

Standardized Information on Dietary Ingredients

SIDITM PROTOCOL

VERSION 3.0



VOLUNTARY GUIDELINE
FOR THE DIETARY
SUPPLEMENT INDUSTRY

*Voluntary Guideline for the Dietary Supplement Industry
Number 1*

Standardized Information on Dietary Ingredients

**(SIDI™) Protocol
Version 3.0**

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DISCLAIMER

The SIDI™ Protocol 3.0 is a voluntary guideline for informational purposes only and intended to assist users with compliance with the current Good Manufacturing Practice for Dietary Supplements, 21 C.F.R. § 111. This Guideline should not be used as a substitute for compliance with applicable federal, state, or municipal laws, codes, rules and regulations (“applicable laws and regulations”). Users may use an alternative approach to satisfy the requirements of the applicable laws and regulations. The Authors make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, or suitability of the Guideline for any purpose. By use of this resource, the user agrees not to hold the Authors liable or responsible for the user’s compliance with all applicable laws and regulations. Use of this Guideline does not constitute any promise, representation or warranty that a product will in fact comply with applicable laws and regulations, nor any assurance, representation or guarantee regarding or relating in any manner to the safety of any product. In no event will the Authors be liable for any loss or damage including without limitation, indirect or consequential loss or damage, or any loss or damage whatsoever arising from loss of data or profits arising out of, or in connection with, the use of the Guideline. Whenever appropriate, users should seek the advice of professionals or other knowledgeable persons to ascertain whether a product will in fact comply with applicable laws and regulations.

ACKNOWLEDGMENTS

SIDI™ Protocol 3.0 was developed by the SIDI Work Group, a coalition of dietary supplement trade associations, including the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the United Natural Products Alliance (UNPA), and their members companies. Previous versions were developed by the American Herbal Products Association (AHPA), CHPA, CRN, and the Natural Products Association (NPA) and their member companies. We greatly appreciate the contributions made by everyone involved with the SIDI Work Group. We also want to extend a special thanks to the International Pharmaceutical Excipients Council (IPEC) for providing guidance in the development of the first version of the SIDI™ Protocol.

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INTRODUCTION

Scope and Purpose

21 CFR 111, *Current Good Manufacturing Practice (CGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*, requires dietary supplement manufacturers to establish and ensure that specifications for the identity, purity, strength, composition, and limits on potential contaminants for their dietary supplements are consistently met to produce quality products. To this end, manufacturers need specific information about the dietary ingredients they use in dietary supplements and about the suppliers that provide those ingredients. To obtain needed information, manufacturers may develop and require their suppliers to complete a supplier questionnaire and/or self-audit assessment. Most ingredient suppliers recognize the need to provide comprehensive ingredient information to the manufacturer; however, they can receive such a high volume of customer questionnaires that it can be difficult to quickly provide information for each customer's specific questionnaire. Since these questionnaires seek similar ingredient quality and regulatory information, the use of a standardized format is beneficial, efficient, and user-friendly for both suppliers and manufacturers.

The Standardized Information on Dietary Ingredients (SIDI™) Protocol is intended to serve as a standardized format that can be used consistently across the dietary supplement industry. The SIDI™ Protocol defines the type and scope of information that manufacturers typically seek from ingredient suppliers. The primary goal of the SIDI™ Protocol is to provide standards, for voluntary use, in the exchange of relevant and required information between ingredient suppliers and dietary supplement manufacturers that enable both parties to maximize resources. Ingredient suppliers will be able to deliver consistent information in a proactive and more efficient manner; and dietary supplement manufacturers will be able to anticipate the type and format of the standard data that they need. The use of the SIDI™ Protocol may also allow for electronic access to the data via a supplier website link or database and may facilitate notification of changes pertaining to previous versions. The SIDI™ Protocol is based on the Excipient Information Protocol (EIP) developed by IPEC. The two protocols are identical in concept, but cover two different classes of products: dietary ingredients and excipients, respectively.

User Guide

The SIDI™ Protocol was first published in 2006, with revisions in 2008 and 2018. The most up-to-date version should be used as a reference. The SIDI™ Protocol contains two main parts: Product Information and Site Quality Overview. The SIDI™ Protocol defines the *minimum* type and scope of information that should be included in each section. However, additional related information may be included at the discretion of the ingredient supplier. The term “not applicable” should be used when particular topics in the SIDI™ Protocol do not apply to a particular dietary ingredient or site. The ingredient supplier may choose to keep certain information confidential; however, the ingredient supplier should explain how the finished product manufacturer might obtain confidential information if needed. For example, a supplier may use a confidentiality or nondisclosure agreement when providing confidential or proprietary information.

The SIDI™ Protocol recommends a format for organizing and presenting dietary ingredient information. A suggested template, known as a Dietary Ingredient Data Sheet (DIDS), provides a convenient, standardized format for communicating important information about a dietary ingredient to manufacturers and may be customized as needed. Precise phrasing is not specified, but suggested phrasing is provided in some sections and can be used if desired. Company letterhead and/or logos should be used along with supplier contact information. DIDS documents may vary in length and include relevant appendices such as Safety Data Sheet, Certificate of Analysis, Allergens list, evidence of GRAS status, and method of analysis. Documents developed based on the SIDI™ Protocol should be version-controlled by the ingredient supplier. It is recommended that suppliers refer to the SIDI™ Protocol and the accompanying templates to assist them in the development of their own DIDS. The SIDI™ Protocol also may be used to develop supporting documentation for supplier qualification, third party certification, NDI notification, international product registration, and other regulatory matters.

The information contained in the SIDI™ Protocol is intended for individuals experienced and competent in evaluating ingredient suppliers. Documents developed based on the SIDI™ Protocol should not be considered a replacement for audits.

SIDI™ PROTOCOL SECTIONS

Part 1. Product Information

This part outlines important manufacturing, physical, chemical, labeling, and regulatory information specific to the dietary ingredient to facilitate its use in dietary supplements. Use the subsection for non-botanical dietary ingredients (Part 1-A) or botanical dietary ingredients (Part 1-B) as applicable. Not every point will apply to every dietary ingredient. The use of "not applicable" may be appropriate in some sections. The term "product" in this document refers to the finished commercial dietary ingredient.

Part 1-A: NON-BOTANICAL DIETARY INGREDIENTS

Section A.1 – Product Information

- Product name
- Supplier's code, if applicable
- "Common or usual name"
- Scientific name, if applicable
- General product description
- Product country of origin

Section A.2 – Manufacturing Information

- Manufacturing site name and address
- CGMP compliance statement; indicate standard (e.g., 21 CFR 117, 21 CFR 111, etc.)
- Method of sterilization and/or fumigation used, if applicable
- Brief description of known or potential sources of impurities and/or contaminants
 - List known or potential economically motivated adulterants and steps taken to ensure they are not present in the product
 - Identify any organic solvents and solvent mixtures (including composition) used in product manufacturing and address potential for residual solvent levels in the product
- Indicate whether this product (or any sub-component) is self-manufactured, contract manufactured (including any toll processes), or brokered
- Flowchart and description of manufacturing process (e.g., grinding, blending, reaction, chemical synthesis, fermentation, purification, etc.)

Section A.3 – Physical and Chemical Information

- List **ALL** components, including excipients (may require confidentiality agreement), in descending order of predominance by weight (in addition to weight, other quantities may be applicable, e.g., colony forming unit (CFU) for probiotics) and provide for each component:

- “Common or usual name” and synonyms, as applicable, or name in accordance with 21 CFR (e.g., FD&C Red No. 40)
- CAS number, UNII, and molecular formula, as applicable
- Percentage by weight (wt/wt)
- Function
- Country of origin
- General source information (e.g., synthetic, animal sourced, vegetable sourced, mineral based, product of fermentation, or botanical)
- List incidental additives and/or processing aids not included in the above components list (may require confidentiality agreement)
 - Include basis for the determination of any component considered incidental
- Attach current product specification sheet including method of analysis and limit of detection, as applicable, for each specified test. Specifications should address identity, purity, strength, composition, and potential contaminants and include, as applicable:
 - Appearance/physical description
 - Method(s) of determining dietary ingredient identity
 - Physical parameters, which may include:
 - Moisture
 - pH
 - Bulk density, tapped density, powder flow characteristics
 - Particle size distribution or mesh size
 - Odor, taste, color, and other organoleptic and macroscopic evaluations
 - Microbial assessments for total aerobic plate count, yeast and mold, Enterobacteriaceae, coliforms, *E. coli*, *Salmonella*, *S. aureus*, *Listeria*, *Pseudomonas*, or other microorganisms, as appropriate
 - Provide basis for determining product is considered low risk for microbial growth, as applicable (e.g., pH, water activity)
 - Disclose known or potential contaminants and/or impurities such as polycyclic aromatic hydrocarbons (PAH), dioxins, acrylamides, elemental impurities, pesticide residues, residual solvents, aflatoxins or other mycotoxins, latex, silicones, etc.
 - Quantitative analysis of bioactive compounds and/or marker compounds by chemical analysis or bioassay method, as applicable

Section A.4 – Labeling Information

- Required finished dietary supplement label statements, including patent attribution, trademark, and/or logo usage
- Recommended restrictions or limitations of use relevant to the end user (see **Section A.5** for possible specifics)
- Nutrition information for compliance with 21 CFR 101.36
 - Macronutrient and micronutrient content
 - Indicate source data, i.e., calculated or analytical

Section A.5 – Regulatory and Compliance Information

Regulatory and compliance information should include supporting documentation, as applicable.

- Information about patent coverage
- Compliance with compendial standard such as USP/NF, ANSI, FCC, PhEur, BP, JP, JSFA, AHP, and BHP
- Regulatory status and citation (CFR reference), as applicable
 - Pre-DSHEA status
 - New Dietary Ingredient (NDI) status
 - Generally Recognized as Safe (GRAS) status, including conditions of intended use
 - Food additive status
 - Other relevant information, which may include compliance status related to 21 CFR, European legislation, or JECFA
- CA Prop 65 (OEHHA) information
 - Level of Prop 65-listed chemicals in the product
 - Prop 65-listed chemicals used in the manufacturing process
- Canadian NNHPD Product Master File availability
- BSE/TSE information (both related to the product and the potential for cross-contact)
- Vegan or vegetarian status
- Gluten status
- Allergens/Sensitivities declarations (both related to the product and the potential for cross-contact)
 - Reference specific allergen(s) and regulation(s), e.g., FALCPA, EU Labelling Directive, Japan, etc. Include exemptions, as applicable, e.g., Highly Refined Oil
- Kosher, Halal, and Organic status, as applicable
- BE/GMO status
- Tariff code for importation/exportation of product

Section A.6 – Other Product Information

DIDS developed using the SIDI™ Protocol are customizable. The dietary ingredient supplier should provide additional product information in this section.

- Explanation of the batch/lot numbering system
- Batch/lot definition
- Expiration date/shelf-life and/or recommended reevaluation interval
- Recommended storage and transporting (if different from storage) conditions
- Special safety/handling instructions for manufacturing
- Packaging
 - Package sizes and/or types offered
 - Packaging materials/tamper-evident features
 - Use of recycled packaging materials
- Safety Data Sheet (SDS), if applicable or required (refer to OSHA regulations)
- Product safety information
 - Safety studies, history of safe use data

- Known chemical incompatibilities with other ingredients, if applicable
- Other product information
 - Suggested product claims, including supporting documentation
 - Sourcing and sustainability, e.g., compliance with CITES

Section A.7 – Document Information

- Version number (provide on each page)
- Revision or review date if no changes since previous version (provide on each page)
- SIDI™ Protocol version used as reference
- Version control history, including description of changes since previous version

Section A.8 – Contact Information

- Contact information for supplier representative(s) including at least one quality team leader
 - Include company name, contact name, title, email and telephone number
- Signature and date (optional)

Part 1-B: BOTANICAL DIETARY INGREDIENTS

This part outlines important manufacturing, physical, chemical, labeling, and regulatory information specific to the botanical dietary ingredient to facilitate its use in dietary supplements. Not every point will apply to every dietary ingredient. The use of "not applicable" may be appropriate in some sections. The term "product" in this document refers to the finished commercial dietary ingredient.

Section B.1 – Product Information

- Product name
- Supplier's code, if applicable
- "Common or usual name" of the botanical used to make the product (according to current edition of *Herbs of Commerce*)
- Latin binomial (in accordance with internationally accepted rules on nomenclature, such as current edition of *International Code of Nomenclature for algae, fungi, and plants*), author(s), variety or strain, as applicable
- General product description
- Product country of origin

Section B.2 – Manufacturing Information

- Manufacturing site name and address
- CGMP compliance statement; indicate standard (e.g., 21 CFR 117, 21 CFR 111, etc.)
- Method of sterilization and/or fumigation used, if applicable
- Brief description of known or potential sources of impurities and/or contaminants
 - List known or potential economically motivated adulterants and steps taken to ensure they are not present in the product
 - Identify any organic solvents and solvent mixtures (including composition) used in product manufacturing and address potential for residual solvent levels in the product
- Indicate whether this product (or any sub-component) is self-manufactured, contract manufactured (including any toll processes), or brokered
- Description of agricultural processes for the botanical starting material
 - Indicate whether botanical was wildcrafted or cultivated in accordance with GACP; provide grower or wildcrafter information
 - Manner of cultivation, including sustainability practices
 - Method(s) of identification for the botanical starting material
 - Source of reference standard e.g., botanical and/or chemical authenticated reference specimen
 - Description of how integrity of the botanical starting material is maintained through the supply chain (see GACP)
 - Post-harvest processing, e.g., drying, milling, etc.
- Flowchart and description of manufacturing process (e.g., milling, freeze-drying, extraction methods, blending, etc.)

- Type of extraction process, if applicable (e.g., maceration, percolation, or supercritical fluid)
- Type of extract, if applicable (e.g., water, aqueous ethanol, or other description)
 - Indicate native and/or final extract ratio
 - Indicate extraction solvent and ratios

Section B.3 – Physical and Chemical Information

- List **ALL** components, including excipients (may require confidentiality agreement), in descending order of predominance by weight (in addition to weight, other quantities may be applicable, e.g., colony forming unit (CFU) for probiotics) and provide for each component:
 - “Common or usual name” and synonyms, as applicable, or name in accordance with 21 CFR (e.g., FD&C Red No. 40). If a botanical, provide “common or usual name” according to current edition of *Herbs of Commerce*.
 - CAS number, UNII, and molecular formula, as applicable
 - Percentage by weight (wt/wt)
 - Function
 - For each botanical component, also identify raw botanical and provide:
 - Latin binomial (in accordance with internationally accepted rules on nomenclature, such as current edition of *International Code of Nomenclature for algae, fungi and plants*), author(s), variety or strain, as applicable
 - Plant part such as rhizome, root, stem, leaf, fruit, or aerial parts
 - Harvest season and/or stage of development
 - Country(s) of harvesting and processing
 - For each non-botanical component, also include:
 - Country of origin
 - General source information (e.g., synthetic, animal sourced, vegetable sourced, mineral based, or product of fermentation)
- List incidental additives and/or processing aids not included in the above components list (may require confidentiality agreement)
 - Include basis for the determination of any component considered incidental
- Attach current product specification sheet including method of analysis and limit of detection, as applicable, for each specified test. Specifications should address the identity, purity, strength, composition, and potential contaminants and include, as applicable:
 - Appearance/physical description
 - Method(s) of determining botanical dietary ingredient identity
 - Physical parameters, which may include:
 - Ash, acid insoluble ash
 - Moisture
 - pH
 - Bulk density, tapped density, powder flow characteristics
 - Particle size distribution or mesh size
 - Odor, taste, color, and other organoleptic and macroscopic evaluations

- Microbial assessments for total aerobic plate count, yeast and mold, Enterobacteriaceae, coliforms, *E. coli*, *Salmonella*, *S. aureus*, *Listeria*, *Pseudomonas*, or other microorganisms, as appropriate
 - Provide basis for determining product is considered low risk for microbial growth, as applicable (e.g., pH, water activity)
- Disclose known or potential contaminants and/or impurities such as polycyclic aromatic hydrocarbons (PAH), dioxins, acrylamides, elemental impurities, pesticide residues, residual solvents, aflatoxins or other mycotoxins, latex, silicones, etc.
- Quantitative analysis of bioactive compounds and/or marker compounds by chemical analysis or bioassay method, as applicable

Section B.4 – Labeling Information

- Required finished dietary supplement label statements, including patent attribution, trademark, and/or logo usage
- Recommended restrictions or limitations of use relevant to the end user (see **Section B.5** for possible specifics)
- Nutrition information for compliance with 21 CFR 101.36
 - Macronutrient and micronutrient content
 - Indicate source data, i.e., calculated or analytical

Section B.5 – Regulatory and Compliance Information

Regulatory and compliance information should include supporting documentation, as applicable.

- Information about patent coverage
- Compliance with compendial standard such as USP/NF, ANSI, FCC, PhEur, BP, JP, JSFA, AHP, and BHP
- Regulatory status and citation (CFR reference), as applicable
 - Pre-DSHEA status
 - New Dietary Ingredient (NDI) status
 - Generally Recognized as Safe (GRAS) status, including conditions of intended use
 - Food additive status
 - Other relevant information, which may include compliance status related to 21 CFR, European legislation, or JECFA
- CA Prop 65 (OEHHA) information
 - Level of Prop 65-listed chemicals in the product
 - Prop 65-listed chemicals used in the manufacturing process
- Canadian NNHPD Product Master File availability
- BSE/TSE information (both related to the product and the potential for cross-contact)
- Vegan or vegetarian status
- Gluten status
- Allergens/Sensitivities declarations (both related to the product and the potential for cross-contact)

- Reference specific allergen(s) and regulation(s), e.g., FALCPA, EU Labelling Directive, Japan, etc. Include exemptions, as applicable, e.g., Highly Refined Oil
- Kosher, Halal, and Organic status, as applicable
- BE/GMO status
- Tariff code for importation/exportation of product

Section B.6 – Other Product Information

DIDS developed using the SIDI™ Protocol are customizable. The dietary ingredient supplier should provide additional product information in this section.

- Explanation of the batch/lot numbering system
- Batch/lot definition
- Expiration date/shelf-life and/or recommended reevaluation interval
- Recommended storage and transporting (if different from storage) conditions
- Special safety/handling instructions for manufacturing
- Packaging
 - Package sizes and/or types offered
 - Packaging materials/tamper-evident features
 - Use of recycled packaging materials
- Safety Data Sheet (SDS), if applicable or required (refer to OSHA regulations)
- Product safety information
 - Safety studies, history of safe use data
 - Known chemical incompatibilities with other ingredients, if applicable
- Other product information
 - Suggested product claims, including supporting documentation
 - Sourcing and sustainability, e.g., compliance with CITES

Section B.7 – Document Information

- Version number (provide on each page)
- Revision or review date if no changes since previous version (provide on each page)
- SIDI™ Protocol version used as reference
- Version control history, including description of changes since previous version

Section B.8 – Contact Information

- Contact information for supplier representative(s) including at least one quality team leader
 - Include company name, contact name, title, email and telephone number
- Signature and date (optional)

Part 2. Site Quality Overview

The Site Quality Overview (SQO) serves as a tool in the evaluation of the manufacturing practices and quality systems of the ingredient supplier. It outlines basic site and system requirements necessary to manufacture dietary ingredients in compliance with applicable CGMP. The SQO does not include all details covered in an audit, and not all points will apply to every site. The SQO is site/facility/company-specific, not ingredient-specific, and should be reviewed periodically.

Section 1 – Site Overview

- General information
 - Site name and address
 - Statement of compliance with 21 CFR 1 – Subpart H, FDA Food Facility Registration
 - Statement of compliance with state and/or other operationally-related license requirements (e.g., State Food Processor’s Registration, Provincial License, etc.)
- Corporate ownership (if different from site identified above)
- Site details
 - General site information, which may include:
 - Size, including building square footage, type of construction, and number of employees
 - History, including age of facility and first year of operation or date of last major modification
 - General and product liability insurance levels
 - Union background
 - List all type(s) of ingredient(s) and other products produced/supplied by the site and their intended applications, such as, pharmaceuticals, foods, dietary supplements, or cosmetics
 - Names of specific products produced at this site (optional)
 - Activities conducted at site, such as blending, packaging, testing, R&D or distribution
 - Indicate whether activity is done in-house or by 3rd party contractor (if applicable, provide contact information and evidence that 3rd party contractor has been qualified)
 - Organizational structure
 - Non-confidential organization chart (or a brief description)

Section 2 – CGMP Information

Provide compliance information related to applicable food CGMP (21 CFR Part 117 – Subpart B) and/or dietary supplement CGMP (21 CFR Part 111).

- Third-party verification (Yes/No); if ‘Yes’ provide documentation
- Summary of recent facility inspections by state, federal, or foreign agency

Section 3 – Food Safety Information

Provide a summary of the site's compliance with food and/or dietary supplement regulations, as applicable. As of July 2018, compliance deadlines have not passed for all FSMA rules.

- Preventive Controls for Human Food (21 CFR 117 – Subpart C) or applicable HACCP Plan (with CFR reference)
- Supply Chain Controls (21 CFR 117 – Subpart G)
- Sanitary Transportation (21 CFR 1 – Subpart O)
- Foreign Supplier Verification Programs for Food Importers (21 CFR 1 – Subpart L)
- Food Defense Plan (21 CFR 121 – Subpart C)

Section 4 – Document Information

- Version number (provide on each page)
- Revision date or review date if no changes since previous version (provide on each page)
- SIDI™ Protocol version used as reference
- Version control history, including a description of changes made since previous version

Section 5 – Contact Information

- Contact information for supplier representative(s) including at least one quality team leader
 - Include company name, contact name, title, email and telephone number
- Signature and date (optional)

GLOSSARY

21 CFR	Title 21 of the United States Code of Federal Regulations.
Bioactive compound	A type of chemical found in small amounts in plants and certain foods. Bioactive compounds have actions in the body that may promote good health.
Aflatoxins	The aflatoxins are a group of structurally related toxic compounds produced by certain strains of the fungi <i>Aspergillus flavus</i> and <i>A. parasiticus</i> . Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins.
AHP	American Herbal Pharmacopoeia.
Allergen	A substance that causes an abnormal response by the immune system to certain proteins found in the substance. <i>Also see Major Food Allergen.</i>
Animal sourced	Contains starting materials of animal origin.
ANSI	American National Standards Institute.
Batch/Lot	<p>A specific quantity of a component that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.</p> <p><i>Lot</i> means a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.</p>
Batch/Lot number	A distinctive combination of letters, numbers, symbols, or any combination thereof from which the complete history of the manufacture, processing, packaging, labeling, holding, and distribution of a batch or lot of a finished dietary ingredient, dietary supplement, or other material can be determined.
BE/GMO	The U.S. Department of Agriculture defines “bioengineering” or “BE” in its proposed rule to implement the National Bioengineered Food Disclosure Standard (Pub. L. 114–216). Both the law and the proposed rule use the term “bioengineering” to refer to a food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and for which the modification could not otherwise be obtained through conventional breeding or found in nature. As of August 2018, a final rule has not been released.

The EU uses the term "genetically modified organism (GMO)" that has a specific definition. See Article 2 of the EU Directive on the Deliberate Release into the Environment of Genetically Modified Organisms (2001/18/EC).

Bioassay method

Method for quantitatively determining the concentration of a substance by its effect on living organisms.

Botanical

A dietary ingredient derived from the crude preparation (whole, dried, powdered, or ground) or extract of a raw material originating from algae, fungi or green plants (including root, stem, flower, fruit and leaf).

BP

British Pharmacopoeia.

BSE

Bovine Spongiform Encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle caused by an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs), which includes the human disease called Creutzfeldt-Jacob Disease (CJD). Consumption of contaminated beef products from BSE-affected cattle may cause a variant form of CJD (vCJD) in humans. Food ingredient materials derived from cattle are regulated by FDA under 21 CFR 189.5.

CA Prop 65

The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as "Prop 65," requires special labeling for consumer goods (including dietary supplements) that contain a chemical known to the State of California to cause cancer or reproductive toxicity.

CAS number

Chemical Abstracts Service Registry Number (CAS). The CAS Registry lists chemical substances by molecular formula and other identifying information and assigns each substance a unique CAS Registry Number.

CGMP

Current Good Manufacturing Practices (CGMP). A system of procedures and documentation, written and analytical, to ensure that the product has the identity, strength, composition, quality, and purity that it is represented to possess. The CGMP regulation for dietary ingredients is codified at 21 CFR 117. The CGMP regulation for dietary supplements is codified at 21 CFR 111.

CITES

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), also known as the Washington Convention. An international agreement between governments aimed at ensuring that international trade in specimens of wild animals and plants does not threaten their survival.

Component

Any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of

the dietary supplement. A component can be a dietary ingredient (as defined by the Federal Food, Drug, and Cosmetic Act) or other ingredient.

Country of origin

The country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the "country of origin," however, for a good of a NAFTA country, the NAFTA Marking Rules will determine the country of origin. See 19 CFR 134.1(b).

Dietary ingredient

An ingredient intended for use or used in a dietary supplement. Defined by the Federal Food, Drug, and Cosmetic Act as a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, or extract of any of the preceding substances.

DIDS

Dietary Ingredient Datasheet (DIDS). The name of the documentation developed by ingredient suppliers based on each of the two main parts of the SIDI™ Protocol: Product Information and Site Quality Overview.

DSHEA

Dietary Supplement Health and Education Act of 1994.

EU Labelling Directive

European Union (EU) legislation on food labeling that includes allergen labeling.

EIP

Excipient Information Protocol (EIP). EIP was developed by the International Pharmaceutical Excipients Council (IPEC) to standardize communication of information between excipient suppliers and users.

Excipient

A substance, other than the dietary ingredient in a product, used to either aid the processing of the product during manufacture, to protect, support or enhance stability, bioavailability or palatability, to assist in product identification, or to enhance any other attribute of the overall safety and effectiveness of the product during storage and use.

Expiration date

The date beyond which a product may no longer conform to relevant specifications.

Extract

The complex mixture obtained after using a solvent to separate soluble constituents in a botanical material from insoluble plant material. Extracts may be in liquid, dry, or semi-solid form.

Extract ratio

The ratio between the quantity of botanical raw material used in the manufacture of the botanical extract and the quantity of botanical extract obtained.

FALCPA	Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) amended the Federal Food, Drug, and Cosmetic Act and requires the label of a food that contains an ingredient that is or contains proteins from a "major food allergen" to declare the presence of the allergen in the manner described by the law. <i>Also see Major Food Allergen.</i>
FCC	Food Chemicals Codex (FCC). FCC is published by the United States Pharmacopeial Convention (USP).
Food additive	A substance whose intended use results or may reasonably be expected to result, directly or indirectly, either in its becoming a component of food or otherwise affecting the characteristics of food; a substance that is used in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food. See 21 CFR 170.
FSMA	FDA Food Safety Modernization Act.
GACP	Good Agricultural and Collection Practices. A system of procedures to ensure that agricultural materials are sustainably produced through cultivation or wild collection.
GRAS	Generally Recognized As Safe (GRAS). A regulatory term used for a substance that is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. FDA's regulations in 21 CFR 170.3 and 21 CFR 170.30 indicate that the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.
HACCP	Hazard Analysis Critical Control Point (HACCP). An internationally recognized management system used to prevent safety hazards in food through the analysis and control of biological, chemical (including allergens), physical, and radiological hazards from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product.
Halal	The term indicates that a food is permitted and fit for consumption according to Islamic law.
Herbs of Commerce	A compilation developed by the American Herbal Products Association (AHPA) of botanicals sold in the U.S. as dietary supplement ingredients.
International Code of Nomenclature for algae, fungi, and plants (ICN)	Internationally recognized rules that govern the scientific naming of algae, fungi, and green plants.

JECFA	Joint FAO/WHO Expert Committee on Food Additives.
JP	Japanese Pharmacopoeia.
JSFA	Japanese Standards for Food Additives.
Kosher	The term indicates that a food is fit for consumption according to Jewish law.
Maceration	An extraction technique in which the botanical material is allowed to soak in the extraction solvent until the cellular structure of the botanical is penetrated and the soluble portions are dissolved.
Macroscopic	Visible to the naked eye.
Major food allergen	Any of the following: (1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans; (2) A food ingredient that contains protein derived from a food specified above except any highly refined oil derived from a food specified above and any ingredient derived from such highly refined oil (See Section 201(qq) of the Federal Food, Drug, and Cosmetic Act).
Marker compound	Chemically defined constituents or groups of constituents used to standardize and/or facilitate the analysis of dietary ingredients and finished dietary supplement products.
Method of analysis	A specific technique used to identify, quantify, or otherwise test the composition of a material.
Mineral based	Contains starting materials of mineral origin.
Mycotoxin	A toxic substance produced by a fungus, especially a mold.
NDI	New Dietary Ingredient (NDI). A dietary ingredient first marketed in a dietary supplement in the United States on or after October 15, 1994; certain NDIs may require a 75-day premarket notification subject to FDA review.
NNHPD	Natural and Non-Prescription Health Products Directorate (NNHPD) is the regulating authority for natural health products for sale in Canada. An NNHPD master file comprises regulatory dossier containing proprietary manufacturing details and/or the technical specifications of the medicinal ingredients/raw materials used in the manufacturing of a natural health product sold in Canada.

OEHHA	California Office of Environmental Health Hazard Assessment (OEHHA). OEHHA administers regulations that govern warnings and other aspects of CA Prop 65. <i>Also see CA Prop 65.</i>
Organic (organically grown)	“Organic” is a labeling term that indicates a product has been made in accordance with the USDA National Organic Program (7 CFR 205).
Organic solvent	A solvent whose molecular structure includes carbon and hydrogen. Most commonly used solvents, with the exception of water, are organic.
Organoleptic testing	Evaluations made using the sense organs (e.g., taste, color, odor, and texture).
Percolation	An extraction technique in which the botanical material is exhaustively extracted with fresh solvent until no further soluble components remain.
PhEur	European Pharmacopoeia.
Processing aids	Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculants, filter aids, and crystallization inhibitors. See 21 CFR 170.3(o)(24).
Product	The finished commercial form of a dietary ingredient, which may include the dietary ingredient, excipients, and processing aids.
Product of fermentation	A product derived from a process in which living cells harvest fuel molecules from a substance in order to generate ATP for their own energy needs. During that process, biochemical and physical alteration of the fermented product occurs.
Recommended reevaluation interval	The interval beyond which the dietary ingredient should not be used without further appropriate re-examination.
Residual solvents	Organic chemical solvents used or produced in the manufacture of a dietary ingredient that may be present in trace amounts in the finished dietary ingredient.
SDS	Safety Data Sheet (SDS). The Hazard Communication Standard (29 CFR 1910.1200(g)), revised in 2012, requires that the chemical manufacturer, distributor, or importer provide a Safety Data Sheet (formerly MSDS or Material Safety Data Sheet) for each hazardous chemical to downstream users to communicate information on these hazards.

Site	A location where the product is manufactured (produced or processed). At any site, there may be one or more operational facilities.
Sterilization	The act of rendering a product free of all viable microorganisms (as by the use of physical or chemical agents).
Supplier	A manufacturer or distributor who directly provides a dietary ingredient to the manufacturer.
Synthetic	Products derived from starting materials other than materials sourced from plants, animals or minerals and are not products of fermentation.
TSE	Transmissible Spongiform Encephalopathy (TSE). TSEs are rare forms of progressive neurodegenerative disorders that affect both humans and animals and are caused by similar uncharacterized agents that generally produce spongiform changes in the brain.
UNII	Unique Ingredient Identifier (UNII). The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information for substances in drugs, biologics, foods, and devices. UNII was developed as part of the joint FDA/USP Substance Registration System.
User	Any user or purchaser of dietary ingredients, including suppliers, distributors, brokers, finished dietary supplement manufacturers, etc.
USP-NF	United States Pharmacopeia/National Formulary.
Vegan	Excludes all animal products.
Vegetarian	Excludes animal flesh, but may include eggs and dairy products.
Vegetable sourced	Contains starting materials of plant origin.
Water activity	Water activity (a_w) is a measure of the free moisture in a component or dietary supplement and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

APPENDIX A

Dietary Ingredient Data Sheet Template

Download MS WORD versions of templates from www.sidiworkgroup.com

SIDI™ Template Form

Dietary Ingredient Data Sheet (DIDS)

This document is intended to be a template or example for how dietary ingredient suppliers might consider organizing the manufacturing, physical, chemical, labeling, and regulatory information for their product. This form is not intended to be binding or required, and has intentionally been developed in MS Word format to allow it to be modified by users, if they so choose, to a format or organization that best meets their needs. In addition, users are not expected to confine their product information to the space provided in this document. However, users are encouraged to follow the same basic flow of information, regardless of the specific format used. Documentation or explanation related to specific sections should be included/attached when applicable.

**COMPANY
LOGO/LETTERHEAD/OFFICIAL
STATIONERY**

DIETARY INGREDIENT DATA SHEET

Section 1. PRODUCT INFORMATION	
PRODUCT NAME & CODE:	
COMMON OR USUAL NAME:	
LATIN BINOMIAL OR SCIENTIFIC NAME:	
GENERAL PRODUCT DESCRIPTION:	
PRODUCT COUNTRY OF ORIGIN:	

Section 2. MANUFACTURING INFORMATION	
NAME AND ADDRESS OF MANUFACTURING SITE:	
CGMP COMPLIANCE:	
STERILIZATION OR FUMIGATION METHOD(S):	
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	
MODE OF MANUFACTURING:	
AGRICULTURAL PROCESS*:	
FLOWCHART AND DESCRIPTION OF MANUFACTURING PROCESS:	
EXTRACT*:	<input type="checkbox"/> Yes; <input type="checkbox"/> No Type of extraction process: Type of extract:
<i>* Complete for botanical products only</i>	

Section 3. PHYSICAL AND CHEMICAL INFORMATION									
COMPONENT(S) (include ALL components and excipients):									
COMMON or USUAL NAME	LATIN BINOMIAL*	SYNONYM	CAS #/UNII/ MOLECULAR FORMULA	WT %	FUNCTION	PLANT PART*	HARVEST SEASON/ AGE*	COUNTRY OF ORIGIN ⁺	SOURCE [^]
<i>*Provide for botanical components only. ⁺For botanical components, provide country(s) of harvesting or processing. [^]Provide for non-botanical components only.</i>									
INCIDENTAL ADDITIVES AND/OR PROCESSING AIDS (include reason for use)									
CURRENT PRODUCT SPECIFICATION SHEET ATTACHED									

Section 4. LABELING INFORMATION	
REQUIRED FINISHED PRODUCT LABEL STATEMENTS:	
RECOMMENDED RESTRICTIONS OR LIMITATIONS OF USE:	
NUTRITION INFORMATION (<i>indicate whether calculated or analytical</i>):	

Section 5. REGULATORY AND COMPLIANCE INFORMATION	
PATENT COVERAGE:	
COMPENDIAL STANDARD:	
REGULATORY STATUS:	
PROP 65 CHEMICALS IN PRODUCT:	
PROP 65 CHEMICALS USED IN MANUFACTURING PROCESS:	
NNHPD PRODUCT MASTER FILE(S):	
BSE/TSE INFORMATION:	
VEGAN OR VEGETARIAN STATUS:	
GLUTEN STATUS:	
ALLERGENS/SENSITIVITIES (<i>Include any and all FALCPA major allergens</i>):	
KOSHER/HALAL/ORGANIC STATUS:	
BE/GMO STATUS (<i>for each component</i>):	
TARIFF CODE for IMPORT/EXPORT:	

Section 6. OTHER PRODUCT INFORMATION	
BATCH/LOT NUMBERING SYSTEM:	
BATCH/LOT DEFINITION:	
EXPIRATION DATE/SHELF LIFE/RECOMMENDED REEVALUATION INTERVAL:	
RECOMMENDED STORAGE CONDITIONS:	
RECOMMENDED TRANSPORT CONDITIONS:	
SPECIAL SAFETY/HANDLING INSTRUCTIONS FOR MANUFACTURING:	
PACKAGING INFORMATION:	
SAFETY DATA SHEET (SDS) ATTACHED:	
PRODUCT SAFETY INFORMATION:	
OTHER PRODUCT INFORMATION:	

Section 7. DOCUMENT INFORMATION			
VERSION NO.:		REVISION/REVIEW DATE:	
SIDI™ PROTOCOL VERSION USED:			
VERSION CONTROL HISTORY:			

Section 8. CONTACT INFORMATION	
COMPANY NAME:	
CONTACT NAME:	
TITLE:	
EMAIL:	
PHONE:	

APPENDIX B

Non-Botanical Product Data Sheet Template

Download MS WORD versions of templates from www.sidiworkgroup.com

SIDI™ Template Form

Dietary Ingredient Data Sheet (DIDS)

Non-Botanical Product Information

This document is intended to be a template or example for how dietary ingredient suppliers might consider organizing the manufacturing, physical, chemical, labeling and regulatory information for their product. This form is not intended to be binding or required, and has intentionally been developed in MS Word format to allow it to be modified by users, if they so choose, to a format or organization that best meets their needs. In addition, users are not expected to confine their product information to the space provided in this document. However, users are encouraged to follow the same basic flow of information, regardless of the specific format used. Documentation or explanation related to specific sections should be included/attached when applicable.

**COMPANY
LOGO/LETTERHEAD/OFFICIAL
STATIONERY**

NON-BOTANICAL PRODUCT DATASHEET

Section 1. PRODUCT INFORMATION	
PRODUCT NAME & CODE:	
COMMON OR USUAL NAME OF PRODUCT:	
SCIENTIFIC NAME:	
GENERAL PRODUCT DESCRIPTION:	
PRODUCT COUNTRY OF ORIGIN:	

Section 2. MANUFACTURING INFORMATION	
NAME AND ADDRESS OF MANUFACTURING SITE:	
CGMP COMPLIANCE:	
STERILIZATION OR FUMIGATION METHOD(S):	
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	
MODE OF MANUFACTURING	
FLOWCHART AND DESCRIPTION OF MANUFACTURING PROCESS	

Section 3. PHYSICAL AND CHEMICAL INFORMATION						
COMPONENT(S) <i>(include excipients)</i>						
COMMON OR USUAL NAME	SYNONYM	CAS #/UNII/ MOLECULAR FORMULA	WT %	FUNCTION	COUNTRY OF ORIGIN	SOURCE
INCIDENTAL ADDITIVES AND/OR PROCESSING AIDS <i>(include reason for use)</i>						
CURRENT PRODUCT SPECIFICATION SHEET ATTACHED:						

Section 4. LABELING INFORMATION	
REQUIRED FINISHED PRODUCT LABEL STATEMENTS:	
RECOMMENDED RESTRICTIONS OR LIMITATIONS OF USE:	

NUTRITION INFORMATION (<i>indicate whether calculated or analytical</i>):	
---	--

Section 5. REGULATORY AND COMPLIANCE INFORMATION

PATENT COVERAGE:	
COMPENDIAL STANDARD:	
REGULATORY STATUS:	<input type="checkbox"/> Pre-DSHEA <input type="checkbox"/> Food additive <input type="checkbox"/> NDI <input type="checkbox"/> Other (describe) <input type="checkbox"/> GRAS
PROP 65 CHEMICALS IN PRODUCT:	
PROP 65 CHEMICALS USED IN MANUFACTURING PROCESS:	
NNHPD PRODUCT MASTER FILE(S):	
BSE/TSE INFORMATION:	
VEGAN OR VEGETARIAN STATUS:	
GLUTEN STATUS:	
ALLERGENS/SENSITIVITIES:	
KOSHER/HALAL/ORGANIC STATUS:	
BE/GMO STATUS (<i>for each component</i>):	
TARIFF CODE FOR IMPORT/EXPORT:	

Section 6. OTHER PRODUCT INFORMATION

BATCH/LOT NUMBERING SYSTEM:	
BATCH/LOT DEFINITION:	
EXPIRATION DATE/SHELF LIFE/RECOMMENDED REEVALUATION INTERVAL:	
RECOMMENDED STORAGE CONDITIONS:	
RECOMMENDED TRANSPORT CONDITIONS:	
SPECIAL SAFETY/HANDLING INSTRUCTIONS FOR MANUFACTURING:	
PACKAGING INFORMATION:	
SAFETY DATA SHEET (SDS) ATTACHED:	
PRODUCT SAFETY INFORMATION:	
OTHER PRODUCT INFORMATION:	

Section 7. DOCUMENT INFORMATION

VERSION NO.:		REVISION/REVIEW DATE:	
SIDI™ PROTOCOL VERSION USED			
VERSION CONTROL HISTORY			

Section 8. CONTACT INFORMATION

COMPANY NAME:	
CONTACT NAME:	
TITLE:	
EMAIL:	
PHONE:	

APPENDIX C

Botanical Product Data Sheet Template

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SIDI™ Template Form

Dietary Ingredient Data Sheet (DIDS)

Botanical Product Information

This document is intended to be a template or example for how dietary ingredient suppliers might consider organizing the manufacturing, physical, chemical, labeling, and regulatory information for their product. This form is not intended to be binding or required, and has intentionally been developed in MS Word format to allow it to be modified by users, if they so choose, to a format or organization that best meets their needs. In addition, users are not expected to confine their product information to the space provided in this document. However, users are encouraged to follow the same basic flow of information, regardless of the specific format used. Documentation or explanation related to specific sections should be included/attached when applicable.

Section 4. LABELING INFORMATION	
REQUIRED FINISHED PRODUCT LABEL STATEMENTS:	
RECOMMENDED RESTRICTIONS OR LIMITATIONS OF USE:	
NUTRITION INFORMATION (<i>indicate whether calculated or analytical</i>):	

Section 5. REGULATORY AND COMPLIANCE INFORMATION	
PATENT COVERAGE:	
COMPENDIAL STANDARD:	
REGULATORY STATUS:	<input type="checkbox"/> Pre-DSHEA <input type="checkbox"/> Food additive <input type="checkbox"/> NDI <input type="checkbox"/> Other (describe) <input type="checkbox"/> GRAS
PROP 65 CHEMICALS IN PRODUCT:	
PROP 65 CHEMICALS USED IN MANUFACTURING PROCESS:	
NNHPD PRODUCT MASTER FILE(S):	
BSE/TSE INFORMATION:	
VEGAN OR VEGETARIAN STATUS:	
GLUTEN STATUS:	
ALLERGENS/SENSITIVITIES:	
KOSHER/HALAL/ORGANIC STATUS:	
BE/GMO STATUS (<i>for each component</i>):	
TARIFF CODE for IMPORT/EXPORT:	

Section 6. OTHER PRODUCT INFORMATION	
BATCH/LOT NUMBERING SYSTEM:	
BATCH/LOT DEFINITION:	
EXPIRATION DATE/SHELF LIFE/RECOMMENDED REEVALUATION INTERVAL:	
RECOMMENDED STORAGE CONDITIONS:	
RECOMMENDED TRANSPORT CONDITIONS:	
SPECIAL SAFETY/HANDLING INSTRUCTIONS FOR MANUFACTURING:	
PACKAGING INFORMATION:	
SAFETY DATA SHEET (SDS) ATTACHED:	
PRODUCT SAFETY INFORMATION:	
OTHER PRODUCT INFORMATION:	

Section 7. DOCUMENT INFORMATION			
VERSION NO.		REVISION/REVIEW DATE	
SIDI™ PROTOCOL VERSION USED			
VERSION CONTROL HISTORY			

Section 8. CONTACT INFORMATION	
COMPANY NAME:	
CONTACT NAME:	
TITLE:	
EMAIL:	
PHONE:	

APPENDIX D

Site Quality Overview Data Sheet Template

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SIDI™ Template Form

Dietary Ingredient Data Sheet (DIDS)

Site Quality Overview

This document is intended to be a template or example for how dietary ingredient suppliers might consider organizing information on the site where their product is manufactured. This form is not intended to be binding or required, and has intentionally been developed in Word format to allow it to be modified by users, if they so choose, to a format or organization that best meets their needs. In addition, users are not expected to confine their site quality information to the space provided in this document. However, users are encouraged to follow the same basic flow of information, regardless of the specific format used. Documentation or explanation related to specific sections should be included/attached when applicable.

<p>COMPANY LOGO/LETTERHEAD/OFFICIAL STATIONERY</p>

SITE QUALITY OVERVIEW DATA SHEET

Section 1. SITE OVERVIEW			
SITE NAME AND ADDRESS:			
FOOD FACILITY REGISTRATION COMPLIANCE:			
STATE AND OTHER LICENSE REQUIREMENTS:			
CORPORATE OWNERSHIP (IF DIFFERENT FROM SITE ABOVE):			
SITE SIZE:		HISTORY:	
GENERAL AND PRODUCT LIABILITY INSURANCE LEVELS:		UNION:	
TYPE(S) OF INGREDIENT(S) PRODUCED/SUPPLIED BY THE SITE AND THEIR INTENDED APPLICATIONS:			
SITE ACTIVITIES:			
ORGANIZATIONAL STRUCTURE:			

Section 2. CGMP INFORMATION	
THIRD-PARTY VERIFICATION:	If yes, provide documentation
SUMMARY OF RECENT FACILITY INSPECTION BY STATE, FEDERAL OR FOREIGN AGENCY:	

Section 3. FOOD SAFETY INFORMATION
PROVIDE A SUMMARY OF HOW THE SUPPLIER COMPLIES WITH FOOD AND/OR DIETARY SUPPLEMENT REGULATIONS, AS APPLICABLE.
PREVENTIVE CONTROLS FOR HUMAN FOOD OR APPLICABLE HACCP PLAN:
SUPPLY CHAIN CONTROLS:
SANITARY TRANSPORTATION:
FOREIGN SUPPLIER VERIFICATION PROGRAMS:
FOOD DEFENSE PLAN:

Section 4. DOCUMENT INFORMATION			
VERSION NO.:		REVISION/REVIEW DATE:	
SIDI™ PROTOCOL VERSION USED:			
VERSION CONTROL HISTORY:			

Section 5. CONTACT INFORMATION

COMPANY NAME:	
CONTACT NAME:	
TITLE:	
EMAIL:	
PHONE	