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# Metabolic Nutrition, Inc.

March 20, 2001

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Elizabeth A. Yetley, Ph.D.  
Director  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety & Applied Nutrition  
Food & Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

**Re: Metabolic Nutrition, Inc.  
Statement of Nutritional Support**

Dear Dr. Yetley:

This letter is being submitted pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 codified at 21 U.S.C. §343(r)(6) by Metabolic Nutrition, Inc., located in Schaumburg, Illinois.

Metacalm®-S is sold as a nutritional supplement to meet the metabolic needs of persons who have stopped smoking. It is not, and will not be promoted as, an aid to stopping smoking. The statements that are being made are carefully designed to refute even a possible inference that Metacalm®-S will aid in stopping smoking; it is useful only as a dietary supplement after a person has elected to stop smoking.

As required by 21 CFR §101.93, Metabolic Nutrition, Inc. submits the following information:

The text of the statements that are being made are as follows:

rebalancing metabolism in the absence of nicotine

promoting cellular rejuvenation

normalizing and optimizing cellular metabolism

normalizing a healthy nicotine-free metabolism

1. The dietary ingredients that are the subject of the statements are the combination of the following nutrients:

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### Metacalm®-S

**Supplemental Facts**  
Serving Size 1 tablet

Proprietary blend 1.33 g

Amount per serving		% daily value
Vitamin A	2500 IU	50 %
Vitamin C	200 mg	333 %
Vitamin D	100 IU	25 %
Vitamin E	10 IU	33 %
Thiamin	20 mg	1333 %
Riboflavin	10 mg	588 %
Niacin	50 mg	250 %
Vitamin B <sub>6</sub>	30 mg	1500 %
Folic Acid	200 mcg	50 %
Vitamin B <sub>12</sub>	30 mcg	5000 %
Biotin	100 mcg	33 %
Pantothenic Acid	20 mg	200 %
Magnesium	50 mg	13 %
Zinc	5 mg	33 %
Manganese	2 mg	100 %
Chromium	20 mcg	17 %
Proprietary Blend	185 mg	†

L-glutamic acid, L-glutamine, lecithin, valerian root, echinacea root

3. The statements appear on the labeling of the dietary supplement marketed under the brand name Metacalm®-S.

I certify that the information contained in this notice is complete and accurate and that Metabolic Nutrition, Inc. has substantiation that the statements in this notice are truthful and not misleading.

If you have any questions regarding this notification, please contact us.

Sincerely,



Anthony Umbdenstock  
President

CC: George Burditt