SEP 26 2000

Food and Drug Administration
Washington, DC 20204

5 6 3 8 '00 OCT -3 P2 :33

Mr. David Litt
Chief Sales & Marketing Officer
MaxCell Bioscience, Inc., dba Oasis Wellness Network
100 Technology Drive, Suite 130
Broomfield, Colorado 80021

Dear Mr. Litt:

This is in response to your letter of July 27, 2000 to the Food and Drug Administration
(FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and
Cosmetic Act (the Act)). Your submission states that MaxCell Bioscience, Inc., dba Oasis
Wellness Network, is making the following claim for the product **Plus 5 Mind/Body
Formula & High Potency Antioxidant**:

> "Helps maintain healthy cholesterol"
> "...reduces plaque".

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 statements that you are making for this product suggests that it is
intended to treat, prevent, or mitigate a disease, namely hypercholesterolemia and dental
disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims
suggest 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 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, 7520 Standish Place, Rockville,
Maryland 20855.

Please contact us if we may be of further assistance.
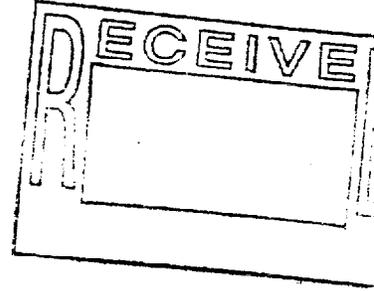
Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
    and Dietary Supplements
Center for Food Safety
    and Applied Nutrition

975-0163

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This notification is being filed on behalf of MaxCell Bioscience, Inc. dba Oasis Wellness Network which is the manufacturer and seller of the product(s) which bear the statements identified in this notification. Its business address is 100 Technology Drive, Suite 130, Broomfield, CO 80021. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is PLUS 5 Mind/Body Formula & High Potency Antioxidant.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Improves cerebral circulation
(Statement 2): Helps maintain healthy cholesterol
(Statement 3): Promotes urinary tract health
(Statement 4): Protects brain function
(Statement 5): Decreases free radical damage to DNA
(Statement 6): Promotes healthy liver function
(Statement 7): Promotes healthy gums and reduces plaque

The following summary identifies the dietary ingredients or supplement(s) for which a statement has been made:
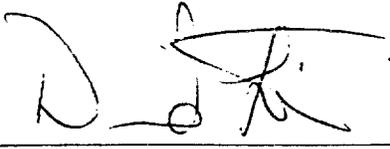
Statement Number	Identity of Dietary Ingredient(s) or Supplement-that is the Subject of the Statement
1.	Gingko Biloba
2.	Aloe Vera and Cranberry and Cherry Concentrates
3.	Blueberry, Cranberry and Cherry Concentrates
4.	Gingko Biloba and Blueberry Concentrate
5.	Cherry, Blueberry, Guava and Cranberry Concentrates and Aloe Vera
6.	Blueberry Concentrate and Wolfberry
7.	Blueberry and Cranberry Concentrates

The following identifies the brand name of each supplement for which a statement is made:

Statement Number	Brand Name	Label or Labeling?
1.	PLUS 5 Mind/Body Formula & High Potency Antioxidant	Label

I, David Litt, am authorized to certify this Notification on behalf of Oasis Wellness Network. I certify that the information presented and contained in this Notification is complete and accurate, and that Oasis Wellness Network has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 7/27/00

By: _____
David Litt, Chief Sales & Marketing
Officer