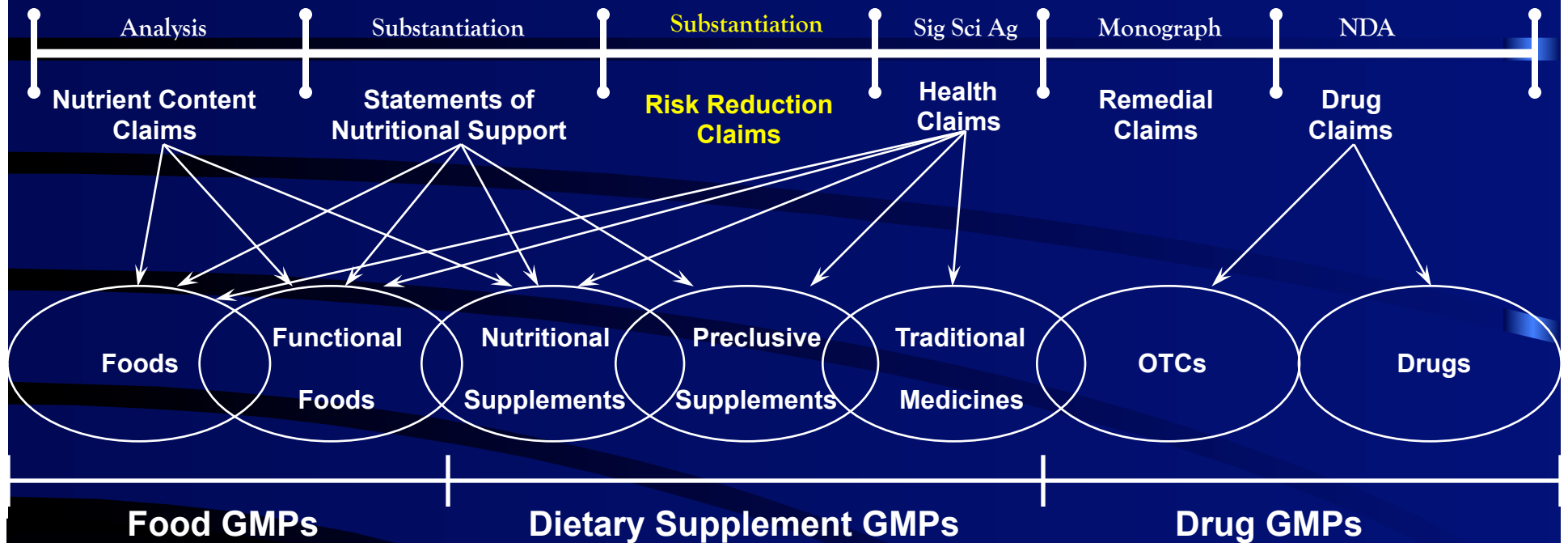
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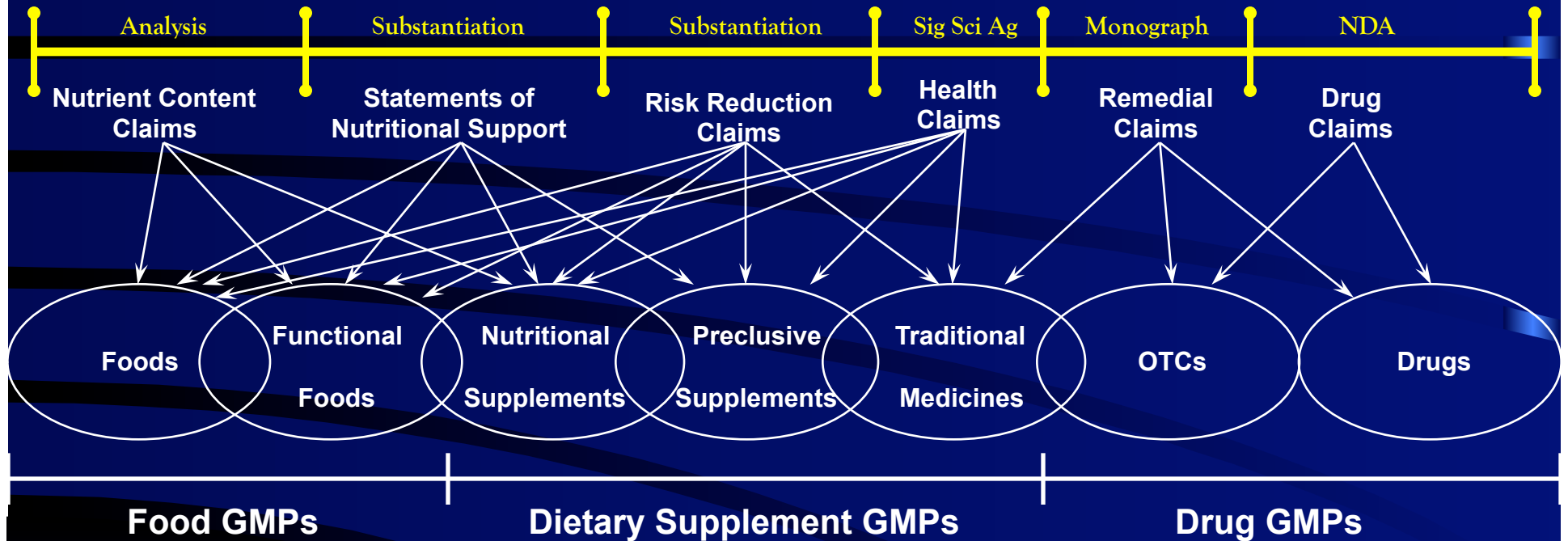
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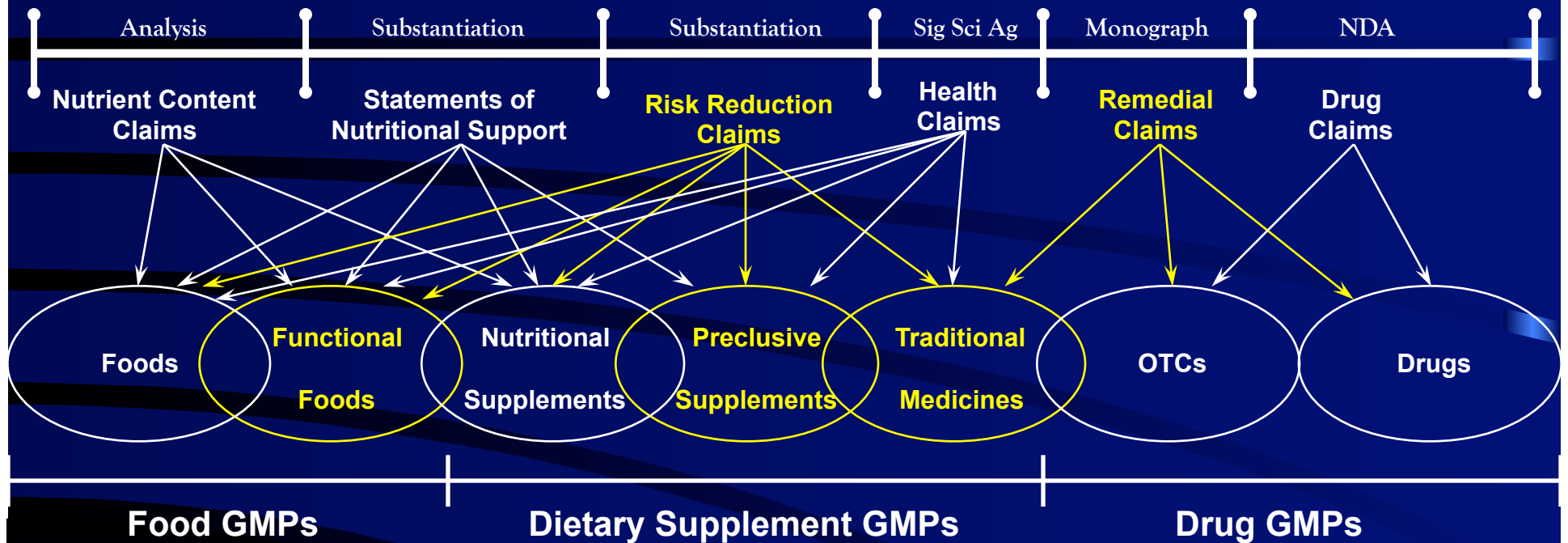


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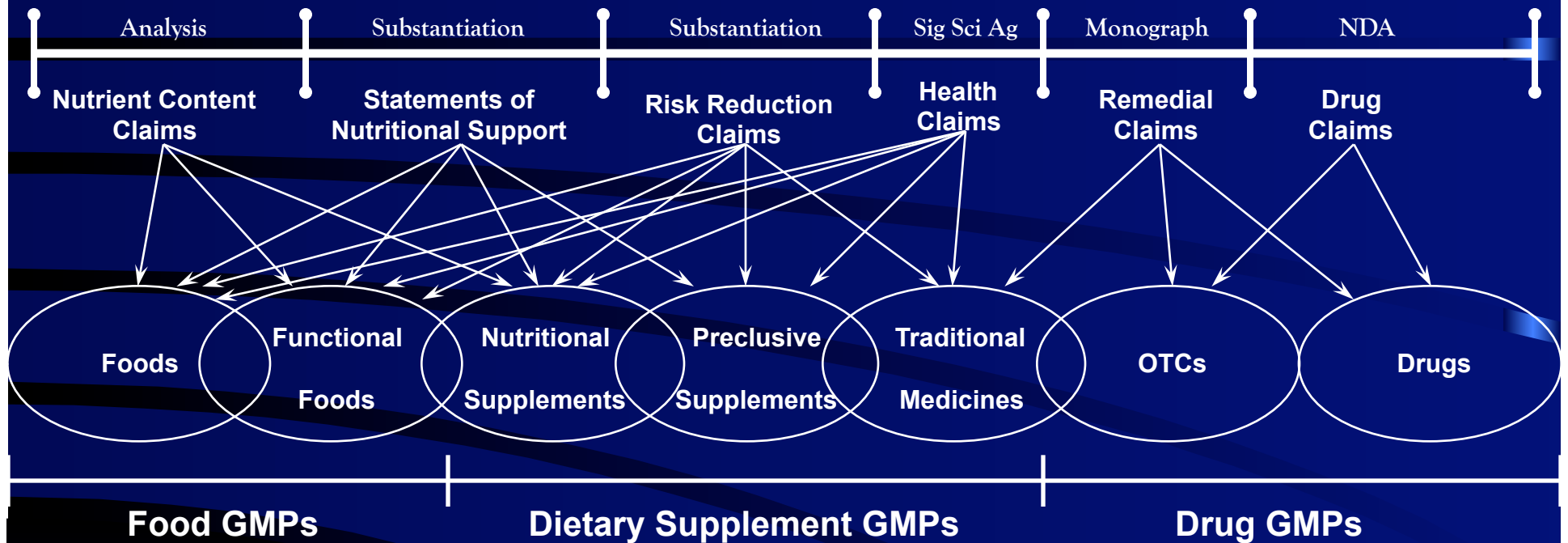
**This is the evidenced Most Obvious Gaps and Solution
Clear Delineation Yields An Obvious Fit**

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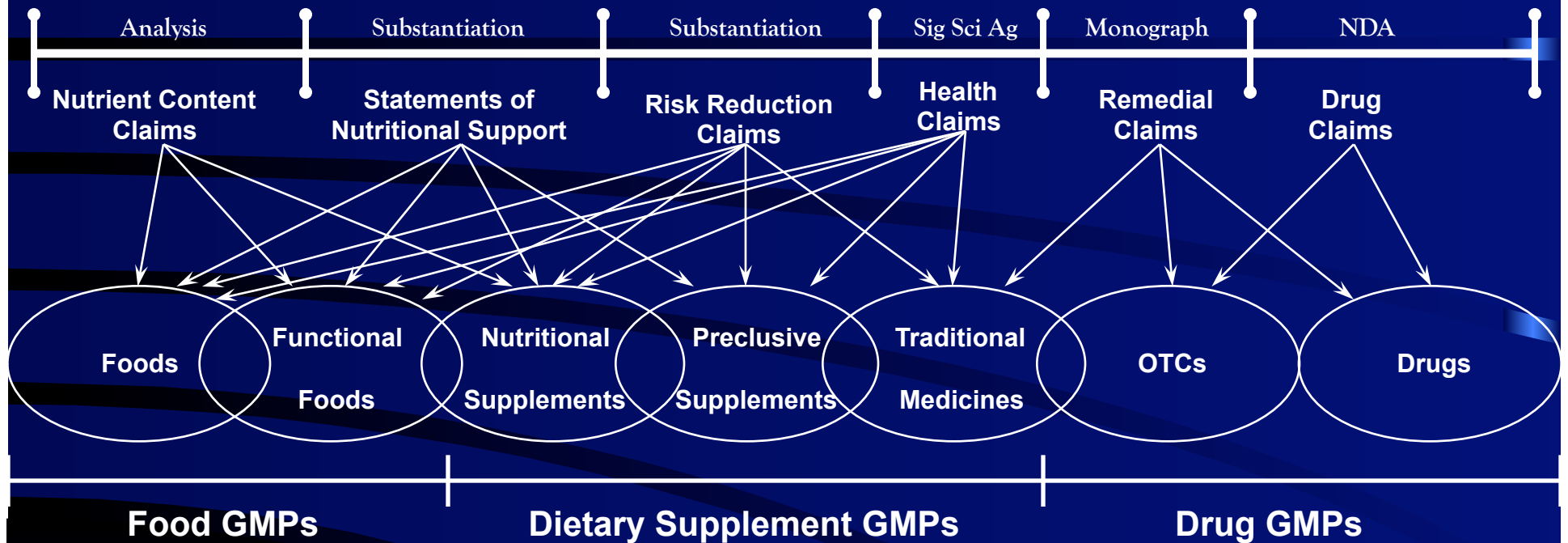
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This continuum is a "Should" Position for the products currently in the scheme of regulatory flux out of the FDC Act. The overlaps are obvious and the non-overlap between OTCs and Drugs is mandatory. This perspective is a roadmap for where things should be in the ultimate future of the Industry.

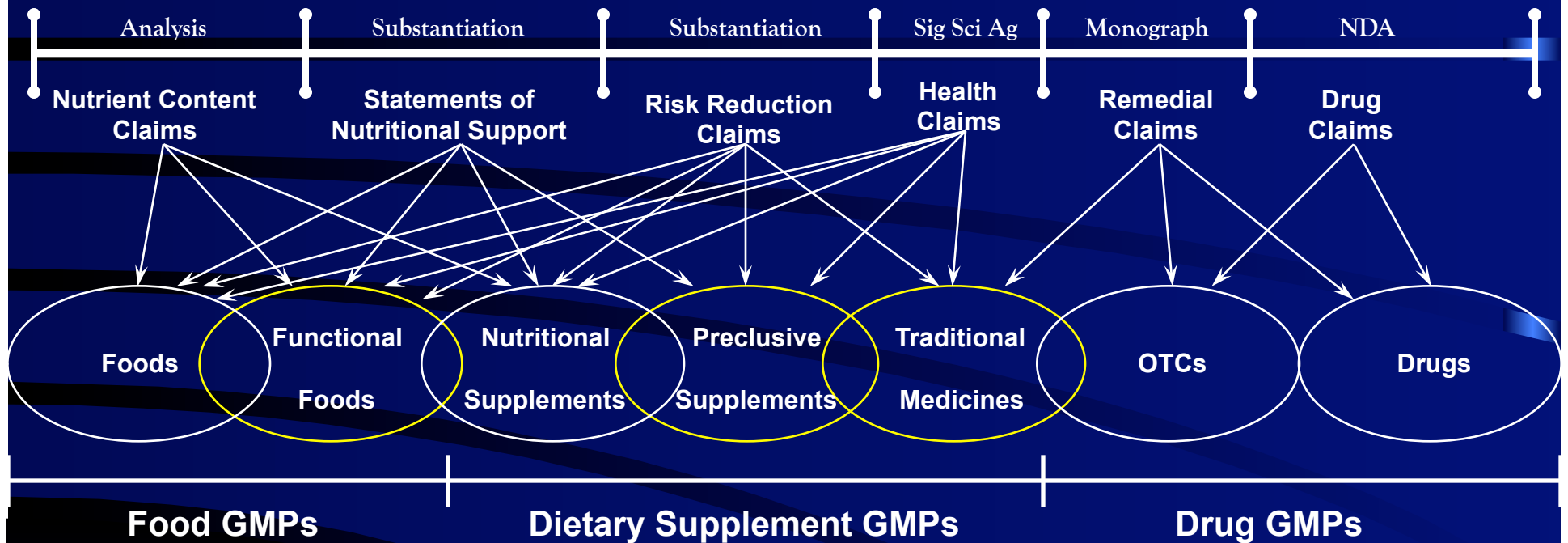
This requires the creation of subclasses of claims demonstrating the *de facto* product categories that exist. These product categories exist within the definition of Dietary Supplements and are defined by the Claims available.

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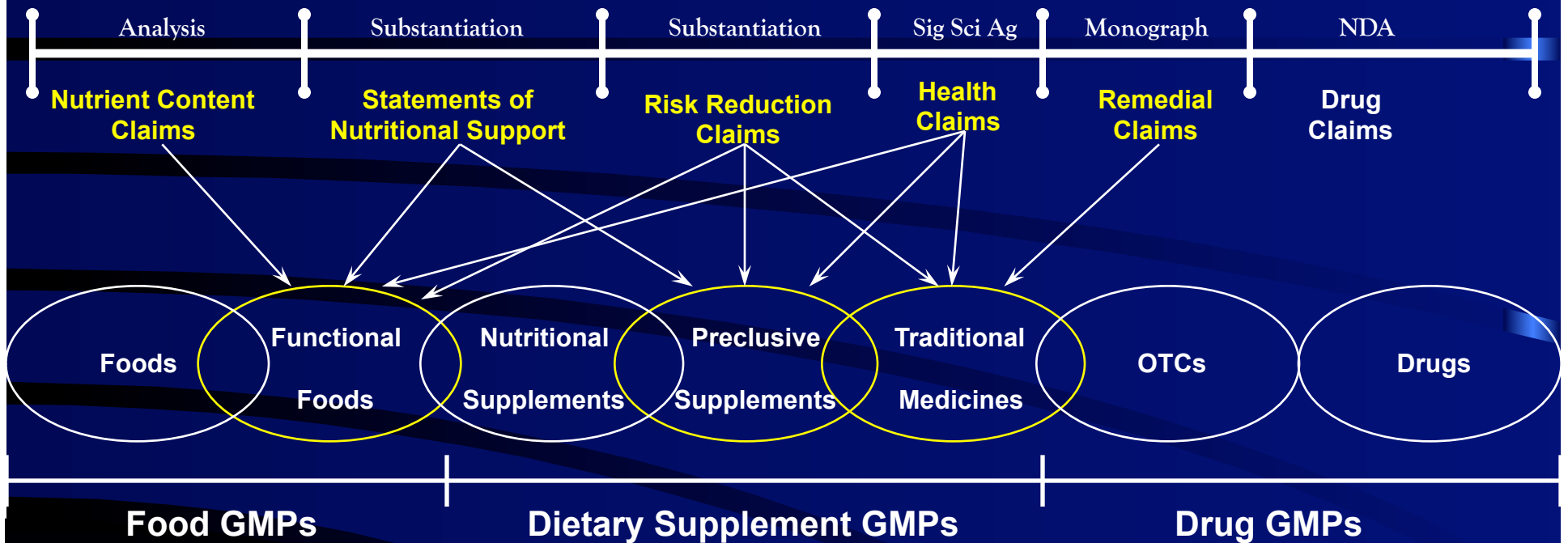
The new claims categories achieve the same effect as the existing categories. They drive forward the flow of information to the consumer as mandated by NLEA, DSHEA, FDAMA, Pearson v. Shalala and other efforts of recent years. The new claim categories also drive information out for existing product classes. The achievement of these claims is what serves as the underpinning and superstructure for providing important health messages to the consumer.

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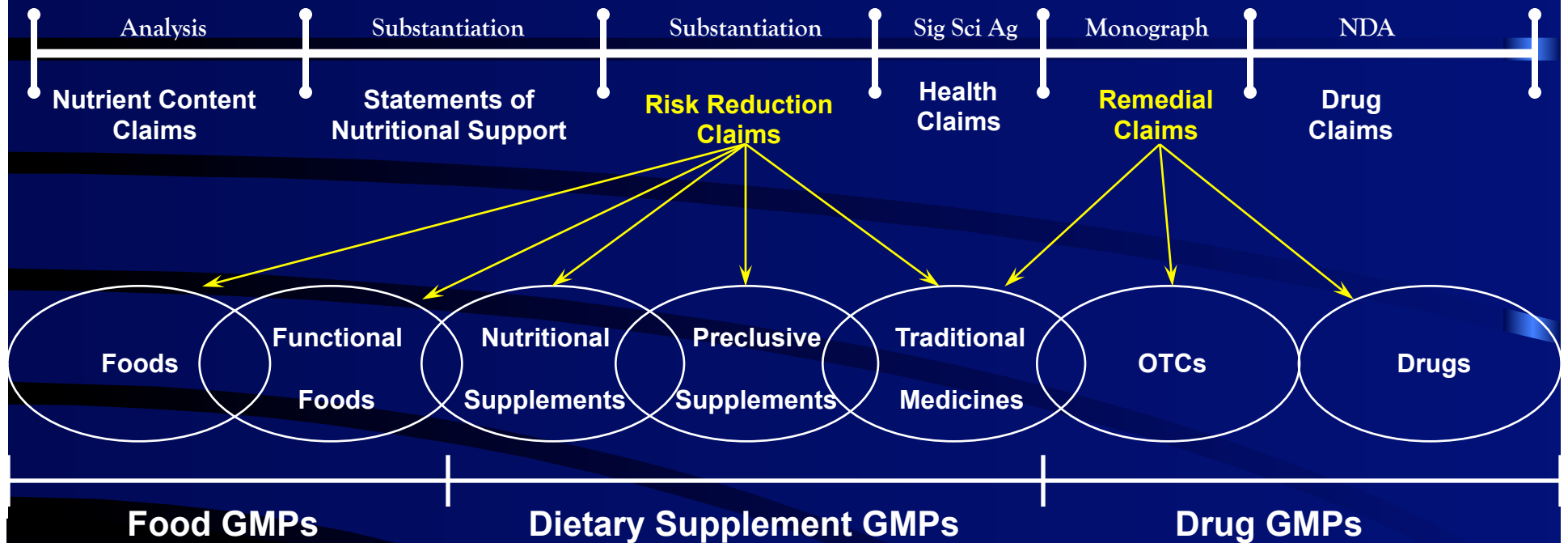
The presence of the new Classes covers the gaps in current classifications, acknowledges products in the industry and market while overlapping appropriately. The coverage and overlap clarifies while allowing for transition between categories in a seamless fashion. The open issue is the substantiation requirements that would allow producers and marketers to legitimately present these product classes with accurate information as to their use and benefit.

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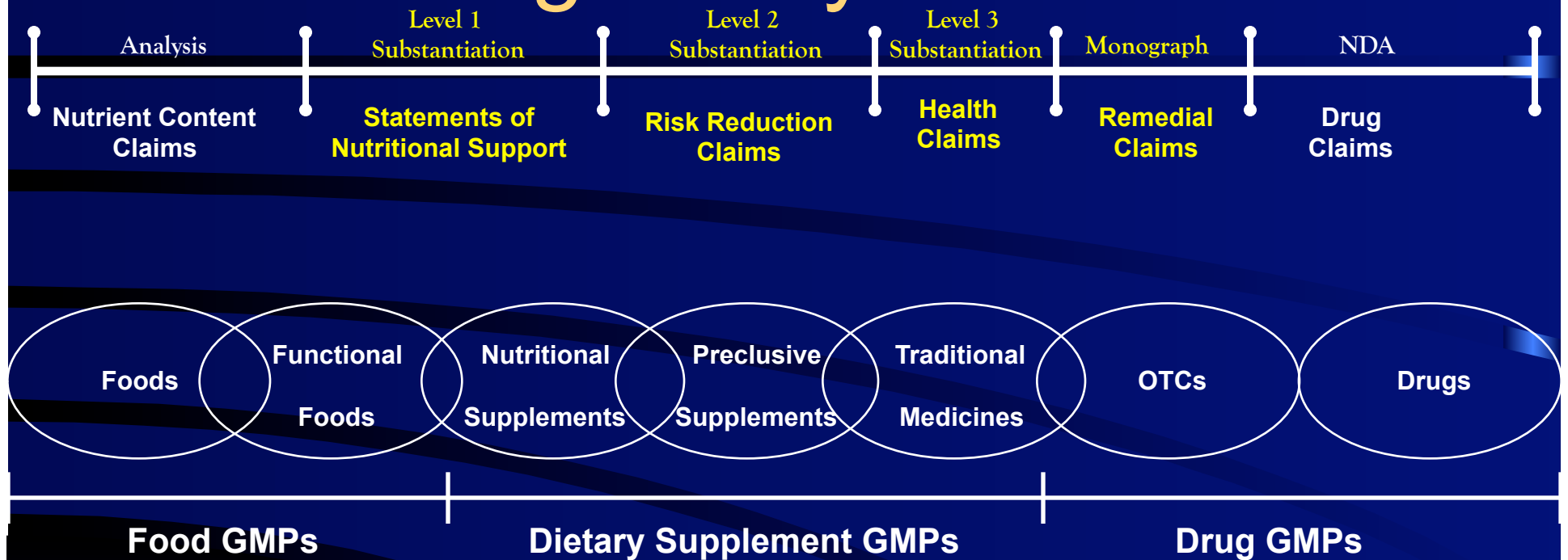


Application of the current and new claims categories to all classes of Dietary Supplements shows coverage for the product type that generated the challenge in the first place.

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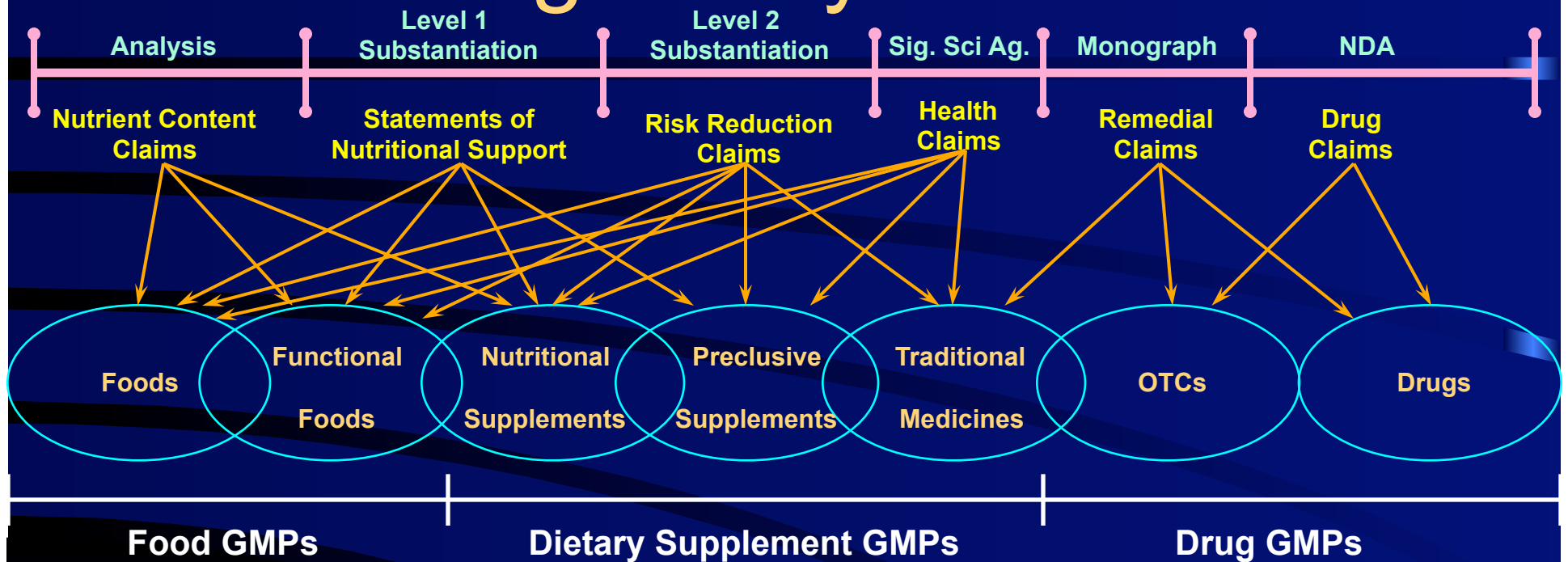


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A look at the requirements for substantiation now completes the puzzle and the gaps. This last piece is key to the success of such this initiative. Substantiation is required for these claims, the challenge is in gaining definition.

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The Future.

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- Nutrient Content Claims
 - *Contains 15 mg Protein per serving*
 - *Is a Good Source of Fiber*
 - *Low-Fat*

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- Statements of Nutritional Support
 - *Helps promote well-being.*
 - *Helps energize you.*
 - *Helps promote mental acuity.*
 - *Promotes restful sleep.*

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- Risk Reduction Claims.
- *Assists in the lowering of cholesterol levels in healthy individuals.*
- *Shown to reduce incidence of migraine headache.*
- *Shown to detoxify the liver.*

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- Health Claims
- *Please see your CFR for the complete listing.*

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- Remedial Claims
 - *Relieves non-chronic constipation.*
 - *Supportive therapy for colds and chronic infections of the respiratory tract.*
 - *Useful in the treatment of class I and class II cardiac insufficiency.*

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- Drug Claims
- *Please See your Prescription Drug Package Insert or Patient Information booklet.*