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June 5, 1997

VIA FEDERAL EXPRESS

Dockets Management Branch (FHA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Proposed Rules on Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements, Docket No. 95N-0417

COMMENTS OF BOTANICALS INTERNATIONAL, A DIVISION OF ZUELLIG BOTANICALS, INC.

Dear Sir or Madam:

Botanicals International (BI) is writing to comment on the advance Notice of Proposed rulemaking concerning CGMP for dietary supplements, Federal Register Vol. 62, No. 25, February 6, 1997.

BI is the leading supplier of bulk herbs and botanicals imported from around the world as well as domestically. BI has been in business for 20 years as the lead supplier to dietary supplement, food and pharmaceutical companies. BI delivers over 700 bulk products in variety forms including powder, tea cut, coarse cut, simple ratio extracts, standardized extracts and blends of botanicals as well as spices, seasoning blends and products designed for specific applications.

BI is in compliance with industry proposed CGMP. Our Vice President, Technical, Dr. Fran Ertl, as the chairperson of the American Herbal Products Association (AHPA) standard committee and as AHPA representative was involved in the development of proposed GMP. BI is a member of AHPA and as such is in agreement with the comments submitted by them. BI is also in support of the position developed by the Council for Responsible Nutrition (CRN). However, we would like to make some further comments in addition to the above submissions as follows:

BI receives large shipments of raw, dehydrated botanicals. Its quality control department takes representative samples and applies an array of tests to establish the product identity and cleanliness. The approved raw materials are then processed and the finished products have to be approved by BI's proprietary QC process. All the documentation is in place to validate the reliability of the Certificate of Analysis (C of A). BI's C of A provides a comprehensive product profile including the microbiological, cleanliness, identification, and when it is applied, analytical results. BI's customers are, in most cases, second manufacturers who sell the products in their finished form (capsule, tablet, etc.).

The following is the response to the ANPR section IV, 2, 7 & 8

2. TESTING REQUIREMENTS FOR INGREDIENT IDENTIFICATION. BI is in agreement with the AHPA and CRN position that the supplier of botanicals shall perform botanical identification on the unprocessed plant part and shall establish botanical identity on the C of A. BI's trademark name for this process is Identilok™.

BI is also of the opinion that in order to identify plant species with a high degree of confidence, a combination approach must be taken. The following will describe in detail our identification process:

Botanical identification is a difficult endeavor that requires extensive experience in the cellular and taxonomical sciences. BI possesses sophisticated equipment in the form of dissecting microscope, a compound microscope with powerful high quality optics/phase turret, filters, and a computerized image database for referencing of cellular features. In addition, BI has developed a reliable herbarium of the botanicals so that they may be used as references against the preshipment samples.

Botanical identification is not restricted to taxonomic features. It also requires extensive knowledge of chemistry for chemical identification and, as necessary, analytical implementation through instrumentation.

Despite a well-established procedure for taxonomic identification, it is not always possible to guarantee the results of an investigation for the following reasons. Botanicals are often wild crafted plants from various ecotypes. In addition, the state of the botanicals may be in the powdered form, and this renders identification arduous especially for roots. Finally, not all parts of the plant may be available for identification. Reproductive structure, whole leaves, stems, and pollens may be missing from the shipment.

To guarantee a thorough investigation, it is highly recommended that the plant be available in as many unprocessed components as possible. In reality that rarely ever happens.

BI possesses the expertise and capabilities to implement extensive identification of every lot of receiving shipments. Combination identification approach will compensate for the above-mentioned limitations. *Thin Layer Chromatography (TLC), Fourier Transfer Infrared Spectroscopy (FTIR), organoleptic profile, microscopic image analysis, macroscopic taxonomic identification and High Performance Liquid Chromatography (HPLC) finger printing are commonly applied to the receiving shipments.* As mentioned above, BI has developed a reference library of herbarium samples, microscopic image analysis, and FTIR spectra for each of our botanicals.

7. SPECIFIC CONTROLS FOR COMPUTER CONTROLLED OR ASSISTED OPERATIONS. BI's software is validated against manual operations. The results correlate within a certain degree of confidence and are duplicated by independent personnel. The validation Dockets procedures and results are documented and the records are retained for at least three years after the date of manufacture.

8. RELEVANCE OF HACCP. *Botanicals International opposes the mandating of HACCP as a legislative or administrative action. Record keeping and actual implementation of the HACCP principles should not be mandated, but rather these activities should remain within the responsibilities of the manufacturer, distributor or retailer of dietary supplements.*

The HACCP program should be mandated for only high risk products such as fresh meat, poultry and seafood. The dietary supplement products, which impose little or no safety risk, should not be burdened by the elaborate requirements much beyond the proposed GMP. *BI therefore proposes that an establishment that chooses to be in compliance with HACCP should be exempt from disclosure of the HACCP records to any regulatory agency.* That is, we oppose the creation of the new authority to access these records for any regulatory agencies. Mandatory HACCP would turn the focus on documentation, not on safety. HACCP is a dynamic process that should be updated as the need arises. The FDA should be involved with the training and education processes rather than legislation.

Of special note here, BI has implemented the HACCP principles in its operations for the last three years. BI strongly believes that the establishment of HACCP makes good business sense. HACCP is the best preventive measure to insure the safety of the foods. The dietary supplement industry is extremely diverse in the variety of the products, safety issues, processing and manufacturing operations. It should be left to the discretion of the manufacturer to decide about elements of hazard assessment, selection of critical control points (CCP) and system establishment for the monitoring of CCP.

Sincerely,

Dr. Fran S. Ertl
Vice President, Technical

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