



The University of North Carolina Umstead Review Panel Determination

May 22, 2013

Request for The North Carolina Arboretum's Botanical Authentication Program

I. Request for Determination

On April 23, 2013, The North Carolina Arboretum submitted a public request for a determination that the proposed activity for a Botanical Authentication Program would be permissible under N.C.G.S. 66-58 (b)(8)o. of the Umstead Act, which provides an exemption for:

Activities that enable the community in which the constituent institution or other University entity is located, or the people of the State to utilize the University's facilities, equipment, or expertise.

The request for determination stated:

The result of years of carefully developed planning and execution has been the emergence of North Carolina as a leading state in natural product research and innovation. Within such organizations as the American Herbal Products Association (the only national trade association that is focused primarily on herbs and botanicals and herbal products) and the United Natural Products Alliance (consisting of 40 large companies and 10 laboratories with combined sales exceeding \$4 billion), North Carolina and the Arboretum's programs are viewed as strategically timely and valuable to the future interests of the industry.

This request of the Umstead panel by The North Carolina Arboretum is the endorsement of the Arboretum's Botanical Authentication Program. Because of the significant legwork over many years to locate in Western North Carolina the target plants for voucher preparation, secure necessary collection permits and landowner permissions, collect and process seeds for seed bank preparation and storage, undertake analytical chemistry procedures for extract production, manage the photographic and data systems for high-level validation and documentation, form agreements with third-party partners, and other unique functions, the Arboretum is now uniquely credentialed to supply researchers and manufacturers with all the necessary GMP [Good Manufacturing Practices] elements of authentication.

The ability to supply vouchers, botanical and chemical reference standards, and validation testing services to researchers and companies will not only strengthen the state's economy but also stimulate increasing discovery of superior plant varieties and cultivars of commercial importance, assist in identifying new compounds beneficial to human and animal health, and strengthen North Carolina competitively among other states building natural product assets.

II. Notice and Proceedings

A hearing was set for May 22, 2013, in Conference Room A at the Spangler Center in Chapel Hill, North Carolina, and by teleconference. The Umstead Review Panel staff gave notice of the Request for Determination hearing to those on its registry on April 29, 2013. Notice of the hearing was given to the press and public, pursuant to the North Carolina Open Meetings Act, on May 13, 2013.

No affected individual or entity gave notice of objection to the request and no affected individual or entity appeared at the hearing to oppose the request, as is allowed under Board of Governors Policy 100.4 VIII (D).

The North Carolina Arboretum was represented at the hearing by George Briggs, Executive Director.

The formal request, evidence, and presentation established the following as support for the determination:

- The international market for herbal supplements and nutraceuticals is both large and proving to be relatively recession proof, averaging 5-8% annual growth since 2000 in the \$5.3 billion U.S. retail market. This expanding growth curve, based on increasing conventional healthcare costs, consumer natural health and wellness trends, the rise of the middle class in such countries as China and India, and other market factors, is placing increasing pressure on static or compromised botanical supply chains.
- In certain global regions historically important for herbal production, high levels of pollution are now contaminating fields and their crops with heavy metals, pesticides, and other contaminants, both reducing suitable regions within which to produce quality crops or worse, allowing adulterated or contaminated raw material to enter the market from both domestic and foreign producers.
- Because many U.S. nutraceuticals depend on public collection of native plants from natural areas, a practice known as wildcrafting, the supply chain is at further risk for contaminated plants mistakenly identified with the target species.
- All of these factors have yielded recent U.S. studies that have found products on our shelves that contain as low as zero percent of the labeled ingredient.
- Positioned in the most biologically diverse region in North America, the Arboretum led the co-founding of the North Carolina Natural Products Association, a means of building networking and education within the state's fledgling industry.

- In recent years with significant advances in life sciences, other member institutions of The University of North Carolina system have also recognized the increasing value of our resident biological diversity as an important ingredient in health, wellness, and economic development.
- The Arboretum began the process of building the only medicinal plant germplasm repository in the United States utilizing cutting-edge standards by hiring Dr. Jo-Ann McCoy as its Germplasm Repository Director.
- The Arboretum has created as its research focus The North Carolina Arboretum Germplasm Repository for development and storage of botanical seeds and extracts. The repository, following six years of field and laboratory work, has now garnered about 2,000 accessions of plant and endophytic fungi that exceed federal curation standards.
- To make the repository asset more available to industry as they struggle to meet the 2010 Federal requirements of Good Manufacturing Practices for herbal dietary supplements in 21 CFR 111, the Arboretum led the formation, and provides continuing leadership, of the 501(c)(3) non-profit corporation Bent Creek Institute, Inc., that serves to foster collaboration between the Arboretum's research and commercialization goals.
- Situated within the heart of Southern Appalachian biodiversity and observing these changes in regulation of botanical supplement research and manufacturing, the Arboretum has been uniquely positioned to address the specific requirements of GMP for botanical extract and nutraceutical manufacturing.
- Five regional partners including the Arboretum's Germplasm Repository are now implementing a "Blue Ridge Naturally" regional brand that will serve as the "Good Housekeeping" seal of quality for local product integrity, quality, and authenticity.
- The North Carolina Arboretum Germplasm Repository, built from local resources over many years, has a unique capacity to set and validate quality standards for botanical ingredient identity.
- The Botanical Authentication Program will give North Carolina a unique natural advantage in addition to its rich botanical heritage and can support emerging entrepreneurs and existing businesses in the state, and also assist in attracting new companies to the region.

III. Determination

The panel deliberated on the submitted request, evidence, and arguments presented and, recognizing the clear potential for the proposed activities to serve the community, voted unanimously to approve the request. It is the determination of the Umstead Review Panel that the request was within the jurisdiction of the Panel, and the proposed activities are authorized under N.C.G.S. 66-58 (b)(8)o, and are not unfair competition.


 /s/ Robert Warwick, Chair