CHR. HANSEN

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Dockets Management Branch (HFA-305)
Food And Drug Administration
5630 Fishers, Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 96N-0417

Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements:

Dear Hearing Clerk:

These comments are submitted in response to the above referenced proposed rule published in the Federal Register March 13, 2003. Chr. Hansen, Inc. is a manufacturer of color additives and excipient ingredients that are used as components in the preparation of dietary ingredients and/or dietary supplements. As components of dietary ingredients, these substances provide binding, flow control, or other functional or technical effects, but are not active dietary ingredients in these formulations. These substances are usually referred to as excipients, ie. inactive components of dietary supplements. We also manufacture a range of phytonutrient specialty ingredients (e.g. anthocyanins and natural carotenes), that are sold as dietary ingredients or dietary supplements.

Our purpose in commenting is to express concerns relating to the proposed rule's treatment of generally recognized as safe (GRAS) substances, which are included as components of dietary ingredients and/or dietary supplements. While we see little, if any, application of the proposed rule to Chr. Hansen as a manufacturer of GRAS components used in dietary ingredients and/or dietary supplements, we believe these proposals overstate FDA's present statutory and regulatory authorities relating to GRAS substances. Furthermore, even assuming proper agency authority, the proposed rule; (1) is contrary to, and inconsistent with, present agency policy regarding GRAS substances; (2) is not clear as to steps required by dietary supplement companies to be in compliance with the proposal; and (3) is not complete in setting out the agency's compliance and enforcement regimen for the new GRAS process proposed. For these reasons, we request that the agency modify any final rule issued to provide for consistent treatment of all GRAS substances used in food, including dietary ingredients and dietary supplements that are used under the "umbrella" of food.

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Most of our excipient products have a long history of safe use in food, as well as in dietary supplements, and as inactive components of pharmaceutical products. As such, many of these substances are used in food as GRAS substances, in full compliance with the Federal Food, Drug and Cosmetic Act (FDCA), with no formal recognition by FDA other than possibly a FDA response to a GRAS notice submission. The proposed rule in Sec. 111.35(d), however, requires that dietary supplement manufacturers who claim that such components are GRAS must support the use of such substances with either a specific citation to a GRAS regulation or by an "...explanation for why there is general recognition of safety of the use of the substance in a dietary ingredient or dietary supplement...". This mandate, if implemented in the final rule, could adversely affect the use of GRAS substances in dietary supplements by imposing a new requirement that would not be applicable to general food use of the substance. That is, under the proposed rule, supplement manufacturers would be required to document GRAS status of these substances, even though in the food area no such requirement exists for documentation of GRAS status of GRAS substances.

Further, the proposed rule is silent as to the type or manner of GRAS documentation that would be acceptable to the agency, or where, when, or to whom the "explanation" of GRAS status of a substance would be made. As FDA has pointed out on many occasions, dietary supplements fall under the food "umbrella", yet the proposed rule treats GRAS components of supplements differently than requirements of the present food law and regulations. Therefore, it is requested that FDA reconsider this requirement as to GRAS substances and harmonize the GRAS substance policy across all food and dietary supplement use categories.

A further concern with the proposed regulation relates to its requirements under Sec.111.35 (d) that a color additive must specify a dietary supplement use in it's listing, and that a listed GRAS substance must specify approval for use in a dietary ingredient or dietary supplement. Under the strictly limiting language of the proposed rule requiring specification of dietary supplement use, many listed GRAS substances and color additives presently permitted for food use would be prohibited from use in dietary supplements. FDA has permitted broad food uses for many GRAS listed substances, with no restrictions other than use in conformance with GMP's. Uses other than those specified in FDA's GRAS listing are also appropriate without further formal FDA action, if a company determines that those uses are GRAS. In the case of color additives, the typical listing for the color authorizes "coloring foods generally in amounts consistent with good manufacturing practice". It would be ironic if GRAS substances and color additives could be broadly used in food, but not be permitted for use in dietary supplements simply due to the fact that use in dietary supplements was not specified at the time the substances were formally listed by the agency to be safe for food use.

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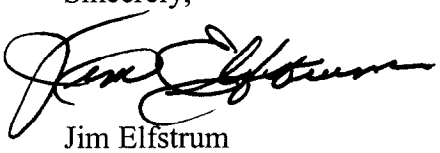
In sum, we believe the agency's proposed rule exceeds its authority in attempting to promulgate GRAS rules by applying requirements different from those that presently exist for foods. The general GRAS rules for food conform to the mandates of the law and regulations, whereas the proposed rule's GRAS requirements remove them from the "umbrella" of current GRAS food rules. At the very least, if the agency persists in changing the GRAS food rules as they relate to components of dietary supplements, FDA should publish a new proposal with specifics as to GRAS "explanation" requirements, procedures, and compliance, giving ample opportunity for notice and public comment on the same. We believe, however, that the better course would be for FDA to maintain consistency in application by recognizing that present GRAS substance procedures and recognition for use in food is sufficient for use in dietary supplements. Consequently, we request that the language of a final rule be so modified to reflect this consistency.

Thank you for the opportunity to comment on the proposed rule.

Sincerely,



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