

Premarket Notification for New Dietary Ingredients



FDA / CFSAN
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AHPA's Presentation

- ★ Herbal dietary ingredients defined
- ★ NDI Notification requirements
- ★ Review of NDIs to date
- ★ AHPA's *HOC* is a presumptive list of 'old' herbal dietary ingredients in 321(ff)(1)(C)
- ★ 'Old' herbal dietary ingredients in 321(ff)(1)(F)
- ★ Suggestions and recommendations

Definition of a DI 21 U.S.C. 321

(ff) The term dietary supplement'—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- ★ (A) a vitamin;
- ★ (B) a mineral;
- ★ **(C) an herb or other botanical;**
- ★ (D) an amino acid;
- ★ (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- ★ **(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)**

Types of Herbal DIs 21 U.S.C. 321

- ★ (C) an herb
- ★ (C) an other botanical

- ★ (F) a concentrate of an herb or botanical
- ★ (F) a metabolite of an herb or botanical
- ★ (F) a constituent of an herb or botanical
- ★ (F) a extract of an herb or botanical
- ★ (F) a combination of herbs or botanicals

NDI Notification 21 CFR 190.6

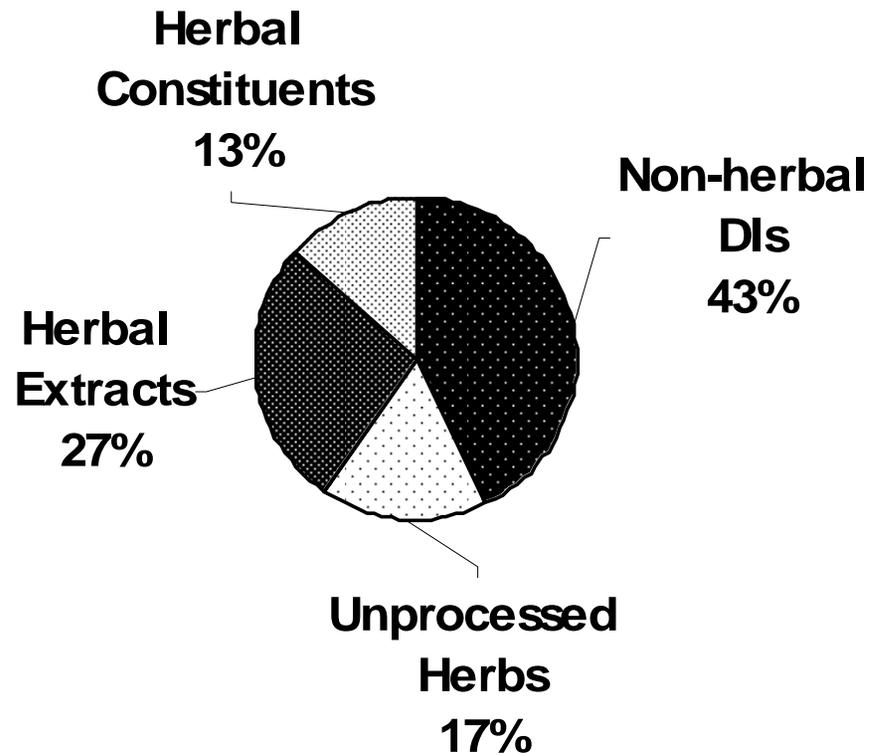
- ★ the name and address of the distributor or manufacturer (either of the DI or the DS)
- ★ **the name of the ingredient, which must include the Latin binomial (including author) if the ingredient is a botanical**
- ★ a description of the supplement containing the ingredient, including the level of use and conditions of use
- ★ **the evidence on which a reasonable expectation of safety is based, including copies and, as necessary, English translations of references**
- ★ a signature

NDIs to date

- ★ 249 as of November 9, 2004
 - ▲ 15 notifications for dietary *supplements*
 - ▲ 194 unique DI notifications
 - ▲ 245 specific ingredients identified
- ★ 194 unique notifications
 - ▲ 83 non-herbal DIs
 - ▲ 111 herbal DIs
 - ★ 33 unprocessed herbs
 - ★ 26 herb constituents
 - ★ 52 herbal extracts (or concentrates, etc.)

NDIs to date

November 2004



NDIs to date November 2004

	# Notifications	# Filed by FDA	% Filed
Non-herbal DIs	83	52	63%
Unprocessed herbs	33	7	21%
Herb extracts, etc.	52	19	37%
Herbal constituents	26	17	65%
TOTAL	194	95	49%

Missing data (per 21 CFR 190.6)

- ★ Plant part not named
 - ▲ No. 238: *Hoodia gordonii*
 - ▲ No. 247: *Phellinus linteus*
- ★ Confused nomenclature
 - ▲ No. 248: kakadu plum fruit extract - *Terminalia ferdinandiana* or *Terminalia lapides*?
- ★ Botanical name not given
 - ▲ No. 216: freeze-dried kimchi

Missing data (per 21 CFR 190.6)

- ★ "it is unclear... whether the test substances used in the referenced studies are qualitatively or quantitatively similar to" the NDI
- ★ "...inadequate information presented in the notification to characterize and identify your specific 'new dietary ingredient.'"

Needed data for herbs

	321(ff)(1)(C)	
Identity (NDI)	Latin name + part	
DS Description	Dose of DI + Conditions of use (inc. labeling); other DIs not needed	
Evidence	History of use; other evidence	

Needed data for herbs

	321(ff)(1)(F)
Identity (NDI)	...+ solvent + ratios + all ingredients + process description + form [+ % 'markers' + characterization + purity]
DS Description	Dose of DI + Conditions of use (inc. labeling); other DIs not needed
Evidence	History of use of <i>similar</i> DI; other evidence

'Old' Herbs - 201(ff)(1)(C)

- ★ 1995: Call for 'old' herbal DIs
- ★ 1996: List of 1656 herbs "believed to have been marketed in the United States as a dietary supplement or dietary ingredient before October 15, 1994" sent to FDA
- ★ 2000: *Herbs of Commerce*, 2nd edition
 - ▲ 2048 species (inc +/- 550 in 1st edition (1992))
 - ▲ Over 500 Chinese herbs
 - ▲ Over 300 Ayurvedic herbs
 - ▲ 25 fungi; 23 seaweeds

'Old' Herbs - 201(ff)(1)(C)

★ Disclaimers:

- ★ *The listing of a particular species of plant in this work is not, therefore, in and of itself, evidence that such species was marketed in the United States prior to October 15, 1994.*
- ★ *Similarly, the exclusion of a particular plant should not be seen as proof of or an indication that such plant was not marketed in the United States prior to October 15, 1994.*

'Old' Herb Extracts - 201(ff)(1)(F)

★ Standard extract forms

- ▲ Decoctions; Extracts (liquid and powdered); Tinctures; Syrups; etc.

★ Standard extract solvents (food grade)

- ▲ Alcohols; Glycerin; Oils; Vinegar; Water or Steam; etc.

★ Standard extraction processes

- ▲ Maceration; Percolation; Spray-drying; etc.

Suggestions

- ★ Modify 190.6:
 - ▲ For herbal NDIs the part of the plant must be stated
 - ▲ Clarify that identity of the NDI is required
- ★ Assume *HOC* herbs are 'old' (+ many extracts)
- ★ Refuse filings for new dietary supplements
- ★ Refuse filings for old dietary ingredients (black pepper; cinnamon; clove; ginger; ginseng; etc.)
- ★ Prioritize enforcement based on safety concerns
- ★ Assume int'l use as "present in the food supply"

Suggestions

- ★ Refrain from overly broad interpretations:
 - ▲ 239: Notice “does not provide specifications of purity... or a compositional analysis” of this **herb**
 - ▲ Also: “...no information [on] other components” in DS
- ★ Clarify when a new dose (of an NDI) is an NDI
- ★ Establish minimum criteria for NDI review, e.g.:
 - ▲ ‘Administrative’ parts of 190.6
 - ▲ Identity of NDI
- ★ More timely access at FDA docket
 - ▲ AHPA / NPI will create searchable database