

# FDA Public Meeting on New Dietary Ingredients

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# COUNCIL for RESPONSIBLE NUTRITION (CRN)

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- A leading trade association for the dietary supplement industry
- Members include:
  - mainstream manufacturers of dietary ingredients and of national brand name and private label dietary supplements
  - marketers with an international scope



# PURPOSE OF DSHEA

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- Ensure consumer access to a wide variety of safe dietary supplements
- Provide consumers with more information about these products
- Affirm the safety of a broad array of existing dietary ingredients and establish a notification process for new dietary ingredients, distinct from and less burdensome than the food additive approach



# DIETARY INGREDIENTS

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- Categories intended to be broad
- Safety is an important factor in determining whether an ingredient may be marketed but is not a factor in defining the category *per se*



# EXAMPLES

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- Minerals – not limited to essential nutrients
- Botanicals
- Dietary substances



# “GRANDFATHERED” INGREDIENTS

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- Dietary supplements on the market in the U.S. prior to October 15, 1994
- Majority of dietary supplements on the market now are “grandfathered”
- “Legally marketed” prior to 1994 not a requirement – selenium, chromium, amino acids



# NEW DIETARY INGREDIENT NOTIFICATION

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- Some of the information outlined may be desirable but not essential and some information may be proprietary
- CRN urges the agency to include some affirmative reassurance regarding the protection of proprietary information



# INFORMATION ABOUT THE DIETARY SUPPLEMENT

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- Appropriate for an NDI notification to include some information about its intended use in the finished product
- However, FDA should not specifically require submission of a label in all cases



# REASONABLE EXPECTATION OF SAFETY

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- Core question: What types of information should be included in an NDI notification in order to establish a reasonable expectation of safety?
  - Questions posed should not be seen as absolute requirements for inclusion in a notification
  - Evidence of traditional use should include evidence from foreign and U.S. uses



# SAFETY STANDARDS

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- “reasonably be expected to be safe”
- No FDA approval of NDI
- But manufacturer or distributor must support conclusion regarding the reasonable expectation of safety



# OTHER SAFETY MODELS

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- GRAS evaluation
- EPA new chemicals program
- Canada's Natural Health Products Directorate
- FDA health claim evaluations for psyllium and stanol and sterol esters
- FDA's guidance on new plant varieties



# OTHER DEFINITIONS

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- All terms should be understood broadly and literally
- Issues having to do with safety or other considerations should be dealt with directly and NOT used as reasons for restricting the definition itself



# NDI NOTIFICATION GUIDANCE

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- CRN endorses the seven recommendations listed in the meeting notice (October 20, 2004 Federal Register), all of which would improve the format and content of the notifications



# CONCLUSION

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- CRN congratulates FDA for undertaking this initiative and for fully involving all stakeholders in the discussion
- CRN looks forward to future opportunities to work cooperatively with FDA in developing regulatory approaches that will best serve the needs of the agency, industry and the consuming public



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