



Dockets Management Branch (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
301-827-6860

Oxford (MS), August 7th, 2003

**RE: DOCKET NO. 96N-0417, GOOD MANUFACTURING
PRACTICES FOR DIETARY SUPPLEMENTS**

The following comments are in response to the proposed GMP's for dietary supplement by Indena SpA with headquarters in Milan Italy. Indena is an ingredient manufacturer that sells standardized botanical extracts and plant derived pure compounds that include a diversity of botanical ingredients that are regulated in Europe, Japan, Australia, Canada and the United States as foods, dietary supplements and pharmaceuticals. Indena is routinely inspected (and approved) by the Italian Ministry of Health, the US FDA for active pharmaceutical ingredients, and audited by the highest quality US dietary supplement manufacturers.

Indena has a long history over many decades (the company was founded in 1921) of furnishing standardized botanical extracts that are manufactured using the most detailed and highest standards of manufacturing controls that include validated analytical methods and stability studies by ICH guidelines. Many of Indena's extracts and plant derived compounds have been used in final products that have been proven safe and effective by standard toxicity testing and clinical trials that are sold as pharmaceuticals in Europe and the United States.

To assure safe botanical extracts that meet the high quality standards necessary to assure the desired effect of the ingredient, Indena has organized our comments in two documents.

- 1) “Dietary Supplement Ingredient (Botanical Origin) Main GMP followed by Indena”. As the title suggests these are the current main GMP practices followed by Indena for dietary supplements ingredients. The proposed GMP’s would require little change from current practices and in fact Indena’s GMP’s for dietary ingredients are more rigorous in several areas to assure a safe and high quality effective botanical ingredient.

- 2) “Indena Comments”. Indena’s comments are underlined and in color following the specific section numbers of the proposed GMP’s for Dietary Supplements and include specific comments for topics that need some further clarification and in other instances Indena has added some suggestions on additional testing or actions needed to assure safe, high quality and effective botanical ingredients.

Thank you for your kind consideration of Indena’s comments that we hope will help assure safe, high quality, and effective botanical ingredients. We will be pleased to have your feedback once Indena documents have been reviewed.

Sincerely,

A handwritten signature in black ink that reads "E. M. Croom, Jr." in a cursive script.

Edward M. Croom, Jr., Ph. D.
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