BAPP Best Practices SOP to Prevent Resale of ‘Irreparably Defective Articles’ Available for Industry and Public Comment

Botanical Adulterants Prevention Program invites broad herb and dietary supplement industry stakeholder input

AUSTIN, TX, USA, December 1, 2020 /EINPresswire.com/ -- The ABC-AHP-NCNPR Botanical Adulterants Prevention Program (BAPP) has issued its second draft “Best Practices Contract Language and Standard Operating Procedure (SOP) Templates for the Disposal/Destruction of Irreparably Defective Articles.” The revised documents, which are intended for members of the herb, dietary supplement, food, and cosmetic industries, are open for public comment until December 14, 2020.

> “We are helping industry to prevent adulterated ingredients from being rejected by one company, only to be resold by an unethical supplier to another company.”
>
> *Stefan Gafner, PhD, chief science officer of ABC*

BAPP — a consortium of three nonprofits: the American Botanical Council (ABC), the American Herbal Pharmacopoeia (AHP), and the National Center for Natural Products Research (NCNPR) at the University of Mississippi — produced the draft contract and SOP template in collaboration with Health Business Strategies, LLC, a natural products industry consulting firm. BAPP defines an irreparably defective ingredient as one that is adulterated and/or contaminated to an extent that the material cannot be effectively and lawfully remediated for use for oral or topical consumption in a consumer product, thereby necessitating its pre-authorized disposal or destruction by a qualified third party.

BAPP received 106 substantive comments in 2019 from industry stakeholders on the original contract and SOP and related forms and templates, which were used to inform this revised draft. In addition to expanded and clarified sections on definitions and dispute resolution, BAPP added an FAQs (frequently asked questions) document that addresses many of the comments received during and after the first public comment round. The documents also include a new Three-Party Non-Disclosure Agreement (NDA) for use by the buyer, seller, and analytical lab to facilitate dispute resolutions. Just as the contract language fairly and carefully protects the interests of both buyer and supplier, the NDA protects the economic interests of the buyer, supplier, and laboratory. All document revisions were reviewed and approved by the BAPP legal advisory

team.

The revised documents have been sent to all qualified stakeholders who previously commented. All other qualified stakeholders can download them after completing a brief survey on ABC's website. After reviewing the document package, all qualified industry stakeholders are invited to submit comments as instructed. To be clear, a qualified stakeholder represents a buyer, supplier, analytical lab, expert consultant, attorney, regulator, or industry association; BAPP is not accepting comments from non-stakeholder consumers on these highly technical legal templates.

In preparing the initial drafts of supply contract and SOP language, BAPP obtained comments from current and former members of the US Food and Drug Administration (FDA), the National Institutes of Health, dietary supplement companies, dietary ingredient supply companies, analytical laboratories, and GMP (good manufacturing practices) consultants. The first drafts were reviewed by members of BAPP's Ad Hoc Legal Advisory Committee, select members of ABC's Advisory Board, and other regulatory and analytical experts. The draft contract and SOP templates were sent to ABC's Sponsor and Small Business Members and BAPP Underwriters and Endorsers in the United States, Australia, Canada and the UK.

This second and revised round of comments is intended to give all stakeholders another opportunity to review and comment before these documents are finalized and proposed for acceptance by industry members.

"We are inviting input from a wide array of stakeholders to shape these final tools for widespread industry adoption to help solve a known supply chain issue that sometimes occurs," said Mark Blumenthal, founder and executive director of ABC and director of BAPP. "Implementing these proposed best practices contract and SOP templates represents a strong measure by responsible industry members to enhance their ability to more effectively control the ingredient supply chain. The SOP helps to ensure that consumers can purchase properly labeled herbal products with authentic ingredients."

Blumenthal also emphasized that "many herb and dietary supplement manufacturers have developed long-term relationships with their suppliers, where the companies have fully qualified these suppliers and the ingredients obtained from them. Most such suppliers consistently use best practices in full compliance with current GMPs to analyze their ingredients before releasing them for manufacturing, packaging, or commerce.

"Though the risks of potential adulteration are real, there is a relatively low potential for such well-qualified ingredients' having any defects that would make them 'irreparably defective' according to appropriate regulations and the BAPP SOP," Blumenthal continued. "However, there are documented cases where unscrupulous sellers of adulterated ingredients offer their fraudulent materials to the market. In such cases, industry buyers must maintain appropriate vigilance in their quality control systems and have the ability to protect themselves.

“This voluntary industry self-regulatory initiative is intended to empower dietary supplement manufacturers to prevent the resale of defective ingredients that are irreparable; that is, they cannot lawfully be made acceptable for any use in consumer products,” added Blumenthal. “For ten years we’ve been alerting industry members about specific botanical materials that we have confirmed as being subject to adulteration and also which analytical methods are most robust and fit for purpose to detect such adulteration. Now we are counseling industry members on the best practices to prevent irreparably defective materials from remaining in the supply chain.”

Michael D. Levin, founder of Health Business Strategies, LLC, noted: “Economic adulteration and low-level contamination represent very real supply chain concerns with all commodities, including botanical and other dietary ingredients regulated by FDA. Ingredient buyers are the ‘Guardians at the Gate,’ who are responsible for approving the use of ingredients for manufacturing. Though this problem is believed to be infrequent, it does happen. Our proposed solution empowers all responsible buyers and suppliers to unite in support of this effort to stop the potential for resale of irreparably defective ingredients through contractual obligations that fairly protect the economic interests of both parties.”

“In short,” said Stefan Gafner, PhD, chief science officer of ABC and technical director of BAPP, “we are helping industry to prevent adulterated ingredients from being rejected by one company, only to be resold by an unethical supplier to another company.”

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