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MAY 23 2006

Ms. Christine M. Humphrey, Esq.  
C. Humphrey & Associates, P.A.  
1001 Brickell Bay Drive  
Suite 2002  
Miami, Florida 33131

Dear Ms. Humphrey:

This is in response to your letter of April 20, 2006 to the Food and Drug Administration (FDA), on behalf of your client Healing Power, Inc.,<sup>1</sup> pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that the following statement will be made for the product DBCARE:

“Helps maintain normal blood sugar levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, claims that do not establish that the claims are about blood glucose levels that are already within normal limits imply that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood glucose levels but does not also include a statement about it being intended to affect blood glucose levels that are already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to

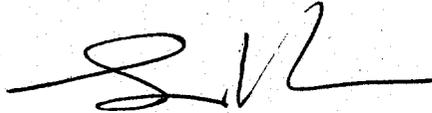
<sup>1</sup>Healing Power, Inc., 30-21 43 Street, Suite #3, Astoria, New York 11103.

Page 2 - Ms. Christine M. Humphrey, Esq.

regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', written over a horizontal line.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

Healing Power, Inc., 30-21 43 St., Suite #3, Astoria, NY 11103



C. HUMPHREY & ASSOCIATES, P.A.

FOOD AND DRUG LAW
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April 20, 2006

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APR 28 2006

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., S.W.
Washington, DC 20204

Re: Notice Pursuant to 21 USC § 343(r)(6) of Intent to Market Dietary Supplement with "Structure/Function" Statements

Dear Sir or Madam:

This notification is being filed pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 343(r)(6). The above is counsel for Healing Power, Inc., 30-21 43 Street, Suite #3, Astoria, NY 11103, which plans to market a dietary supplements bearing the following statements on the label and/or in the labeling:

Name of Supplements:

DBCARE

Dietary ingredients:

- Karela extract
Amla extract
Jambubej extract (eugenia jambolana)
Mamejava extract (enicostemma littorale)
Kadiyatu extract
Methi extract
Galo extract (Gulanshe Tino)
Gudmaar extract (gymnema sylvestre)
Kadu extract (Swertia chirayita)
Neempan extract (azadirachta indica)
Halki extract

Structure/Function statements:

"Carbohydrate metabolizer;" and
"Helps maintain normal blood sugar levels"

Handwritten note: 2006-4441

#1687

Office of Special Nutritionals

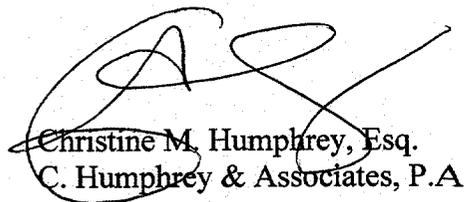
April 20, 2006

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The effect on the structure/function of the body arise from the proprietary blend of dietary ingredients present in DBCARE as listed on page 1 of this notice.

Should the FDA or the Office of Special Nutritionals have any questions, concerns, or comments regarding this 21 U.S.C. § 343(r)(6) notice, they may be directed to this office at the address, telephone, or fax number contained in this letter.

Very truly yours,



Christine M. Humphrey, Esq.  
C. Humphrey & Associates, P.A.

**C. HUMPHREY & ASSOCIATES, P.A.**

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