



Council for Responsible Nutrition

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May 22, 1996

TO: CRN Executive Contacts and
Industry Quality Standards Working Group

FROM: Annette Dickinson *AD*

SUBJECT: Grandfathered Dietary Ingredients

**ACTION REQUESTED: Review "Grandfathered" List
and Make Additions/Suggestions
as Appropriate**

As you know, dietary ingredients are "grandfathered" by DSHEA if they were on the market before October 15, 1994. Otherwise they are "new dietary ingredients," and special provisions apply.

NNFA has compiled a list of grandfathered dietary ingredients, based on the ingredients contained in products submitted to NNFA's Trulabel Program. The herbal industry has also compiled a list of herbals which were on the market before October 15, 1994. At this time, it appears that these lists will not be submitted to FDA, but they clearly are a useful reference for internal use by companies in the industry.

CRN's Board of Directors has requested that staff circulate the NNFA list for comment by CRN members. Please review this list and submit any additions or suggestions by the end of June 1996. If you have additions, please submit them along with a letter affirming that the ingredients were in use prior to October 15, 1994. We will then make the modifications and circulate a revised list for your information and use.

It is CRN's view that the grandfathering provision applies only to "dietary ingredients" of the type defined in DSHEA, and does not apply to excipients such as colors and fillers. Therefore we would anticipate omitting the section of the NNFA list entitled "capsule and tablet ingredients." We also question

the inclusion of some of the trace minerals (gold, platinum) in the NNFA list, which we believe must have appeared on labels as part of a complete chemical analysis of some natural ingredient (such as sea salt) and not as discreet added ingredients. Comments are invited on these issues.

NNFA's original list was a unified alphabetic list, which gave a somewhat chaotic impression of dietary supplement ingredients. At CRN's suggestion, the list has been reorganized into separate categories, to permit better understanding of the types of ingredients used in dietary supplements. Comments are invited on the categories. Are these appropriate and sufficient? Would you suggest additional categories? Should some ingredients appear in more than one category?

NNFA's list contains "botanicals" and also "botanical components." Please review these categories and make additions as appropriate, reflecting ingredients used in your products prior to October 15, 1994. (This mailing does not include the AHPA list of almost 2000 herbal ingredients. Since the CRN list will reflect only those ingredients used by CRN or NNFA members, it will probably not be as comprehensive as the AHPA list. However, we could include a footnote cross-referencing the AHPA list. Please call Kate Gorton at the CRN office if you need a copy of the AHPA list.)

It has been suggested that CRN's list should also include any dietary ingredients which currently appear on FDA's lists of GRAS substances or approved food additives, in Title 21 of the CFR. Comment is requested on this issue.