December 26, 2005

1297 5 DEC 28 10:38

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: *PlantSterol/Stanols Esters and Coronary Heart Disease Claims Dockets Nos.2000P1275 and 2000P1276 (65 Fed. Reg. 54685) and FDA Letter Regarding Enforcement Discretion With respect to Expanded Use of an Interim Health Claim Rule about Plant Sterol/Stanol Esters and Reduced Risk of Coronary Heart Disease (Feb 14, 2003)*

Dear Sir or Madam:

Heart Blend Foods LLC is a small company devoted to developing, manufacturing, and marketing heart-healthy products that fit with the American consumers' lifestyle and daily eating habits. Heart Blend Foods LLC has developed patent-pending technology to allow plant sterol esters to be incorporated into aqueous-based foods, such as coffee, and respectfully submits the following comments.

Action Requested

Heart Blend Foods LLC requests that FDA exercise enforcement discretion with respect to use of the interim final rule authorizing a health claim for plant sterol/stanol esters and the reduced risk of coronary heart disease (21 CFR 101.83) for a plant sterol ester-enriched ground coffee product, and also requests FDA to extend the exemption from the minimum 10% Daily Value nutrient content requirement ("jelly bean rule") to encompass plant sterol ester-enriched coffee.

Background

Over the past five years a number of products containing plant sterols/ stanols and their respective esters have been introduced into the market place to provide consumers with a choice of food products that are safe and effective in reducing blood cholesterol levels. In order for these products to be effective they should be consumed twice daily. Current product offerings include spreads, orange juice, yogurt, snack bars, and cereals. Through consumer research, Heart Blend Foods LLC identified the need for a plant sterol ester-enriched food that is low in fat, carbohydrates, calories, and affordable. The research also showed that the food should fit with the daily eating patterns of the American

2000P-1275

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consumer. Based on these criteria, coffee was identified as an ideal beverage to deliver plant sterol esters to the target consumer -- adults concerned about their blood cholesterol level. Plant sterol ester-enriched coffee is suitable for dieters and diabetics due to its low calorie, fat, and sugar content. Fifty-two per cent of adult Americans consume coffee on a daily basis and another 25% drink it occasionally. The average consumption of coffee among coffee drinkers is approximately 2.5 cups per day (U.S. Department of Agriculture and National Coffee Association), thus coffee is an ideal compliment/addition to the foods already approved to bear the health claim by providing a source of plant sterol esters without appreciable calories, fat, carbohydrates or sodium. In addition, the American Heart Association states moderate consumption of coffee doesn't seem to be harmful **www.americanheart.org**

Product

The product that is the subject of this request is ground coffee that has been enriched with plant sterol esters (Heart Blend ™ Coffee). The ratio of coffee to plant sterol ester is typically 9:1 (w/w). The consumer will use 2 tablespoons (~10 g) enriched ground coffee per 8 oz water to yield a serving that contains at least 0.65 g plant sterol esters. Further information concerning the product can be found in GRN 177. The plant sterol esters (CardioAid-S) used by Heart Blend Foods LLC are obtained from ADM and each batch is accompanied by a certificate of analysis (see Appendix B.).

Safety

Heart Blend Foods LLC submitted a GRAS Notification to the Office of Food Safety and Applied Nutrition, Office of Food Additive Safety. It has been assigned GRN 177. A letter of no objection was issued on December 20, 2005.

Evidence Supporting an Exemption from the Minimum 10% Daily Value Requirement ("Jelly Bean Rule")

FDA has previously exempted certain foods from the minimum 10% DV nutrient content requirement when it was determined that such exemptions could assist consumers in maintaining healthy dietary practices. For example, the agency exempted spreads and dressings for salads (and vegetable oils) from this requirement in the plant sterol/stanol ester and CHD health claim interim final rule (65 FR 54868 at 54711). Coffee also is an appropriate vehicle for delivering plant sterol esters to consumers because it contains no fat, carbohydrates, calories or sodium and is consumed on a daily basis by a majority of the target consumers-- adults concerned about their cholesterol levels. Since plant sterol ester-enriched coffee has the potential for good compliance to the requirements of the health claim -- consumption of at least 0.65g twice per day with meals -- the exemption would provide a significant public health benefit by providing a plant sterol ester-enriched food that fits seamlessly with the lifestyle and eating habits of the typical

American consumer without adding calories, fat, sodium or carbohydrates to their diet. The product will be available in regular and decaffeinated varieties, the latter for those concerned about or sensitive to caffeine.

The product is designed for home use due to the requirement to use an automatic drip coffee maker equipped with a "permanent" filter (e.g. wire mesh or equivalent) to brew the coffee. Consumers will be specifically instructed not to use a paper filter because the plant sterol esters become "trapped" within the filter.

Heart Blend Foods LLC strongly believes the exemption is justified based on the public health benefit of providing a plant sterol ester-containing food with no fat, carbohydrates, calories or sodium that can be consumed twice daily with meals. A statement that plant sterol ester-enriched coffee should be consumed in moderation will be included on the label.

Directions for Preparation and Recommended Usage

Consumers will be instructed to use two slightly rounded tablespoons (~10 g) of plant sterol ester-enriched coffee per 8 oz of water. Brew using an automatic drip coffee maker equipped with a wire mesh permanent filter or equivalent. Do not use paper filters. Add sweetener or creamer as desired.

As with any food, plant sterol ester-enriched coffee should be consumed in moderation.

Proposed Claim

Foods containing at least 0.65 g plant sterol esters, consumed twice a day with meals for a total intake of at least 1.3 g per day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. Each 8 oz serving of Heart Blend™ Coffee, prepared as directed, contains at least 0.65 g plant sterol esters per serving.

Determination of Plant Sterol Ester Content of Brewed Coffee

In the case of coffee brewed from plant sterol ester-enriched ground coffee, extractability of the plant sterol ester from the ground coffee is a key variable in delivery. A simple, accurate and reproducible method described in Appendix A was developed to measure extractability and delivery of plant sterol esters in coffee brewed using various popular home coffee makers and permanent filters. The delivery of plant sterol esters was determined using four different automatic drip coffee makers that accept permanent wire filters (Braun, Mr. Coffee, Toastmaster, DeLonghi) and 4 permanent filters sold under the brand names Brew Rite, Mr. Coffee, (Manufacturers Components, Cooper City, FL), Braun, and Swissgold (elfo ag Sachseln, Switzerland).

Following package directions, the average delivery of plant sterol esters was 0.85 g/ 8 oz with a range of 0.75 to 0 .95 g per 8 oz. for the drip coffee makers and filters evaluated (n=12). In all cases, the minimum level of 0.65 g/ 8 oz serving to qualify for a health claim was delivered.

Analytical Methods

Since coffee brewed through a metal screen is virtually free of lipid material (50 mg/150 ml; Ratnayake et al 1993), a total fat analysis can be used to determine the plant sterol ester content of plant sterol ester-enriched brewed coffee. GC analysis can be used to verify the sterol composition and content of the extracted lipid, if required (fifth edition of the Food Chemicals Codex, Jan 2004, p. 493

Volumetric Method.

A simple, accurate and environmentally friendly volumetric method (modified Babcock) was developed to measure extractability of the plant sterols esters from enriched coffee brewed using various types of filters and coffee makers. The volumetric method employs a round bottom 250 ml volumetric flask and relies on the separation of the weakly emulsified lipid phase (plant sterol esters) from the aqueous phase (coffee) after standing 8 hours at room temperature. The height of the plant sterol ester plug in the stem of the flask was measured using a metric rule and the amount of plant sterol ester determined from a standard curve prepared using coffee spiked with various levels of plant sterol esters. The detailed method and standard curve can be found in Appendix A.

The average efficiency of extraction of the plant sterol ester-enriched coffee was determined to be 85% (n=12) by the modified Babcock volumetric method.

Solvent Extraction / Gravimetric Methods

As a further check of the plant sterol ester content of brewed coffee, a spiked sample and a test sample, brewed using a Braun drip coffee maker and permanent wire filter, was submitted to independent laboratories for fat analysis by the Mojonnier method.

The average efficiency of extraction determined by the Mojonnier method was 77% (n=2)

The results from the solvent extraction /gravimetric method agreed well with the volumetric method, considering the low fat / high moisture level of the sample and the small sample size required for the Mojonnier method.

Both the volumetric and solvent extraction / gravimetric method demonstrated that sufficient plant sterol esters are extracted from the enriched coffee to deliver at least 0.65 g of plant sterol esters per serving.

Conclusion

Heart Blend™ plant sterol ester-enriched coffee delivers at least 0.65 g of plant sterol esters per serving when prepared according to package directions and two servings will deliver at least 1.3 g/day. The consumer will be instructed to consume the coffee with meals. The product contains no fat, carbohydrates, calories or sodium. Other foods higher in fat, calories and sodium have been granted an exemption from the minimum 10% DV nutrient content requirement ("jelly bean rule") and Heart Blend Foods LLC believes FDA should exercise enforcement discretion based on the public health benefit of providing adult consumers with a no calorie, fat or sodium plant sterol ester-enriched food that can easily be consumed on a daily basis and fits seamlessly with their lifestyles.

References

Ratnayake, W.M.N., Hollywood, R., O'Grady, E., Stavric, B. Lipid content and composition of coffee brews prepared by different methods. Food and Chemical Toxicology 31, 4: 263-69, April 1993.

Fifth Edition of the Food Chemicals Codex, Jan 2004, p. 493

Sincerely,

William C. Franke

William C. Franke, Ph.D.
Heart Blend Foods LLC
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Cranbury, NJ 08512

CC:
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Appendix A

Analytical Methods

Heart Blend Foods LLC developed a simple environmentally friendly method (Modified Babcock) to measure plant sterol esters in plant sterol ester enriched brewed coffee. The method relies on the fact that the lipid content of brewed coffee (50 mg/cup) is negligible compared to the quantity of lipid (plant sterols ester, 1.0 g) added to the ground coffee.

A. Modified Babcock

Equipment: 250 ml Kimax Class A round bottom flasks, metric rule

Procedure:

1. Brewed plant sterol ester-enriched coffee (10.25 g enriched coffee/8 oz water) is poured into the flask and brought to volume with water
2. A drop of Dow antifoam is added
3. Coffee is allowed to sit undisturbed for 8 hours at room temperature to allow the loosely emulsified plant sterols esters to separate.
4. A plant sterol ester "plug" forms in the neck of the flask. See Figure 1.
5. The height of the plug is measured in centimeters using calipers and a rule. Optionally, a digital photograph can be taken and measurements made from the photograph.

Calculation:

The weight of plant sterols is read directly from a standard curve or calculated from the equation: x (grams of plant sterol ester) = 0.79 y (cm "plug" height). See Figure 2.

B. Mojonnier Method for Milk Fat

AOAC Method 989.05 (Base Hydrolysis)

C. Plant Sterol Ester composition and content of extracted lipid

The plant sterol ester composition and content of the plant sterol ester "plug" or a hexane extract can be determined by the method found in the fifth edition of the Food Chemicals Codex (Jan 2004) p.493.

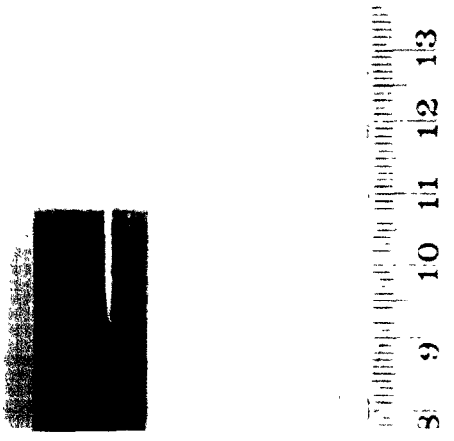

Fig. 1. Plant sterol ester plug and metric rule.

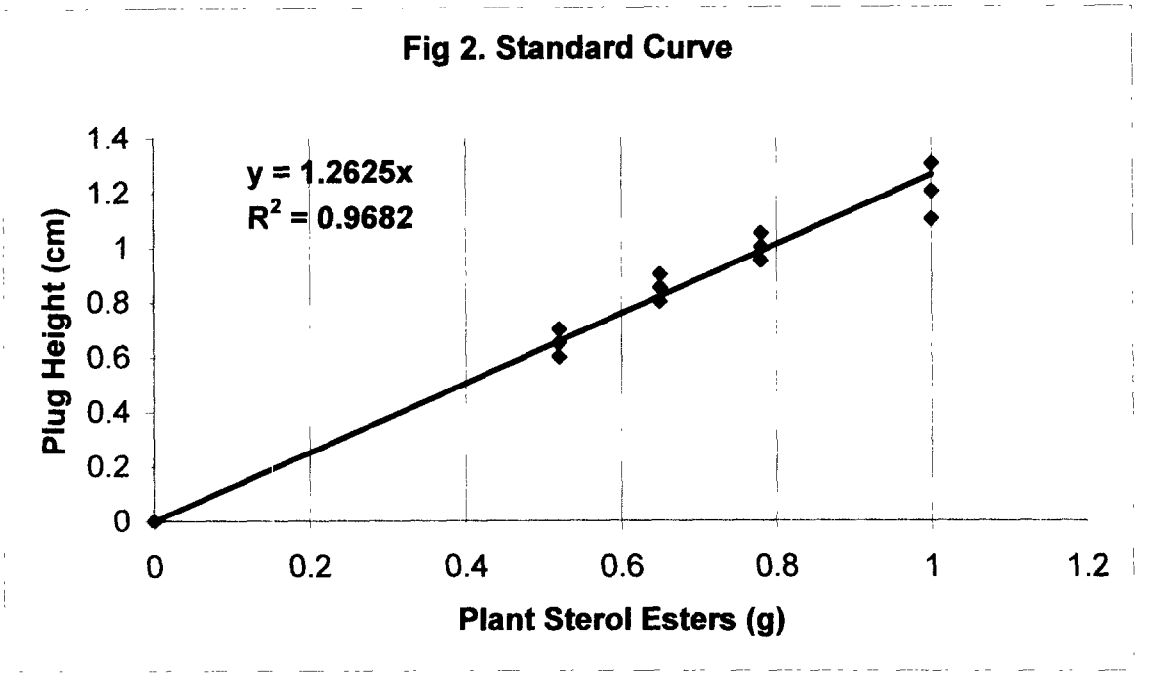

Fig 2. Standard curve generated from coffee spiked with 0.52, 0.65, 0.78 and 1.0 g of plant sterol esters. Plug height measured after spiked coffee was allowed to stand for 8 hours in a 250 ml round bottom volumetric flask.

Appendix B

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RUN-DATE: 04/25/05
RUN-TIME: 08:16:27

ADM PROCESSING - NUTRACEUTICALS
3700 EAST DIVISION

DECATUR IL 62526

** CERTIFICATE OF ANALYSIS **
*** ARCHER DANIELS MIDLAND ***

** SHIPTO **
[illegible]741 HEARTBLEND FOODS
[illegible]4 SILVERS LN
CRANBURY NJ

CUSTOMER PO# VERBAL BILL ADM ORDNO # 113C96 *INVOICE # [illegible]3096 1034
PRODUCT CD: 040087 CUSTOMER PRODUCT CD:
PRODUCT DESC:CARDIOAID-S
LOTNO: PER0205500 TEST DATE: 02/24/05 DATE OF EXPIRY: 02/24/06
SHIP DATE: 04/25/05 CARNO:
SHIP FROM: DECATUR , IL
MANUFACTURE DATE: 02/24/05
QTY 1 NET WEIGHT 10.000 K
CONTAINER CD: GC 10KG P.

TEST	ASSAY RESULTS	
LAB NUMBER	022B5	
TOTAL STEROLS (TS)	59.2	%
CHOLESTEROL (%TS)	0.4	%
BRASSICASTEROL (%TS)	2.4	%
CAMPESTEROL (%TS)	26.3	%
CAMPESTANOL (%TS)	1.1	%
STIGMASTEROL (%TS)	18.3	%
SITOSTEROL (%TS)	44.1	%
SITOSTANOL (%TS)	3.9	%
OTHER STEROLS (%TS)	3.4	%
ACID VALUE	0.2	MG KOH/G
ACIDITY	0.04	ML [illegible] NEOF
PEROXIDE VALUE	0.0	
MOISTURE %	0.0000	

THIS PRODUCT IS TESTED PERIODICALLY TO ENSURE IT MEETS THE FOLLOWING CRITERIA:
HEAVY METALS < 10 PPM, LEAD < 2 PPM
OVI CONTENT COMPLIES WITH USP STANDARDS

COUNTRY OF ORIGIN: USA

CHRIS SCHUETTE

QC MANAGER

Chris Schuette