

Public Meeting New Dietary Ingredient Program

November 15, 2004

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FDA/CFSAN/ONPLDS

Division of Dietary Supplement Programs

Branches/Teams

- **Compliance - Robert Moore, Ph.D.**
- **Regulations and Review - Linda Pellicore, Ph.D.**
- **Clinical Evaluation - Jason Woo, M.D.**

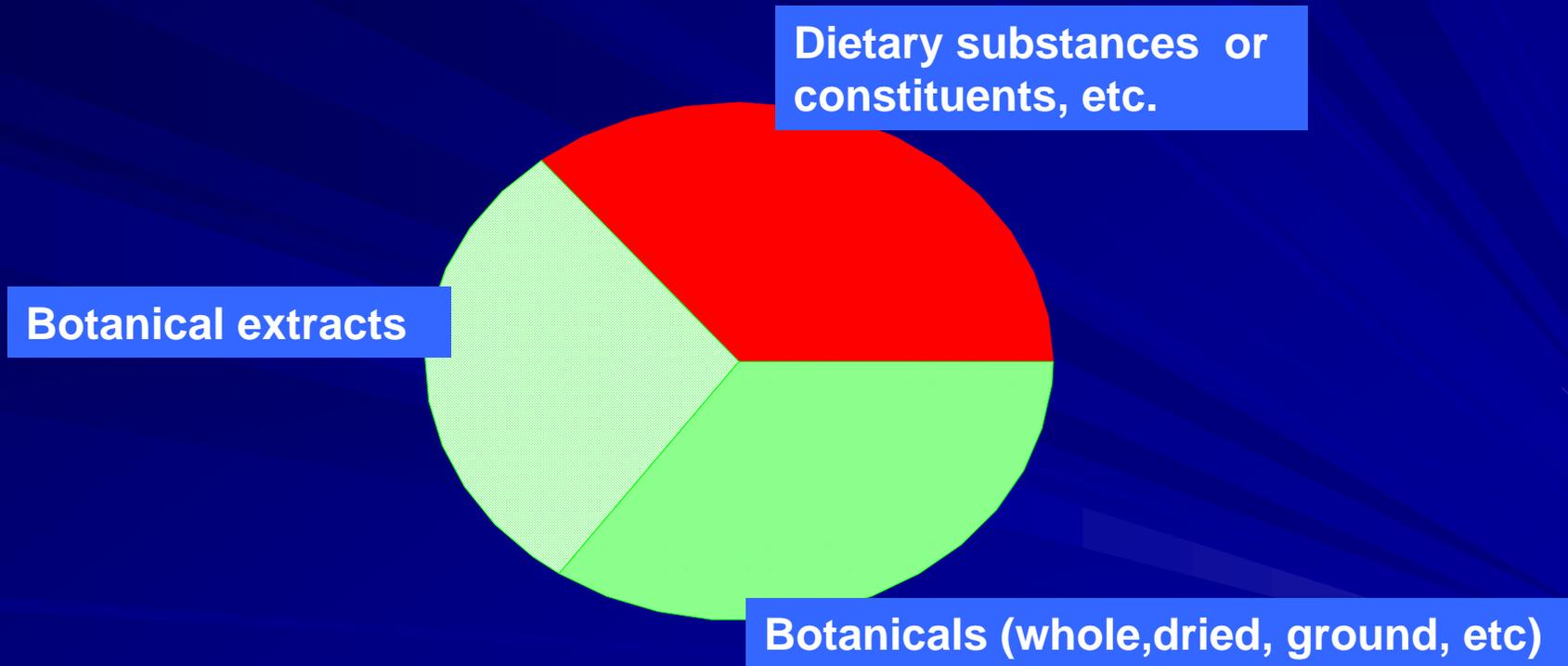
Special Assistant for Science Review

- **Vasilios Frankos, Ph.D.**

Additional Panel Members

- **Michael Landa,**
 - Deputy Director for Regulatory Affairs
- **Barbara Schneeman, PhD**
 - Director, ONPLDS
- **Jeanne Rader, PhD**
 - Director, Division of Research Applied Technology
- **Alan Rulis, PhD**
 - Senior Advisor for Special Projects

75 day New Dietary Ingredient Notifications



Vitamins, minerals and amino acids ?

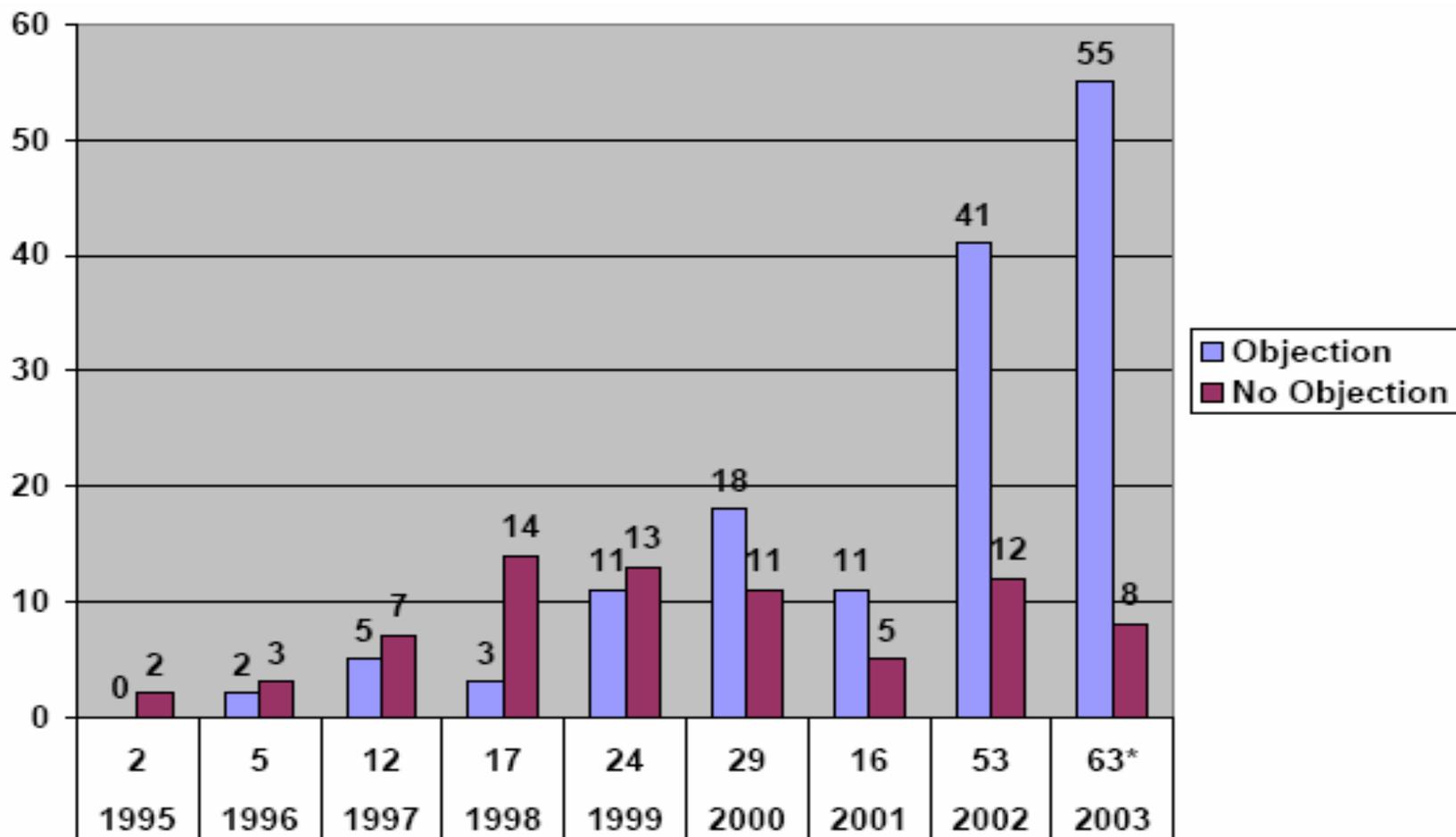
Concerns with Notifications

■ Failure to:

- Describe the new dietary ingredient
- Show why it is a new dietary ingredient
- Provide adequate safety information
- Provide other necessary information

■ Notifications and FDA responses publicly available in dockets

75 Day Notifications - Outcomes



**Is the substance an eligible dietary ingredient
Section 201(ff) (1), (2), (3)**

**Was the dietary ingredient marketed in the US
prior to October 15, 1994?**

No

**New Dietary Ingredient
Section 413 (c)**

Yes

**Not
New Dietary Ingredient**

New Dietary Ingredient

Has the ingredient been present in food supply as article used for food not chemically altered

No

Does there exist a history of use or other safety evidence for DS

Notify FDA
(75 day NDI requirement)

Adulteration provision

Scope of Meeting

- **Status of substance as a new dietary ingredient**
- **Chemical identification of the NDI**
- **Information about the dietary supplement**

Scope of Meeting

- **Establishing a reasonable expectation of safety**
- **Role of definitions in evaluating new dietary ingredients**
- **Is there a need for guidance or amendment of current requirements?**