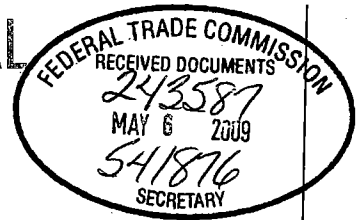


ORIGINAL



IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of

DANIEL CHAPTER ONE,
a corporation, and

JAMES FEIJO,
individually, and as an officer of
Daniel Chapter One

) Docket No.: 9329

) PUBLIC DOCUMENT

RESPONDENTS' STIPULATED MOTION TO INCLUDE EXHIBIT
IN HEARING RECORD

On May 5, 2009, Complaint Counsel and Respondents' Counsel agreed – pending approval by the hearing officer – that the attached THE JOURNAL OF THE AMERICAN BOTANICAL COUNCIL, "HerbalGram," No. 81 (Feb-Apr 2009) constitutes the correct and complete Exhibit 1 to Exhibit R18 (Deposition Transcript of James A. Duke), which was provided to the reporter at the deposition but may not have been included in the final hearing record.

Respectfully submitted,

Dated: May 6, 2009

Dated: May 6, 2009

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Complaint Counsel

Counsel for Respondents

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3 **[PROPOSED] ORDER**

4 The parties having agreed that Exhibit 1 to Exhibit R18 consists of THE JOURNAL OF THE
5 AMERICAN BOTANICAL COUNCIL, "HerbalGram," No. 81 (Feb-Apr 2009),

6 IT IS ORDERED that

7 To the extent it is necessary to change the hearing record such that Exhibit 1 to Exhibit
8 R18 shall consist of THE JOURNAL OF THE AMERICAN BOTANICAL COUNCIL, "HerbalGram," No.
9 81 (Feb-Apr 2009), the hearing record shall be so changed.
10

11 **ORDERED:**

12
13 _____
14 D. Michael Chappell
15 Administrative Law Judge

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Dated: May ____, 2009

CERTIFICATE OF SERVICE

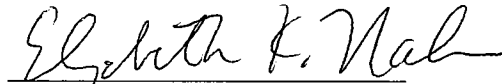
I HEREBY CERTIFY that on May 6, 2009, I served the attached **RESPONDENTS' STIPULATED MOTION TO INCLUDE EXHIBIT IN HEARING RECORD** upon the following:

The original and two paper copies via hand delivery to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room H-159
Washington, DC 20580

Two paper copies via hand delivery to:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., N.W., Room H-528
Washington, DC 20580


Elizabeth K. Nach

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The Journal of the American Botanical Council

Number 81 | February – April 2009



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bilberry extracts to treat diabetic retinopathy, blindness, cataracts, glaucoma, and macular degeneration, with retinopathy showing the most promise.¹³ In a meta-analysis of 30 clinical trials on bilberry extract for vision in reduced light, the 4 most recent randomized controlled trials (RCTs) had negative outcomes. However, one RCT and 7 non-randomized controlled trials reported positive effects on outcome measures relevant to night vision.¹⁷ However, the use of bilberry extract for vision in reduced light has been based mainly on anecdotal experience during the Second World War and today is generally dismissed.

The primary application of anthocyanoside-enriched bilberry extracts in ophthalmology focuses on diabetic retinopathy, where bilberry can be used as an adjuvant in combination with conventional pharmaceutical therapies. Bilberry extract improves capillary fragility, reducing vessel proliferation through an anti-angiogenic mechanism related to the high content of delphinidin. This appears to be a unique property of bilberry compared to most other anthocyanoside-containing, fruit-derived extracts. In diabetic patients bilberry extract improves cicatrization (healing of a wound by producing scar tissue) of leg ulcers, combining a proteases inhibitory effect with anti-edema (anti-inflammatory) properties.

A recent uncontrolled trial found that a standardized bilberry extract (Myrtoselect®, Indena, Milan, Italy) combined with a patented French maritime pine bark extract (Pycnogenol®, Horphag Research, Geneva, Switzerland) called Mirtogenol® was able to lower ocular pressure in non-glaucoma patients with ocular hypertension.¹⁸ Additional clinical trials have documented the benefits of bilberry extracts in treating venous insufficiency.¹³ The concentrated extract also has been evaluated for its possible effects in treating inflamed oral and pharyngeal membranes¹² as well as on painful menstruation.¹⁹

FUTURE OUTLOOK

Bilberry is currently commercially harvested in several countries including the Russian Federation, Bulgaria, Romania, Sweden, Poland, Ukraine, Finland, Bosnia and Herzegovina, Croatia, Serbia and Montenegro, and Kosovo, among other eastern European countries.²⁰ Most bilberry (fruit and leaf) is still collected via wild harvest, much of it under organic wild certification (J. Brinckmann, e-mail to M. Blumenthal, November 21, 2008). Some attempts are being made to commercially cultivate the crop in the Northwestern United States; however, most have been unsuccessful thus far.²¹ Large-scale efforts to grow bilberry are considered risky and are not recommended; small-scale agricultural trials are appropriate depending on the site.²¹

Owing to the relatively high commercial value of bilberry extracts, intentional adulteration has been detected, not only with anthocyanosides obtained from other plant sources, but even with synthetic dyes, e.g., amaranth dye, a synthetic dye used in foods (not related to what is often called “grain amaranth” [*Amaranthus* spp., Amaranthaceae], the increasingly popular food cultivated and marketed for its relatively high protein content.) Analytical methods have been developed to determine such adulteration for use by responsible manufacturers.²²

—Gayle Engels

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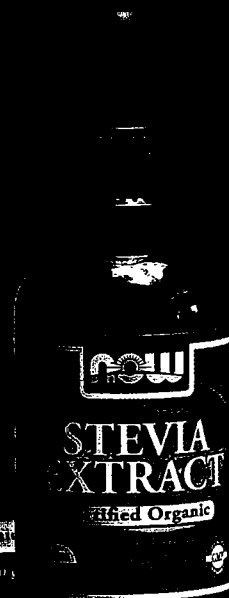
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