ABC AHP NCNPR

Botanical Adulterants Prevention Program

Botanical Adulterants Prevention Program (BAPP) Best Practices Standard Operating Procedure (SOP) for the Disposal / Destruction of Irreparably Defective Articles

CONTENTS

Section 1: Introduction

October 2022

The documents in this packet have been produced to help ensure the authenticity of botanical and non-botanical raw materials, extracts, and essential oils used in consumer products. They are the result of the research and educational efforts by the ABC-AHP-NCNPR Botanical Adulterants Prevention Program (BAPP), a consortium of three nonprofit organizations: the American Botanical Council, the American Herbal Pharmacopoeia, and the National Center for Natural Products Research at the University of Mississippi, a center of excellence funded in large part by the United States Food and Drug Administration. Since its inception in 2010 BAPP has been supported and/or endorsed by over 200 companies in the international botanical industry, trade associations, professional medicinal plant research societies, and more.

While it is very difficult to measure the actual extent of economically motivated adulteration in the global trade of botanical raw materials, extracts, and essential oils, it is possible to document and confirm the fact that various botanical ingredients are subject to intentional adulteration and fraud. As of the time of this writing, the ABC-AHP-NCNPR Botanical Adulterants Prevention Program has published more than 75 peer-reviewed documents designed to aid responsible members of the international herb and medicinal plant community in authenticating the identity of botanical ingredients and to help protect buyers from purchasing and processing adulterated, fraudulent botanical ingredients. These BAPP publications include, but are not limited to, Botanical Adulterant Prevention Bulletins that confirm the adulteration of specific botanical ingredients, Laboratory Guidance Documents that assess and document the reliability and fitness of purpose of specific analytical methods for identifying botanical ingredients and detecting adulteration, and “Botanical Adulterants Monitor” newsletters that summarize recent publications in the scientific literature related to the detection of adulteration and fraud in the botanical market. Since 2011 all BAPP publications have been available on a free-access basis on the BAPP homepage on the ABC website (registration required): https://www.herbalgram.org/resources/botanical-adulterants-prevention-program/.

There are numerous definitions of adulteration. For the present purposes, according to the United States Pharmacopeial (USP) Convention:

> Food fraud in the context of food ingredients refers to the fraudulent addition of non-authentic substances or removal or replacement of authentic substances without the purchaser’s knowledge for economic gain of the seller. It is also referred to as economic adulteration, economically motivated adulteration, intentional adulteration, or food counterfeiting. (Johnson R. Food Fraud and “Economically Motivated Adulteration” of Food and Food Ingredients. Congressional Research Service, Washington, DC., 2014. https://sgp.fas.org/crs/misc/R43358.pdf.)

Economically motivated adulteration(EMA) can occur by numerous means: the concealed substitution of an ingredient with one of lesser economic value, the undisclosed dilution of a labeled ingredient with another of lesser value, the undisclosed addition of various natural and/or synthetic chemicals to extracts to attempt to deceive various laboratory analytical methods, and more.

As extensively documented in BAPP's initial peer-reviewed publication, intentional adulteration of herbs, spices, and botanical drugs has been occurring for centuries, even millennia (Foster S. A Brief History of Adulteration of Herbs, Spices, and Botanical Drugs. *HerbalGram* 2011;92;42-57). Fraud occurs in various industries, including foods (olive oil, wine) and even in the pharmaceutical industry. Adulteration and fraud are an unfortunate fact of life, in commerce, and of history.

But it is not enough to simply identify botanicals that are subject to adulteration, how they are adulterated, and which laboratory analytical methods are fit for purpose to authenticate ingredients and detect adulteration. The purpose of this Best Practices Standard Operating Procedure (SOP) is to provide responsible members of the botanical industry with additional resources to remove ingredients from the supply chain if they are deemed, according to the SOP, to be "irreparably defective", a new term created for this SOP. That is, irreparably defective articles cannot be lawfully reconditioned or remediated to the extent that they can be legally allowed in products used as foods, dietary supplements (food supplements), cosmetics, or nonprescription medications.

The documents in this packet include the following:

The **SOP Decision Tree**: a flowchart graphically depicting the decisions related to quality control of all material receipts.

Contract Language that industry members can customize to fit their specific needs. Modular in design, it can be appended to existing supply contracts or referenced via a standalone memorandum of understanding. To achieve the goal of mandatory Destruction of "irreparably defective articles," we anticipate the definitions, dispute resolution process, and notification and recordkeeping process to be widely adopted by companies committed to defect-free quality ingredients in their finished products.

A draft SOP template, with two supporting document templates, for recordkeeping and to explain the process by which buyer and seller agree to document to each other the certified Destruction of irreparably defective articles.

A three-party nondisclosure agreement (NDA) among buyer, seller, and analytical laboratory to protect the confidentiality of data and define the specific process by which dispute resolution might occur. This fairly protects the economic interests of all parties, including the labs. (When asked in an interview "Who pays for the testing in the event the supplier disagrees with the buyer who rejects an ingredient based on the assessment of irreparably defective?" Michael D. Levin, primary author, answered, "The loser." Buyer and seller agree upfront which lab to use and how to test, and the lab has financial guarantees contractually obligated while confidentiality is appropriately preserved.)

The Frequently Asked Questions (FAQs) section addresses numerous comments received during two rounds of public comment and team review. The FAQs are in very plain language and provide the reasoning behind the choices for specific language and the final recommendations taken.

The online version of this entire document is available here:
http://herbalgram.org/resources/botanical-adulterants-prevention-program/laboratory-guidance-documents/BAPP-SOP/

BAPP is deeply grateful to its many regulatory and quality control experts and financial underwriters who have participated in and supported the development and publication of this SOP.

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Section 2: Disclaimer

The Botanical Adulterants Prevention Program (BAPP) Best Practices Standard Operating Procedure (SOP) for the Disposal / Destruction of Irreparably Defective Articles ("BAPP SOP Guidance") was prepared under the auspices of the ABC-AHP-NCNPR Botanical Adulterants Prevention Program.

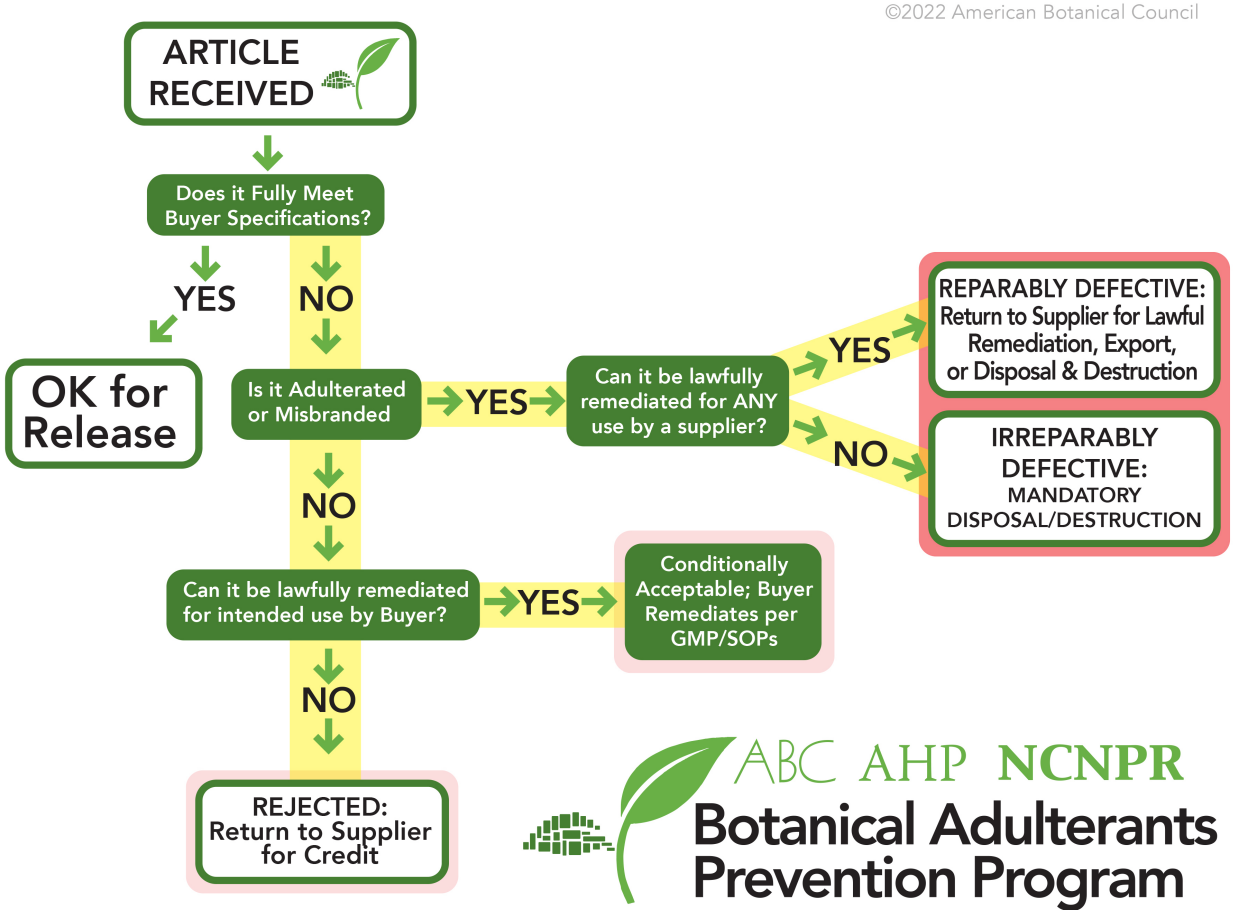
The BAPP SOP Guidance, a voluntary set of guidelines, is intended for use by suppliers, manufacturers, and distributors of herbal raw materials, other dietary ingredients, food ingredients, cosmetic ingredients, and finished products in implementing best practices in supply agreements and quality control operations to protect against intentional and accidental adulteration and ensure that irreparably defective raw materials and products are destroyed or appropriately disposed of and thereby removed from the supply chain.

This document is intended for general informational purposes only and is not intended to provide any legal advice or substitute for the advice or professional services of an attorney or law firm. Users of this document are advised to seek competent legal counsel in connection with any commercial contracts, quality agreements, and standard operating procedures to verify specific legal and regulatory compliance.

Although the authors and publishers, BAPP, and its individual representative organizations, ABC, AHP, and NCNPR, have exercised significant efforts to provide a complete, accurate, and reliable document, including, but not limited to soliciting public input from industry members and other interested parties on two occasions, the authors and publishers make no representations or warranties of any kind regarding the completeness, accuracy, reliability, or suitability of the BAPP SOP and related guidance documents for any purpose, and hereby disclaim all express and implied warranties, including the implied warranty of fitness for any particular purpose. Neither the publishers nor the authors of the BAPP SOP Guidance shall be liable for any loss or damages of any kind, including but not limited to direct, indirect, special, incidental, consequential, exemplary, or punitive damages, related to the use of or reliance upon this information, whether in whole or part, by any company, entity, or individual.

Section 3: SOP Graphic Decision Tree for Defective Articles

SOP Decision Tree for Defective Articles



Section 4: Supply Chain Contract Language Template

Section 4.A: Definitions

1. **"Adulterated"** Adulterated foods, dietary ingredients, and dietary supplements are defined in 21 US Code Subchapter 342. Adulterated cosmetics are defined in 21 US Code Subchapter 361.

2. **"Article"** refers to a dietary ingredient or other component used in the manufacture of dietary supplements, a food used in the manufacture of food products, or ingredients used in the manufacture of cosmetic products.

3. **"Company"** Unless otherwise specified as "Supplier" or "Buyer," the term "Company" may refer to a Buyer, Supplier, or Analytical Laboratory.

4. **"Component"** means 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. Components include dietary ingredients (as described in section 201(ff) of the (US) Food, Drug and Cosmetic Act (FDCA) and other ingredients, processing aids, etc. used in the manufacture of food and cosmetic products.

5. **"Defective"** describes any Article that does not fully meet the Buyer's currently approved specifications and/ or does not comply with applicable laws (e.g., adulterated and/or misbranded with an undeclared ingredient; the adulteration could be deliberate (e.g., economic adulteration of glycerin with DEG) or accidental (e.g., contamination with an unlawful pesticide). NB: Whereas BAPP previously focused only on adulterated products, this language is expanded in scope to now include contaminated ingredients; this deliberate expansion is an effort to contractually stop the resale of both health.

6. **"Dietary Ingredient"** The Dietary Supplement Health and Education Act of 1994 (DSHEA – Public Law 103-417) defines in Section 3 a dietary ingredient "as a vitamin; mineral, herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances." For a complete definition, refer to https://ods.od.nih.gov/About/DSHEA_Wording.aspx#sec3

7. **"Disposal" and "Destruction"** Any Article that is not approved for use by the Buyer's Quality Unit must remain quarantined to prevent its release into manufacturing. Under cGMPs and in a manner fully compliant with the Company's SOPs, the disposition of the quarantined Article will be determined by the Quality Unit (for dietary supplements examples, see 21 CFR 111.87 and 111.90). After consultation and agreement is reached with the Supplier, when the material review determines that the final disposition does not include lawful reprocessing OR lawful return to Supplier, the quarantined article will be labeled for Disposal. Articles labeled for Disposal must be lawfully destroyed by Buyer,

Supplier, or a licensed third party as approved by the parties hereto. The parties hereto agree that evidence of all instances of lawful remediation, lawful export, and lawful Destruction will be provided to and retained by both Buyer and Supplier and in compliance with the notification requirements in the SOP.

8. **"Food"** has the meaning given to it in 21 CFR 117.3, namely: "food means food as defined in section 201(f) of the Federal Food, Drug and Cosmetic Act and includes raw materials and ingredients. Specifically, the term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for any such article."

9. **"Ingredient"** Unless modified by the term "dietary," in which this term refers to a special class of ingredients used in dietary supplements, as defined by DSHEA and noted above, it has the meaning given to it in 21 CFR 700.3(e), namely: "The term *ingredient* means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product." or as it is defined in 21 CFR 117.3 when used in reference to food ingredients (i.e., "Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.").

10. **"Irreparably Defective"** describes an Article that is Defective and cannot be lawfully remediated by Supplier or any third party for any use. For avoidance of doubt, this description can apply to "components" (used in dietary supplements [DS]), "ingredients" (used in cosmetics), and/or "food" (used in foods). An Irreparably Defective Article that cannot be lawfully remediated for any use (example: used as a cosmetic ingredient instead of a DS component) must be disposed of and/or destroyed to prevent its re-entry into commerce. Examples of Irreparably Defective Articles include, but are not limited to, the following:

    a. Articles containing illegal, undeclared drugs, unlawful levels of biological or chemical contaminants
    b. Articles containing botanical ingredients adulterated with one or more undeclared species, undeclared dyes, and other economically motivated adulterants that cannot be removed and lawfully remediated
    c. Irreparable failure to meet all Buyer specifications for identity, purity, strength, composition, and limits on contaminants for specific ingredients: e.g., melamine in protein powder, DEG in glycerin, palm oil and/or animal fats in saw palmetto, sodium alginate and alginate sulfate di-ester in chondroitin, etc. Reference 21 CFR 111.70(b)

11. **"Lawful Export"** means that all conditions of sale, transfer, and shipment are in full compliance with all applicable laws of both the exporting and importing countries.[1]

[1] For more on export regulations, see https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/imports-exports-guidance-documents-regulatory-information

12. **"Misbranded"** A food shall be deemed to be misbranded in accordance with the definitions provided in 21 USC Subsection 343. A cosmetic shall be deemed to be misbranded if it meets the standards defined in 21 USC Subchapter 362.

13. **"Non-Conforming Article"** is any article that does not fully meet the Buyer's specifications. A non-conforming article may be determined after inspection by the parties to be either Reparably Defective or Irreparably Defective; if the latter, the article will be scheduled for Disposal or lawful Destruction.

14. **"Qualified Laboratory"** means a laboratory used for analytical and/or microbiological testing that, at minimum, satisfies FDA and all other applicable regulations, is compliant with Buyer's supplier qualification SOPs and is compliant with 21 CFR Part 111. Additionally, a Qualified Laboratory uses testing methods that are appropriate and fit for purpose or published compendial methods that have been verified as such within the laboratory; all methods used are scientifically valid, statistically sound, and fit for purpose in the matrix. Unless otherwise prescribed by local regulation, a Qualified Laboratory's compliance with ISO/IEC 17025:2005 or equivalent is recommended but not mandatory.

15. **"Quality Officer"** is the individual authorized on behalf of a dietary supplement company to make final disposition decisions (21 CFR 111.3 and 21CFR 111.12(b)) for acceptance or rejection of any component, package, dietary supplement, or label that does not meet established specifications as defined in 21 CFR 111.77. In a dietary ingredient or other food ingredient company, the "Quality Officer" is the individual authorized to assure compliance with 21 CFR 117.80(b) and Subpart C of Part 117 (Hazard Analysis and Risk-Based Preventive Controls). As of October 2021, Cosmetic companies are subject to non-binding FDA cGMP Draft Guidance that was last revised in June 2013 (https://www.fda.gov/media/86366/download); in Cosmetic Companies, "Quality Officer" would be the individual authorized to make disposition decisions on all Raw Materials as described therein. In companies that market more than one category of product, the Quality Officers are those individuals authorized to make disposition decisions on a category of product as defined in the regulations and/or non-binding guidance for cosmetics.

16. **"Reparably Defective"** describes any Article that is non-conforming with Buyer's complete set of specifications associated with the purchase order, has evidence of improper storage or transportation conditions, has damage to the product or product containers, or is otherwise "adulterated" or "misbranded" as defined in [FD&C Act, sec. 301(a) and (d); 21 U.S.C. 331(a) and (d)]. It may be possible for the Supplier to lawfully remediate a Reparably Defective Article or lawfully export it to a foreign country where the Article would fully comply with all locally governing regulations.

17. **"Samples"** means samples of an Article used for testing that are lot representative, collected in compliance with appropriate compendial standards

(e.g., USP, Canadian Food Inspection Agency[2], etc.) and handled with fully documented records, preserving chain of custody. Samples must be properly packaged and stored to ensure their integrity before, during, and after testing. Documentation of storage and handling conditions must be maintained.

18. "**Specification**" refers to the Buyer's revision-controlled component specifications required under 21 CFR 111.70 (for dietary supplements) and as may be detailed by Buyer on orders to Suppliers for Articles used in cosmetics, and in other foods.

Section 4.B: Inspection and Rejection

1. Buyer (or its representative) reserves the right, but has no obligation, to inspect the Articles at factory, warehouse, or other location prior to shipment. Final inspection shall be on Buyer's premises unless otherwise agreed to in writing. Buyer shall have the right to reject any non-conforming Article, which may be either a Reparably Defective or Irreparably Defective at the sole discretion of the Buyer, subject to provisions for Dispute Resolution (below). Articles determined to be non-conforming or Reparably Defective (but not Irreparably Defective) may be returned to Supplier at the Supplier's sole expense, including transportation and handling costs. Upon determining the Article is Defective, Buyer shall promptly notify Supplier of any such rejection and the reasons thereof, including whether such Article is Reparably Defective or Irreparably Defective.

2. Buyer's right to reject shall not be deemed to have been waived solely because Buyer paid for the Article prior to discovery of the defect.

3. Upon Buyer's proper notice to Supplier that any shipment contains non-conforming, Reparably Defective, or Irreparably Defective Articles and is rejected, Supplier shall, upon receipt of such notice, promptly investigate its records and initiate a quality control investigation which may include testing of retain samples and related batches.

4. If Supplier's investigation confirms that a shipment contains non-conforming, Reparably Defective Articles (but not Irreparably Defective Articles), the following shall apply:

    a. **Replacement and Credit of Defective Articles:** Supplier shall, at Buyer's option and Supplier's sole expense, arrange for timely delivery of replacement Article, or issue a credit to Buyer's account or refund, as appropriate and agreed to by and between the parties.

    b. **Return, Export, or Disposal of Reparably Defective Articles:** Buyer shall, at Supplier's sole discretion and expense, return Article to

[2] http://www.inspection.gc.ca/food/compliance-continuum/guidance-for-inspectors/sip/general-principles-of-sampling/eng/1540234969218/1540235089869

Supplier for lawful remediation, lawful export, or lawful Disposal of all such Defective Articles.

c. **Recordkeeping and Notice:** Supplier shall provide a report to Buyer within 30 (thirty) business days of receipt of the returned Defective Articles that documents the specific actions taken by Supplier to lawfully remediate, resell, or lawfully dispose of or destroy Defective Articles.

5. If Supplier's investigation confirms that a shipment contains Irreparably Defective Articles, the following shall apply:

a. **Mandatory Destruction of Irreparably Defective Articles:** If Supplier's investigation confirms Buyer's finding that the Articles are Irreparably Defective, the parties agree that the Irreparably Defective Articles must be lawfully destroyed to prevent their re-entry into the supply chain. The Supplier shall, at its sole expense, approve the lawful Disposal (Disposal is, as defined above, the intent to lawfully destroy) and Destruction of the Irreparably Defective Articles by either the Buyer or the Supplier, as the parties may agree. Articles designated for Disposal and Destruction shall remain in quarantine and labeled in such a way as to prevent their unauthorized release into manufacturing. For hazardous material Disposal and general guidelines from the Food Safety Inspection Service and FDA, see: https://www.fsis.usda.gov/shared/PDF/Disposal_Decontamination_Guidelines.pdf

b. **Recordkeeping:** The party who arranges for the lawful Destruction of Irreparably Defective Articles shall provide the other with certified documentation of the lawful Destruction of the Articles. If Destruction is made by Supplier, Supplier shall provide Buyer with certified documentation within 21 (twenty-one) business days of receipt of Irreparably Defective Articles after they have been returned by Buyer. If Destruction is made by Buyer, Buyer shall provide Supplier with certified documentation of the lawful Destruction of the Articles within 21 (twenty-one) business days of receipt of authorization from Supplier. Certified documentation shall include, at minimum, date of Disposal/Destruction, complete description of Articles (complete commercial name, weight, supplier lot number, manufacturer ID number [if any]), disposing party name, certified waste Disposal company with full contact information and signed receipt of waste by a duly authorized employee of the waste management firm. Copies shall become records retained by the Quality Units at both Buyer and Supplier pursuant to applicable regulations and Company policies. (The 21 days for notice is suggested but may be changed based upon agreement between Buyer and Seller.)

c. **Agreement to Share Disposal Information:** Notwithstanding other provisions of non-disclosure contained in any agreement by and between the parties, the parties agree to share, at either party's option, without restriction, non-financial information pertaining to the Disposal and/or Destruction of Irreparably Defective Articles with (1) appropriate regulatory authorities (e.g., FDA) and/or (2) academic researchers investigating adulteration of Articles in the supply chain (as agreed to and documented by the parties). The submitting party is solely responsible for the accuracy of all reports concerning Destruction of Irreparably Defective Articles. The parties hereto agree that having this information compiled in a searchable database will serve as a tool to help satisfy supplier verification requirements, help facilitate regulatory enforcement against criminal activity, and is in the public interest.

Section 4.C: Dispute Resolution Process: If the parties disagree on whether the Articles are Irreparably Defective, the following provisions shall apply:

1. **RFQ:** The parties agree to attempt to resolve their disagreement in a timely manner by soliciting requests for quotation ("RFQs") from up to three Qualified Laboratories to resolve the dispute. All RFQs must be signed by an authorized Quality Officer from both companies. The Quality Officers will review the quotations and jointly determine which proposal to accept. Preference will be given to Qualified Laboratories which have demonstrated proficiency in use of a compendial method and/or performed a single lab validation ("SLV") of a specific analytical method suitably validated in the matrix. Such lab must be willing to share documentation proving the SLV and demonstrating such things as accuracy, precision, repeatability, intermediate precision, specificity, detection limits, quantitation limit, linearity, and range, as the Quality Officers deem appropriate. The selected Qualified Laboratory must make available all communications, including but not limited to internal lab documents, methods, workbooks, and reports pertaining to this project, without prejudice, equally to both parties. The lab shall exercise its expert judgment in proposing an analytical approach that will generate scientifically defensible data.

2. **Disqualification:** A Qualified Laboratory shall not be disqualified from performing such testing solely because the laboratory has performed work for either Buyer or Supplier.

3. **Scientifically Valid Methods:** Wherever available, published analytical methods demonstrated to be scientifically valid and fit for purpose in the matrix at issue will be used. If test methods to be used are not those set forth in the Specifications for the Article in question, analytical test methods and necessary reference materials shall be agreed upon by the parties as detailed in the RFQ. If an official compendial method (e.g., USP, AOAC, BAM [USFDA Bacteriological Analytical Manual], European Pharmacopeia, Chinese, Pharmacopeia, Japanese Pharmacopeia, etc.) exists, it will be considered for use. Chain of

sample custody will be preserved and documented. Number of replicates needed will be recommended on a case-by-case basis by the laboratory and specified in the response to the RFQ. Results will be reported to the Quality Officers of both Buyer and Supplier along with indicators of precision and accuracy (if applicable). The Quality Officers from Buyer and Supplier will approve an acceptable RFQ that they, as quality experts by training, education, and experience, agree will resolve the matter in dispute in a scientifically defendable manner.

4. **Approvable Laboratories and Methods (optional):** The parties hereto agree that the testing laboratories identified on Addendum B in the Three-way Confidentiality Agreement and the specific tests with method citation for each analyte and/or specification set forth in Addendum A in the Three-way Confidentiality Agreement may be used as is without prejudice.

5. **Acknowledgement:** The parties hereby acknowledge that the testing standards and methods in the approved RFQ and the Specifications therein are acceptable to both parties as evidenced by authorized signatures by both Quality Officers.

6. **Binding Results:** The results obtained by the Qualified Laboratory shall be binding upon the parties. In the event the parties cannot agree on which Qualified Laboratory proposal should be selected for dispute resolution (pursuant to 6. a, above), the parties will select the mid-priced proposal to perform the necessary work.

7. **Economic Consequence:** The party found to be in error regarding the conformance with specifications and/or compliance with applicable laws of the disputed Articles shall bear all expenses relating to such testing, including any reasonable and necessary consulting costs charged by the Qualified Laboratory to develop the project design, and will fully reimburse the other party for all direct costs it incurred. This may be paid from an escrow account established in advance of the dispute resolution process by the parties or as otherwise agreed and appropriately documented.

8. **Supplier Investigation of Defective Articles**. Supplier agrees to promptly investigate the cause of any Defective Article and (i) report the results of such investigation in writing to Buyer, (ii) provide to Buyer in writing the corrective action Supplier has taken or will take to prevent a reoccurrence of the problem in the future, and (iii) advise Buyer of the estimated time for replacement of any Defective Article. Buyer acknowledges that any report it receives pursuant to the foregoing is subject to any non-disclosure agreement already in place by and between the parties.

Section 4.D: General Representations, Warranties, and Covenants

1. Supplier represents and warrants that in the event any Article is determined to Irreparably Defective pursuant to section 5.a. herein, Supplier will not object to its proper Disposal and Destruction by Buyer consistent with all provisions in Section 5 (above).

2. Buyer will provide Supplier with revision-controlled specifications for all Articles that are referenced in the purchase order. Supplier will provide Articles that are lawful and meet revision-controlled specifications. Specifications will not change without adequate prior written notice by Buyer to Supplier.

3. Supplier represents that every lot of Component, Food, or Ingredient delivered to Buyer will (a) meet Buyer's then current specification (on record) for such Article, (b) meet signed certificate of analysis (COA) that accompanies shipment of such Article, and (c) be lawful for its intended use and not be adulterated or misbranded.

4. Supplier represents that every lot of Component, Food, or Ingredient delivered to Buyer will (a) meet Buyer's then current specification (on record) for such Article, (b) meet signed certificate of analysis (COA) that accompanies shipment of such Article, and (c) be lawful for its intended use and not be adulterated or misbranded.

5. Supplier will provide Buyer with technical support concerning specifications, testing methods and references used to define the Article as required under current Good Manufacturing Practices for the respective Article.

Section 5: Article Disposal/Destruction SOP

[This SOP establishes procedures for documenting the disposition of a Reparably Defective Article and the lawful Destruction of an Irreparably Defective Article. Reparably Defective Articles may be returned for lawful remediation or lawful export. In contrast, Irreparably Defective Articles cannot be lawfully remediated to meet Buyer specifications and are unlawful for any use. As such, they must be lawfully destroyed to prevent their re-entry into the supply chain. In all cases, the Buyer must record disposition details to assure the lawful disposition of Reparably Defective and Destruction of Irreparably Defective Articles to prevent their unlawful reentry into the supply chain.

With few exceptions, there are no statutory requirements to destroy non-conforming materials; the only requirement is that they be rejected for use, leaving their disposition and fate unknown. However, in clear cases of intentional, unlawful, and potentially dangerous adulteration, assuring their Destruction is a wise and ethical business practice. The same is true for articles that are contaminated to an extent that they may be reasonably expected to pose an unacceptable health risk.

This SOP defines the minimum procedures that must be followed by authorized individuals qualified by training and experience. All performance dates are proposed and subject to negotiation between the parties; the negotiated contract will define the performance dates to be used for this SOP and all related SOPs.

Intentionally designed to be a modular SOP that can be referenced in existing Company SOPs pertaining to material review, SOP training, OOS (out of specification), etc., two related forms are offered. They are:

a. *Material Disposal and Destruction Form (MDD Form) which serves as input and close-out record for all Disposal/Destruction events and*

b. *Material Disposal and Destruction Log (MDD Log) which serves as sequential directory to all MDD events.]*

1.0 PURPOSE

This SOP describes the steps that Quality Control must follow when performing a material review of Reparably Defective or Irreparably Defective articles, to ensure the review is documented correctly at the time of performance in accordance with cGMP's, and to document the disposition decision.

2.0 SCOPE

This procedure applies to all dietary supplement, food, and cosmetic products and components distributed by [COMPANY NAME]. This SOP applies to the investigation of non-conforming materials used in the manufacture of dietary supplements, foods, and cosmetics.

3.0 DEFINITIONS

3.1 "Adulterated" An adulterated food, dietary ingredient, and dietary supplement is defined in 21 US Code Subchapter 342. Adulterated cosmetics are defined in 21 US Code Subchapter 361.

3.2 "Article" refers to a dietary ingredient or other component used in the manufacture of dietary supplements, a food used in the manufacture of food products, or ingredients used in the manufacture of cosmetic products.

3.3 "**Defective**" describes any Article that does not fully meet the Buyer's currently approved specifications and/or does not comply with applicable laws [e.g., adulterated and misbranded with an undeclared ingredient; the adulteration could be deliberate (e.g., economic adulteration of glycerin with DEG) or accidental (e.g., contamination with an unlawful pesticide)].

3.4 "**Disposal" and "Destruction**" Any Article that is not approved for use by the Buyer's Quality Unit must remain quarantined to prevent its release into manufacturing. Under cGMPs and in a manner fully compliant with the company's SOPs, the disposition of the rejected Article will be determined by the Quality Unit (for dietary supplements examples, see 21 CFR 111.87 and 111.90). After consultation and agreement is reached with the Supplier, when the material review determines that the final disposition does not include lawful reprocessing OR lawful return to Supplier, the quarantined Article will be labeled for Disposal. Articles labeled for Disposal may be lawfully destroyed by Buyer, supplier or a licensed third party as approved by the parties hereto. The parties hereto agree that evidence of all instances of lawful Destruction will be provided to and retained by both Buyer and Supplier and in compliance with all contractually defined recordkeeping and notification requirements (Sections 5 and 6, below).

3.5 "FSIS" Food Safety and Inspection Service of the US Department of Agriculture.

3.6 "Ingredient" has the meaning given to it in 21 CFR 700.3(e), namely: "The term *ingredient* means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product", or as it is defined in 21 CFR 117.3 when used in reference to food ingredients, "Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients."

3.7 "Irreparably Defective" describes an Article that is Defective and cannot be lawfully remediated by Supplier or any third party for any use. For avoidance of doubt, this description can apply to "components" (used in dietary supplements [DS]), "ingredients" (used in cosmetics), and/or "food" (used in foods). An Irreparably Defective Article that cannot be lawfully remediated for any use (example: used as a cosmetic ingredient instead of a DS component) must be lawfully destroyed to prevent its re-entry into commerce. Examples of Irreparably Defective Articles include, but are not limited to, the following:

a. Articles containing illegal, undeclared drugs, or unlawful levels of biological or chemical contaminants
b. Articles containing botanical ingredients adulterated with one or more undeclared species, undeclared dyes, and other economically motivated adulterants that cannot be removed and lawfully remediated
c. Other examples as may be specified in a specific ingredient/supplier supply contract

3.8 "**Lawful Export**" means that all conditions of sale, transfer and shipment are in full compliance with all applicable laws of both the exporting and importing countries.[3]

3.9 "**Misbranded**" A food shall be deemed to be misbranded in accordance with the definitions provided in 21 USC Subsection 343. A cosmetic shall be deemed to be misbranded if it meets the standards defined in 21 USC Subchapter 362.

3.10 "**Non-Conforming Article**" is any article that does not fully meet the Buyers Specifications. A non-conforming article may be determined after inspection by the parties to be either Reparably Defective or Irreparably Defective; if the latter, the article will be scheduled lawful Destruction.

3.11 "Qualified Laboratory" means a laboratory used for analytical and/or microbiological testing that, at minimum, satisfies FDA and all other applicable regulations, is compliant with Buyer's supplier qualification SOPs (Standardized Operating Procedures) and are compliant with 21 CFR Part 111. Additionally, a Qualified Laboratory uses testing methods that are appropriate and fit-for-purpose or published compendial methods that have been verified as such within the laboratory; all methods used are scientifically valid, statistically sound, and fit for purpose in the matrix. Unless otherwise prescribed by local regulation, a Qualified Laboratory's compliance with ISO/IEC 17025:2005 or equivalent is recommended but not mandatory.

3.12 "**Quality Officer**" is the individual authorized on behalf of a dietary supplement company to make final disposition decisions (21 CFR 111.3 and

[3] For more on export regulations, see https://www.fda.gov/RegulatoryInformation/Guidances/ucm125799.htm#

21CFR 111.12(b) for acceptance or rejection of any component, package, dietary supplement, or label that does not meet established specifications as defined in 21 CFR 111.77. In a dietary ingredient or other food ingredient company, the "Quality Officer" is the individual authorized to assure compliance with 21 CFR 117.80(b) and Subpart C of Part 117 (Hazard Analysis and Risk-Based Preventive Controls). As of October, 2021, Cosmetic companies are subject to non-binding FDA cGMP Draft Guidance that was last revised in June, 2013 (https://www.fda.gov/media/86366/download); in Cosmetic Companies, "Quality Officer" would be the individual authorized to make disposition decisions on all Raw Materials as described therein. In companies that market more than one category of product, the Quality Officer are those individuals authorized to make disposition decisions on category of product as defined in the regulations and/or non-binding guidance for cosmetics.

3.13 "Reparably Defective" describes any Article that is non-conforming with Buyer's complete set of specifications associated with the purchase order, has evidence of improper storage or transportation conditions, or has damage to the product or product containers, or is "adulterated" or "misbranded" as defined in [FD&C Act, sec. 301(a) and (d); 21 U.S.C. 331(a) and (d)]. It may be possible for the Supplier to lawfully remediate a Reparably Defective Article or lawfully export to a foreign country where the Article would fully comply with all locally governing regulations.

3.14 "Samples" means samples of an Article used for testing that are lot representative, collected in compliance with appropriate compendial standards (e.g., USP, Canadian Food Inspection Agency[4], etc.) and handled with fully documented records, preserving chain of custody. Samples must be properly packaged and stored to ensure their integrity before, during, and after testing. Documentation of storage and handling conditions must be maintained.

3.15 "**Specification**" refers to our revision-controlled component specifications required under 21 CFR 111.70 (for dietary supplements) and as we detail on purchase orders to Suppliers for Articles used in cosmetics, and in other foods.

4.0 RESPONSIBILITIES

4.1 Quality Control personnel must conduct a material review to make a disposition decision for all non-conforming Articles to determine if they are Reparably Defective or Irreparably Defective (as defined herein).

5.0 PROCEDURE

5.1 Quality Control must determine a non-conforming Article is Reparably Defective or Irreparably Defective (5.3.3, below). Quality Control must complete, date and

[4] http://www.inspection.gc.ca/food/compliance-continuum/guidance-for-inspectors/sip/general-principles-of-sampling/eng/1540234969218/1540235089869

sign Material Disposal and Destruction (MDD) reports. The person who conducts the material review and makes the disposition decision must, at the time of performance, document that material review and disposition decision and log it into the MDD log.

5.2 Immediately label all materials subject to a Material Review and hold in Quarantine until the outcome of the Material Review and Disposition Decision.

5.3 Complete the MDD Form

5.3.1. Assign the next available MMD number, log the name and date of QC individual who opened the investigation.

5.3.1.1. Provide the name and SKU number of the defective material being investigated.

5.3.1.2. Provide the Supplier Name, lot or batch number and the manufacturer's stock number (if available).

5.3.1.3. Provide the batch or lot size received, the date received, and the suppliers invoice date.

5.3.1.4. Provide the manufacturer's name (in the event the supplier is not the primary manufacturer) the manufacturing site address, the country of origin and manufacturing date.

5.3.2. Describe the specific defect found. Attach documentation, including analytical data, as appropriate.

5.3.3. Determine if the material is REPARABLY DEFECTIVE or IRREPARABLY DEFECTIVE.

5.3.4. Determine if the defective Article is non-hazardous and suitable for municipal waste (ref: page 21, FSIS Guidelines[5]) or if it either hazardous waste or otherwise requires special handling (ibid).

5.3.5. Disposition decision must be one of the following:

5.3.5.1. Reparably Defective Article: return to supplier for certified Disposal, lawful remediation and resale, or lawful export.

5.3.5.2. Irreparably Defective Article: return to supplier for certified Destruction.

5.3.5.3. Arrange for delivery to registered and QC approved waste management service for certified Destruction (include name and contact information).

5.3.6. Sign and date disposition decision, attaching all documentation necessary to fully support the decision.

5.3.7. When the defective Articles are disposed of/destroyed, complete EVENT

[5] https://www.fsis.usda.gov/shared/PDF/Disposal_Decontamination_Guidelines.pdf

CLOSE OUT SECTION:

5.3.7.1. For supplier certified Disposal and Destruction, attach their certified confirmation.

5.3.7.2. For waste we delivered for certified Destruction, log the date and attach proof of delivery and paid invoice (proof of lawful Disposal).

5.3.7.3. Sign and date the close out. Log the close out on the MDD log.

6.0 REPORTING

6.1.1. Assign a unique MDD number as defined in 5.3.1. File the MDD Form and all related documents such as the results of tests and examinations for the lot number(s) investigated.

6.1.2. Records must be kept for at least 3 years from MDD close date.

7.0 ATTACHMENTS

7.1. Material Disposal and Destruction Form

7.2. Material Disposal and Destruction Log

8.0 REFERENCE

8.1. Guidelines for the Disposal of Intentionally Adulterated Food Products and the Decontamination of Food Processing Facilities, April 14, 2006: https://www.fsis.usda.gov/shared/PDF/Disposal_Decontamination_Guidelines.pdf

9.0 CHANGE HISTORY

Revision #	Description	By	Date
001	Initial version	Authorized Individual	MM/DD/YY

Section 7.1: Material Disposal and Destruction Form ("MDD FORM")

INSTRUCTIONS

1. Material must be clearly labeled and quarantined pending the result of the Material Disposal and Destruction Review by our Quality Officer.
2. Fill out the form below. Give each MR a unique sequential number. Attach all supporting documents, such as test results, supplier COA, receiving documents, purchase documents, OOS report, etc.

MDD #	**Date Opened: Opened By** **(Print Name)**
Check one: ☐ Dietary Ingredient ☐ Other Ingredient ☐ OTHER (describe):	
Material Name/Our SKU Number	
Supplier Name; Lot/Batch Number and MSN	
Batch or Lot Size Received; Date Received; Supplier Invoice Date	
Manufacturer Name, Country of Origin and Date Manuf.	
Description of the specific deviation, failure, or unanticipated occurrence (attach analytical data as appropriate)	
Is this material defective OR irreparably defective? Defective ☐ Irreparably Defective ☐	
Is the article non-hazardous and suitable for municipal waste? Yes ☐ No ☐ OR Is the article categorized as hazardous waste or non-hazardous waste that requires special handling? Yes ☐ No ☐ - OR Other (describe):	
Disposition: *Attach an explanation of what you did with the article* A; ☐ Defective Article Returned to Supplier (circle one) for Lawful Remediation, Lawful Export, or Certified Disposal ☐ on DATE: _____ - OR B: ☐ Irreparably Defective Article Returned to Supplier	

for Certified Destruction on DATE: _____ - OR - **C: ☐ Defective Article will be promptly delivered for Disposal to registered and QC approved waste management service**
If C: Name of QC Approved Waste Management Service: If C: Waste Management Company Contact Information:_____
Disposition decision by: _____ **Signature: _____ Date:**

DISPOSAL/DESTRUCTION EVENT CLOSEOUT	
Local Waste Management Service Received Waste for Disposal on (date) *[Attach Delivery Receipt and Paid Invoice (Proof of Lawful Disposal)]*	**Date We Delivered Waste for Disposal: _____ (Proof of delivery attached)**
For Supplier certified Disposal/Destruction, attach their certified confirmation within 21 Business Days of Delivery *[This form remains open until confirmation of certified Disposal is received from Supplier; in the event Supplier does not respond in a timely manner, notify Quality Officer for guidance).*	**Date We Received Certified Conformation of Disposal/Destruction from Supplier*** **(Certified proof attached)**
For Supplier lawful remediation or lawful export, attach confirmation of same due within 30 days of delivery.	**Date We received Confirmation of Lawful Remediation or Export from Supplier:_____ (ATTACHED)**
Date Closed:	**Closed by (Print Name)**
Authorized Signature:	

Section 7.2: Material Disposal and Destruction Log ("MDD LOG")

INSTRUCTIONS

1. This log serves as a master directory to all MDD Disposition decisions.
2. QUALITY will complete the form below. As new log pages are required, add them sequentially, thus preserving the complete history of all MDD Disposition decisions.

#	MDD Number	SKU #	Date Opened	Opened by	Date Closed	Closed by
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

Section 6: THREE-WAY CONFIDENTIALITY AGREEMENT

This Agreement ("Agreement") is made and entered into as of [date] ("Effective Date"), by and among:

[COMPANY LEGAL NAME] a corporation organized and existing under the laws of the [STATE], with an office at [full legal address] ("Company")

[SUPPLIER LEGAL NAME] a [entity type] with its principal business at [full legal address] ("Supplier") and

[LABORATORY], a [entity type] with its principal business at [address] ("Third-Party Lab"), (individually a "Party" and collectively the "Parties").

WHEREAS,

Company markets and sells products regulated by the United States Food and Drug Administration (FDA) containing either food ingredients, dietary ingredients, components used in the manufacture of dietary supplements, and/or cosmetic ingredients.

And

WHEREAS,

Pursuant to [Company's purchase orders/the supply agreement between Company and Supplier dated {insert date}] (the "Supply Agreement"),
Supplier sells ingredients and/or components for use in such products to Company and has represented in the Purchase Agreement that such ingredients and/or components (i) when used in such products will not result in the products being misbranded or adulterated and (ii) fully satisfy the current specifications approved by Company).

And

WHEREAS,

The ingredients and/or components sold by Supplier to Company, and the finished products in which such ingredients and/or components are used, as well as the specifications for each (the "Specifications") are attached as ADDENDUM A – INGREDIENTS, COMPONENTS, FINISHED PRODUCTS, and SPECIFICATIONS to this Agreement. (Addendum A may be updated from time to time as agreed to by all Parties as evidenced by dated and signed updates by all Parties hereto.)

And

WHEREAS,

Third-Party Laboratory (aka Lab) is qualified by education, training, experience, registration, and/or certification (as defined in ADDENDUM B – LAB QUALIFICATIONS) to perform analytical and/or microbiological testing as may be required to confirm material compliance with the Specifications using scientifically sound methods fit for purpose for ingredients, components, and/or finished products listed in Addendum A.

And

WHEREAS,

From time to time, Supplier and Company may wish Third-Party Lab to test the ingredients, components, and/or finished products listed in Addendum A for compliance with the Specifications and provide Supplier and Company with the results of such testing (the "Results").

WHEREAS, the Parties acknowledge that each Party's Confidential Information is proprietary to and of value to that Party and that the Results constitute the Confidential Information of both Supplier and Company; and

WHEREAS, the Parties are willing to disclose Confidential Information to each other only for the purpose of permitting the Third-Party Lab to analyze and confirm if all Specifications have been met. The terms and conditions of payment to the Third-Party Lab for services rendered is defined in ADDENDUM C – LABORATORY TERMS AND CONDITIONS.

NOW, THEREFORE, the Parties, intending to be legally bound hereby, agree as follows:

1. The foregoing recitals are incorporated herein by reference.

2. Each of the Parties shall treat and maintain the Confidential Information of the other Parties in the strictest confidence and, at a minimum, will take reasonable precautions, in accordance with procedures that each Party follows from time to time with respect to its own confidential information, to prevent disclosure, directly or indirectly, to any other party of the other Parties' Confidential Information, except with prior written consent of the Party whose Confidential Information is proposed to be disclosed.

3. Each of the Parties will not make use of the Confidential Information of the other Parties except for the purpose contemplated by this Agreement.

4. The Parties' obligations as expressed in Sections 2 and 3 above shall not apply to: (a) any information known to or received by a Party prior to the Effective Date, as demonstrated by written records of said Party; (b) any information lawfully obtained, subsequent to Effective Date of this Agreement, by a Party from a third party not under an obligation of confidentiality to the disclosing Party; (c) any information that is in the public domain at the date of the disclosure or thereafter enters the public domain (but this exception applies only after the release of the information into the public domain) without the receiving Party's breach of any obligation to the Party whose Confidential Information is at issue; (d) any information that is independently developed by a receiving Party without use of, benefit of, knowledge of, or reference to the Party whose Confidential Information is at issue, as demonstrated by written records of the receiving Party; (e) any information that is required by law, court order, or government regulation to be disclosed; and (f) any information pertaining to the Disposal and/or Destruction of Irreparably Defective Articles (as such term is defined in the Supply Agreement), including without limitation the Results that is permitted to be shared under the Supply Agreement provided it is shared only as permitted in the Supply Agreement. If a disclosure is required under Section (e) above, and if legally permitted to do so, receiving Party shall as soon as possible give written notice of such requirement to the Party whose Confidential Information will be disclosed to allow such Party reasonable opportunity to seek a protective order or its equivalent.

5. Notwithstanding any other provision of this Agreement, Company and Supplier understand and agree that they are subject to, and agree to abide by, any and all applicable United States laws and FDA regulations, including the Food Safety Modernization Act (FSMA) and Current Good Manufacturing Practices controlling the import, manufacturing, packaging, and sale of foods (21 CFR Part 117), dietary supplements (21 CFR Part 111), and cosmetics (21 CFR Part 301).

6. At the completion of the purpose of this Agreement, or at the request of the Party whose Confidential Information was disclosed, the receiving Party shall promptly (within ten [10] business days) destroy or return to the Party whose Confidential Information was disclosed all tangible embodiments of Confidential Information and any and all related materials and notes and erase all electronic embodiments of Confidential Information and certify Destruction thereof while maintaining one copy of Confidential Information as may be required for archival/legal recordkeeping purposes. Nothing contained in this Agreement shall require a Party to search and destroy Confidential Information maintained on back-up drives (or their other electronic equivalent), but all such Confidential Information shall continue to remain confidential.

7. This Agreement grants no copyright, trademark, trade secret, patent rights, or licenses express or implied, and the disclosure of Confidential Information does not result in any obligation to grant any such right in and to the Confidential Information.

8. Each Party's obligations of confidentiality as set forth herein shall continue for a period of five (5) years from the date of each disclosure of Confidential Information.

9. Except for the Results, Confidential Information is provided "as is." With the exception of the Results, each of the Parties, including their agents and/or employees, make no warranty or condition of any kind, express, implied or otherwise, with respect to the accuracy, completeness or performance of the Confidential Information that they have disclosed. Except for the Results, each of the Parties, including their agents and/or employees, make no representation or warranty that the use of the Confidential Information that they have disclosed will not infringe any patent or other proprietary right.

10. No Party may assign or transfer any of its rights or obligations under this Agreement without the prior written consent of the other Parties.

11. This Agreement may be amended only by the mutual written consent of authorized representatives of all Parties.

12. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability or any other term or provision of this Agreement.

13. This Agreement is made under, and shall be construed according to, the laws of the [STATE OF RESIDENCE for COMPANY] without regard to any conflict of laws principles thereof.

14. This Agreement together with all attachments and exhibits, and as between Supplier and Company the Supply Agreement, represents the entire understanding of the Parties with respect to the subject matter hereof. In the event of any inconsistency between the terms of this Agreement and the Parties' understanding, the terms of this Agreement shall govern. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall be one document binding on all the Parties even though each Party may have signed different counterparts. This Agreement shall also be considered executed by the Parties upon receipt by the Parties of electronic or facsimile transmission of the counterparts signed by all the Parties. Any Party that delivers a signature page by electronic or facsimile transmission shall deliver an original counterpart to the other Parties upon request.

IN WITNESS WHEREOF, each of the Parties represent and warrant that it has the authority to sign this Agreement and have executed this Agreement as of the date indicated above.

For Company

COMPANY NAME
AUTHORIZED SIGNATORY NAME
Signature
Date

For Supplier

COMPANY NAME
AUTHORIZED SIGNATORY NAME
Signature
Date

For Third-Party Lab

COMPANY NAME
AUTHORIZED SIGNATORY NAME
Signature
Date

Section 6.A: THREE-WAY CONFIDENTIALITY AGREEMENT

ADDENDUM A – INGREDIENTS, COMPONENTS, FINISHED PRODUCTS, and SPECIFICATIONS

[This should be as complete as possible, and should include revision numbers, specification document numbers w/dates, for ingredients, components and finished product, as appropriate. Objective: all parties must agree on the baseline testing requirements, including methods, sample sizes, etc. as fully as possible to avoid any potential misunderstanding. Change control for these products must include all three Parties and may best be handled by updating the Change Control SOPs to reflect this Agreement and its connection to the Supply Agreement that incorporate the BAPP SOP Contract Language in re: Dispute Resolution.]

Section 6.B: THREE-WAY CONFIDENTIALITY AGREEMENT

ADDENDUM B – LAB QUALIFICATIONS

[Insert pertinent qualifications for the specific lab. Be as granular as necessary without over-engineering. Third-Party Lab must sign off on all language they agree to represent.]

Section 6.C: THREE-WAY CONFIDENTIALITY AGREEMENT

ADDENDUM C – LABORATORY TERMS AND CONDITIONS

Representations:

1. The parties hereto wish to comply with FDA cGMP regulations as they relate to Laboratory Operations, Change Control, and Specifications.
2. The Parties hereto acknowledge that the Supplier and Company have entered into the Supply Agreement, which contains several performance requirements, including without limitation that Supplier will provide ingredients and/or components to Company that meet the Specifications approved by the Company.
3. As provided in the Supply Agreement, in the event an ingredient or component does not meet the approved Specifications, Company retains the right to reject the materials. As provided in the Supply Agreement, the Supplier retains the right to challenge the Company's claim; if Supplier does make such a challenge, the Supplier and Company have agreed to:
    a. Request a quotation for analytical services from the Third-Party Lab pursuant the terms contained in the Supply Agreement, and which are reflected below.
    b. Should the Supplier and Company agree to retain the Third-Party Lab's services, as evidenced by their signatures accepting the Third-Party Lab's quotation which includes itemized work detail, terms and due dates, they each agree to provide directly to the Third-Party Lab 50% of the retainer required to commence work described in the quotation. The parties also agree to cooperate fully with the Third-Party Lab by providing all data, samples, etc. as may be required, with each Party being copied on all Confidential Information supplied to the Third-Party Lab.
    c. Upon completion of the testing and analysis by Third-Party Lab and delivery of the Results to Supplier and Company, the following shall apply:
        i. If the Results demonstrate that the ingredients and/or components tested did not meet the Specifications, the Supplier shall pay to Third-Party Lab the balance due on Third-Party Lab's Invoice and reimburse Company for the 50% of the retainer paid by Company within 15 days of receipt of the Results.
        ii. if the Results demonstrate that the ingredients and/or components tested met the Specifications, the Company shall pay the balance due on the Third-Party Lab's Invoice and reimburse Supplier for the 50% of the retainer paid by Supplier within 15 days of Receipt of the Results.

This document addresses the "Botanical Adulterants Prevention Program (BAPP) Best Practices Standard Operating Procedure (SOP) for the Disposal / Destruction of Irreparably Defective Articles". BAPP received over 150 comments and questions from various parties in the herb and medicinal plant and dietary supplement communities during two periods of public comment in which the BAPP SOP was released for such comment. This document contains various questions that arose and BAPP's responses. This document is intended to be used as clarification and as a form of guidance for anyone interested in the BAPP SOP.

Botanical Adulterants Prevention Program (BAPP) Best Practices Standard Operating Procedure (SOP) for the Disposal / Destruction of Irreparably Defective Articles

Section 7: FREQUENTLY ASKED QUESTIONS

General

Question1: Why do you call these templates? Why can't I use them as they are written?

Answer 1: Since every business is unique, yours may have unique needs that should be addressed in your supplier contracts. BAPP is simply providing these templates for review by your quality and legal teams for customization wherever needed and for inclusion by reference and/or appended to existing supply chain and quality agreements you already may have in place.

For example, your business may want to include certain representations and warranties that pertain to multi-national commerce. You may have certain specific ingredient specifications your legal advisor suggests be attached to the supply contract as an addendum, whereas other attorneys might advise attaching a current ingredient specification to each and every purchase order. Your company may have certain qualified laboratories vetted through your supplier verification and validation programs that you might want to reference in the supply contract as being the only laboratories approvable for dispute resolution on specific ingredients or finished products. Likewise, you might want to memorialize specific analytical methods on a per-ingredient basis that you wish to clearly identify in the supply contract to be used specifically for analytical testing of that analyte. While we would caution you to not get so granular as to make the supply contract unwieldy, we encourage you to consider all those things you believe are

necessary to fulfill your obligations under current Good Manufacturing Practices (cGMPs) and negotiate them in advance with your supplier.

In short, these templates are intended to be tools that will facilitate communication and define legally binding expectations by and between trading partners. In addition to their use in supply and/or quality agreements, certain representations and warranties may be added to all purchase orders; example: "Supplier warrants that dietary ingredients delivered to Buyer will not be adulterated or misbranded as defined in [FD&C Act, sec. 301(c); 21 U.S.C. 331(c)]."

Q2: Why should I or my company do this?

A2: Simply put, to mitigate business risk and to help prevent the resale of irreparably adulterated and/or contaminated, and possibly dangerous articles into the supply chain. The end goal here is to always keep the best interests of the consumer in mind.

Background: FDA regulations prohibit the use of ingredients or components that do not meet specifications (or are managed by exception with a planned deviation). But they are silent on what to do with non-conforming materials.

Some non-conforming materials may be adulterated and/or misbranded. Some non-conforming materials may not be able to be lawfully remediated and may, in fact, represent a health threat (example: aflatoxin at > 20 PPB in foods). Sometimes these non-conforming materials are simply rejected by the buyer, returned to the supplier, and, according to some reports, might be resold by the supplier into the supply chain. Depending on the situation, this unethical practice may be illegal on several levels.[6]

In recent years, the problem of marc[7] or otherwise "spent ingredients" (i.e., authentic but devoid of the native chemistry necessary to produce any meaningfully intended [or implied] biological activity) has been recognized as an increasing problem. When they enter commerce and are labeled as an "active ingredient" bearing a false activity/potency claim (rather than as an "other ingredient"), the products are misbranded, fraudulent, and being of exceedingly low in, if any, biological activity and in most cases literally impotent; they undermine consumer confidence in botanical products. This category of adulterated material can be detected only through the use of robust analytical methods integrated into carefully crafted ingredient specifications. For all practical purposes, "spent ingredients" cannot be lawfully remediated for intended labeled use as an "active ingredient" and, unless resold as an "other ingredient", should be considered irreparably defective and lawfully destroyed.

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed

[7] Marc: the residue remaining after a fruit has been pressed; the organic residue from an extraction process. https://www.merriam-webster.com/dictionary/marc

In developing robust ingredient specifications, we invite industry members and stakeholders to refer to the many advisories, botanical ingredient-specific Botanical Adulterant Prevention Bulletins and Laboratory Guidance Documents freely available from the Botanical Adulterants Prevention Program on the American Botanical Council website: https://www.herbalgram.org/resources/botanical-adulterants-prevention-program/.

Monographs from the American Herbal Pharmacopoeia, the USP/NF, European Pharmacopoeia, Health Canada, and other global regulatory resources can also be extremely helpful.

In providing these templates, BAPP's goal is simply to empower trading partners with the contract language and SOP tools to prevent the resale of irreparably defective articles into the supply chain.

Risk Management: The contract language defines the party who is at **economic risk**. One of the most fundamental representations in the language of the BAPP SOP documents is that a supplier will never sell an ingredient that is adulterated and/or misbranded as defined under the U.S. Food, Drug and Cosmetic Act; in the event that occurs, the contract provisions describe methods for managing this situation and for resolving disputes. The dispute resolution language also protects the economic interest of third-party labs approved by the parties to perform the testing necessary for dispute resolution.

The SOP also provides the logic for transporting irreparably defective materials for lawful destruction (which can be used to support a defense when companies ship an adulterated or misbranded product into interstate or international commerce for lawful destruction).

Trading partners who fail to clarify and memorialize these issues in a supply contract do so at their own peril and may find themselves in wholly avoidable legal and regulatory disputes.

Q3: Wasn't BAPP initially focused on intentional adulteration (aka: economically motivated adulteration)? These best practices guidance documents include unintentional contamination (e.g., pesticide residues, solvent residues, etc.) as well as BAPP's primary focus: economically motivated adulteration (EMA). Why?

A3: Yes. After considerable internal debate, we recognize that EMA is only one form of what constitutes an 'adulterated' article or product that must be addressed. Contamination with pesticides, excess solvent residues, aflatoxins, etc., represent another form of adulteration (technically speaking, i.e., under federal law) that are sometimes found in commerce. In both cases, the articles may be irreparably defective and must be destroyed to prevent their resale into the supply chain. It does not really matter if the problem is St. John's wort extract adulterated with illegal red dyes (EMA) or

botanical materials unintentionally contaminated with aflatoxins at levels > 20PPB. The former example is a case where the undisclosed ingredient cannot be removed to the point where the material can be considered lawfully remediated, and the latter example is potentially injurious to health and cannot be lawfully remediated: both materials must be scheduled for lawful destruction to prevent their resale into the supply chain.

Just as BAPP correctly expanded the scope of this effort to include non-botanical substances and components in commerce, so too must we expand the scope to include "known or reasonably foreseeable hazards", which include hazards associated with economic adulteration, and as defined in 21 CFR 117 ("cGMPs, Hazard Analytics, and Risk-based Preventative Controls for Human Food") to best serve all consumers and stakeholders, everywhere, in the food, dietary supplement, and cosmetic industry supply chains.[8]

Q4: Why did you add the word "cosmetic" to the disclaimer language?

A4: One reviewer noted that the intention for this document included use in the cosmetic ingredient industry and the use of the qualifier "dietary" excluded cosmetic ingredients. We agree. Just as we have distinguished between reparably defective from irreparably defective articles, so too have we added the word "cosmetic" as an adjective to modify the noun "articles".

Q5: Why did you use the term "article"?

A5: This supply chain contract language template was developed for use in three distinctly different supply chain applications: dietary supplements, conventional foods (including "medical foods"[9] and "foods for special dietary use"[10], and cosmetics. For that reason, the term "article" is used generically for convenience to represent (1) a "dietary ingredient or component" when used in the context of dietary supplements (in the United States and China, among others), (2) a "food ingredient" when used in the context of "medical and conventional foods" (US, EU and elsewhere), "food supplements" (Belgium, Israel, and elsewhere), "foods for special dietary use" (in the US), "novel foods" (in the EU), "natural products" (e.g., in Canada), and (3) as an "ingredient" when used in cosmetics, respectively.

Q6: Why did you add definitions for the terms "adulterated" and "misbranded"?

A6: Rather than trust that all trading partners understand the legal definitions of this word, and upon advice of one reviewer from the United States, we have now included legal definitions for the terms "adulterated" and "misbranded" under the U.S. Federal

[8] 21 CFR 117.3: "A known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food." The reference to economic adulteration is at 21 CFR 117.130 (b)(2)(iii) "the hazard may be intentionally introduced for purposes of economic gain."
[9] (21 U.S.C. 360ee (b) (3))
[10] 21 CFR Part 105

Food, Drug and Cosmetic Act, citing the appropriate statutes as they apply for dietary supplements, foods, and cosmetics.

Q7: Is an "ingredient" the same thing as a "component"?

A7: No, not always. For the purposes of this contract language in the United States, a "component" refers to the following:

1. "Components" as defined when applied only to dietary supplements. Bottle, cap/closure systems, seals, labels, processing aids, etc. are all "components" used to manufacture dietary supplements; the "dietary ingredients" and "other ingredients" are also "components" used in the manufacture of a dietary supplement.
2. When applied to cosmetics, the term "ingredient" refers to all ingredients contained in the cosmetic product as defined under law.
3. When applied to foods, the term "ingredient" refers to all food ingredients disclosed on the product label.

Q8: The original draft of this best practices guidance distinguished only between "defective" and "irreparably defective" articles. Why did you change the language to "reparably defective" and "irreparably defective"?

A8: During the public comment period, several comments urged further clarification between those defective articles that can be lawfully remediated and those that cannot. In the interest of clarity, we agree. While a defective article may not meet specifications but may be accepted by the buyer and/or lawfully remediated for a certain use, an irreparably defective article cannot, and must therefore, by this contractual agreement between the parties, be scheduled for Disposal and lawful Destruction. Other commenters noted that a non-conforming article to one buyer might be fully lawful and approvable to another; consequently, this revised version draws clearer distinctions among three categories of articles, to wit: "non-conforming", "remedially defective", and "irreparably defective" articles. With that understanding as the framework for this entire effort, we fully expect these best practices templates to be widely embraced by all stakeholders who want to improve the quality of all ingredients in the supply chain, to protect consumers, and to ensure that irreparably defective ingredients are never resold into commerce. For additional clarification and as advised by our Legal Advisory Committee, we have added a definition for the term "Defective" in the contract language and SOP templates in this final revision.

Q9: Several reviewers commented on the definitions of "irreparably defective". Their questions include the following two questions:

Q9a: Does remediation include accepting an OOS (article that is "out of specification") that is unadulterated?

A9a: No. Accepting an unadulterated OOS can be a planned deviation under cGMPs. In contrast, remediation refers to a Quality Assurance process that addresses a problem,

creates a plan to solve that problem from recurring, and executes to that plan. Remediation is taking an action; accepting an unadulterated OOS is simply authorizing a deviation from an existing specification.

Q9b: Must a product be adulterated in order to be irreparably defective?

A9b: In theory, no. For example, non-conforming but authenticated material devoid of biological activity (e.g., the "marc" left after extraction) is not adulterated per se but might be irreparably defective for intended use. After deliberation, we concluded and have drafted definitions that the scope of this contract draft language and SOP is limited to irreparably defective ingredients that are adulterated and/or misbranded; "spent ingredients", such as marc, are identified as non-conforming upon receipt, and may be handled pursuant to SOPs regarding non-conforming components. If the supplier of "spent ingredients" intends to lawfully repurpose the material for another use, in another country, etc., best practices demand that the supplier *must* provide the buyer who returns such non-conforming material with supporting documentation evidencing its destination; this documentation protects both buyer and seller when shipping irreparably defective material into interstate and international commerce.

We recognize that this "repurposing" exercise may be cost prohibitive, in which case lawful Destruction is the best practice option. From the perspective of risk management, returning any irreparably defective material to a supplier absent any documentation may (1) put the shipper at risk and (2) might allow the defective material to be resold into the supply chain—which is unacceptable and defeats the purpose of this consumer protection effort.

For those buyers wishing to protect themselves against the receiving and use of "marc", it is strongly advisable to *focus first* on building a robust set of revision-controlled specifications and testing strategies to guard against that form of fraud. Beyond that, the definition of "irreparably defective" may be expanded to include this form of fraud. We must quickly add that this can be very difficult to express in clear language with universally complete precision and is best handled on an ingredient specification basis.

Q10: Does remediation include reselling the article under a different specification?

A10: This may be more a question of semantics, rather than of regulation. If an ingredient/lot is misbranded, a factual error exists on the label, sometimes to mislead or defraud. To make a label factually correct, and selling that article under a different specification is, in our opinion, an example of rebranding, rather than remediation. Put differently, rebranding simply fixes the label to meet the actual ingredient/lot specifications; lawful remediation fixes the ingredient/lot to meet the actual label claims and original specifications acceptable to the buyer as required on the original purchase order.

Q11: Regarding "specifications associated with a purchase order" in the context of an article being considered "defective", one commenter rightly observed, "in

our experience in a highly regulated market (Australia), the buyer does not provide a specification with the purchase order. All that is provided is a unique item code."

A11: Understood. Best practices demand that both buyer and supplier know the precise specification of the article being ordered. This may be achieved in variety of ways. Whether a current revision-controlled specification accompanies a purchase order or if a PO references a revision-controlled specification the supplier has on file from the Buyer does not really matter. What matters is that the supplier knows exactly and agrees to supply an article that fully satisfies the Buyer's specifications knowing that, if the article received does not meet those specifications, the article may be rejected and possibly deemed "irreparably defective" and scheduled for lawful Disposal or Destruction.

We sincerely hope that our effort underscores the need for controlled and complete specifications known by both trading partners to avoid disputes; this failure appears to be the most common root cause for supply chain disputes and subsequent legal actions.

Q12: Under your definition, a product "not conforming with a complete set of specifications is defective"; however, a buyer may choose to accept an OOS of an unadulterated material and should not be considered defective since it was accepted.

A12: Agreed. In our definitions, "non-conforming" (or "OOS") is "defective"; it may be remedially defective, or it may be irreparably defective. If the buyer chooses to accept a non-conforming ("OOS") ingredient, the buyer may certainly do so lawfully under certain conditions, in which case there is no dispute with the supplier on this transaction that needs to be resolved. That acceptance is done at the buyer's sole discretion and risk. In point of regulatory law, non-conforming materials may not be used when specifications are not met (21 CFR 111.77). The Quality Unit must conduct a material review and make a disposition decision (21 CFR 111.87). If the Quality Unit decides to reprocess, treat, or make an in-process adjustment, as allowed under 21CFR 111.87 (a)(1), the non-conforming/defective material may be lawfully used provided all provisions of cGMPs are followed. Thus, the defective/non-conforming article may be used under those circumstances. The non-conforming material may also be returned to the supplier for failure to meet all of buyer's specifications and lawfully remediated and lawfully resold, provided it is not also adulterated and "irreparably defective" as defined herein.

Q13: Why does the contract language contain a provision (Section 5c) to share Disposal information concerning irreparably defective articles with third parties?

A13: Two critically important reasons: (1) In the event of adulteration that could reasonably be expected to present a health hazard, having this language explicitly grants permission to either party to notify authorities as appropriate without violating any non-disclosures that might be in effect. (2) Being able to share this information with academic researchers empowers quality benchmarking, trending data, and analysis that

could benefit the industry in many ways, provided, however, that all parties are adequately protected against the "weaponizing" of these data and that all information is truthful and responsibly shared only with qualified, academic, and/or scientific researchers. To help protect public health, we hope this provision will be adopted and exercised responsibly by all stakeholders.

Q14: Can I use this template as is?

A14: No. Our templates must be customized and properly integrated into your Quality and Compliance Programs. Best practices require this MDD (Material Disposal and Destruction) template be appropriately modified to contain references to those other relevant SOPs, including, but not limited to, receipt of materials, incoming inspection, material review, Quality Unit responsibilities, etc.

Q15: What are the most essential provisions in the Supply Chain Contract Language (Section 2) required to halt the resale of irreparably defective articles?

A15: Great question; not so easy to answer. "Definitions" are essential to establish a common language. "Inspection and Rejection" provisions are essential to clearly define the rights and obligations of buyer and seller (including recordkeeping and notification) and the dispute resolution using third-party labs. "General Representation and Warranties" are essential to protect the interests of both buyer and seller.

Q16: The recordkeeping and notice provisions, under Inspection and Rejection, paragraph 4(d) seems unduly burdensome. Can our objective be achieved without this required notice provision described in the contract language, and outlined in the SOP?

A16: Unfortunately, not. A clear trail of documentation concerning disposition management of irreparably defective articles and articles returned to the supplier is essential. If company X returns an irreparably defective, adulterated and/or dangerously contaminated ingredient to supplier A but does not get certified confirmation from supplier A of its Destruction, it could be resold to another company. This provision is critical and, based on extensive feedback, will presumably be widely embraced by responsible industry leaders.

Q17: Can the timelines and other operational details proposed in the SOP be modified?

A17: Yes, of course. The SOP template is intended to be adjusted to meet your business needs while preserving the integrity of the initiative.

Q18: We are a small company. We definitely want to participate but want to do it at the lowest possible cost. What advice can you offer?

A18: For companies that do not already have robust supply chain contracts already in place with all suppliers, a simple MOU (memorandum of understanding) can be drafted and referenced to the final contract language template, for negotiation and authorized signature by all parties after appropriate review. All purchase order boilerplates can be changed to reflect the existence of the MOU and other specific warranties a company might want to emphasize. One option might be to reference these details (which will appear on the BAPP homepage on the ABC website (https://www.herbalgram.org/resources/botanical-adulterants-prevention-program/) as a condition of your purchase order requirements; in so doing, you have made your conditions of purchase clear, and might have legal recourse should a problem arise. (Please consult with your legal advisor on applicable contract law in your jurisdiction; this is offered only as general guidance to help you efficiently adopt this initiative and is not to be construed as binding legal advice for your specific situation in your jurisdiction, wherever in the world that may be.)

Q19: Where should I address technical questions regarding this material?

A19: bappsop@herbalgram.org

Q20: After all versions are finalized, will they be readily available? Is training and education planned?

A20: Yes. They will be readily available and widely publicized. Training and educational events are being considered; we welcome stakeholder guidance on this at this email address: bappsop@herbalgram.org. Please visit www.herbalgram.org for information. If you have specific suggestions to improve this BAPP initiative, please contact Stefan Gafner, PhD, ABC Chief Science Officer, and Technical Director of BAPP at: stefan@herbalgram.org. To contact the principle author, Michael D. Levin, with specific questions, you may do so at: mlevin2016@icloud.com, BAPPSOP@herbalgram.org.

Q21: Why didn't you include "lawful remediation" in your set of definitions?

A21: Intended for universal global use, we chose to use linguistically precise but generic common language to describe a process defined in a variety of ways, depending upon country and circumstance.

As opposed to "remediation", "rework", or other phrases that could have been used, "lawful remediation" clearly defines the expectation that any failure to meet incoming specifications must be fully resolved lawfully. If they cannot be lawfully resolved, and the material cannot be otherwise lawfully used, anywhere for any lawful use, it is irreparably defective and must be destroyed, and supported by evidence shared between buyer and supplier that it has been destroyed.

Different rules in different jurisdictions and other variables, including those pertaining to lawful Destruction, cannot easily be captured in one legal phrase for universal use;

hence, “lawful remediation” (and its companion, “lawful Destruction”) are used as default language to clearly communicate intent by and between the supply chain partners.

Q22: Does the resale of irreparably defective articles happen often?

A22: We do not think this problem happens often. Surveys among our stakeholders suggest that this does sometimes happen but is relatively infrequent. When it does happen, irreparably defective articles are sometimes returned to the supplier, which allows them to be resold. That is precisely what this voluntary industry-supported consumer protection effort is intended to stop.

Q23: Must the notification dates outlined in the template always be used as proposed?

For example, the Recordkeeping and Notice provision in 4.c. under Inspection and Rejection proposes 21 (twenty-one) days as the maximum time allowed for the Supplier to provide a report to the Buyer that documents the specific actions taken by the Supplier to lawfully remediate, resell, or lawfully dispose of Defective Articles returned to the Supplier. Must it be 21 days in all contracts?

A23: No. All performance dates are negotiable between the parties. If Buyer and Supplier agree that this performance can be accomplished within 15 days of the Supplier’s receipt of returned Defective Articles, that will become the negotiated contractual performance standard. In this example, the Buyer will expect to receive notice of disposition within 15 days of its receipt by Supplier and can adjust internal SOPs to reflect that fact. The notice serves as evidence that all irreparably defective articles are lawfully destroyed, thus accomplishing the intent of this contract.

Large or small, all buyers share in the responsibility to prevent the resale of irreparably defective ingredients and other “articles”.

If the irreparable defects are illegal dyes in St. John’s wort intended to spoof an analytical test, or melamine in protein powders used as economic adulterants to do the same thing, a mixed species of botanical ingredients such as germander in skullcap (or Chinese *Actaea* in black cohosh, or palm oil in saw palmetto), or even an unintentional contaminant that puts human health at risk (e.g., aflatoxins, E. coli, residual solvents and/or pesticides in unlawful levels which cannot be lawfully remediated by “dilution”) does not matter. Those are the particulars. There are almost endless examples. What matters is the universal truth: if the material cannot be lawfully remediated, all supply chain partners must contractually agree to “Burn It! Don’t Return It”. Period. That is the only way to prevent resale into interstate or international commerce.

As a companion teaching, it is important to recognize that economically motivated adulteration is dynamic. It is always changing. And all buyers, large and small, share in the responsibility to be vigilant to protect the consumers’ interests and to deliver a company’s Brand Promise of a health-promoting natural product.

There are numerous resources that responsible members of the herb, dietary supplement, and natural products industry can use to help enhance quality control efforts. For example, BAPP (https://www.herbalgram.org/resources/botanical-adulterants-prevention-program/), the American Herbal Pharmacopoeia, the American Herbal Products Association (www.ahpa.org), and the myriad compendial resources are all readily accessible tools buyers can use to inform ingredient specifications and update them when new circumstances dictate. These include, but are not limited to, the following:

- American Botanical Council (www.herbalgram.org)
- American Herbal Pharmacopoeia (www.herbal-ahp.org)
- American Herbal Products Association Compendium (http://www.botanicalauthentication.org/index.php/Main_Page)
- National Center for Natural Products Research (https://pharmacy.olemiss.edu/ncnpr/)
- National Institutes of Health Office of Dietary Supplements (https://ods.od.nih.gov/)
- United States Pharmacopeia (www.usp.org)
- European Food Safety Authority (https://www.efsa.europa.eu/en)
- Health Canada (https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html)
- Therapeutic Goods Administration (https://www.tga.gov.au/))

Foundational to the implicit public value in the production and marketing of natural products intended for health purposes are robust specifications, regulatory compliance, and ingredient testing that is scientifically valid and fit for purpose.