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October 10, 2001

**VIA UPS NEXT DAY AIR**

Dr. Robert Moore - Chief  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street, S.W.  
Washington, DC 20204

***Re: Fulfillment of reporting Obligation  
Under 21 U.S.C. § 343(r) and 21 CFR § 101.93***

Dear Dr. Moore:

Vital Basics, Inc.,<sup>1</sup> in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, hereby submits an original and two copies of its structure/function claim notification to the Food and Drug Administration. Vital Basics retains scientific documentation supporting the statements.

**1. Supplement Brand Name**

Focus Factor

**Supplement Ingredients**

Vitamin A (from natural beta-carotene and mixed carotenoids); Vitamin C (as ascorbic acid, sodium ascorbate, calcium ascorbate, potassium ascorbate, zinc ascorbate, and ascorbyl palmitate); Vitamin D (as cholecalciferol); Vitamin E (as natural d-alpha-tocopheryl); Thiamin (as thiamin mononitrate); Riboflavin; Niacin (from inositol hexanicotinate and 50% as niacinamide); Vitamin B6 (as pyridoxal-alpha-ketoglutarate, pyridoxal-5-phosphate); Folate (as folic acid); Vitamin b12 (as ion exchange resin); Biotin; Panthoenic acid (as d-calcium pantothenate); Calcium (as calcium citrate, calcium succinate, and calcium ascorbate); Iron (as Ferronly carbonyl Iron); Iodine (as kelp (Ascophyllum nodusum)); Magnesium (as magnesium citrate, magnesium malate, and

<sup>1</sup> The address for Vital Basics, Inc. is 510 Congress Street, Portland, ME 04101.

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magnesium taurinate); Zinc (as zinc citrate and copper Chelazome); Manganese (as manganese citrate); Chromium (as chromium polynicotinate); Molybdenum (as molybdenum amino acid chelate); Potassium (as potassium citrate, potassium aspartate, and potassium ascorbate); Synergistic and proprietary formulation of: DMAE (as DMAE bitartrate); L-Glutamine; Bacopin/Bacopa monnieri extract; L-pyroglutamic acid; phosphatidylserine; DHA concentrate (15% DHA from fish body oil); choline (as choline bitartrate); inositol; pyridoxal-alpha-ketoglutarate; N-acetyltyrosine; bilberry fruit standardized extract (25% anthocyanosides); GABA; grape skin extract and Activin (grape seed extract); vinpocetine, Trace-Lyte Electrolyte concentrate, Huperzine (extract of Huperzia serrate), boron (as boron chelate); vanadium (as vanadyl sulfate).

### **Text of Statements of Nutritional Support**

Focus Factor provides a complete spectrum of nutritional and dietary ingredients that support, protect, and enhance healthy brain function.

It includes the key vitamins, minerals and botanicals, herbs and cutting edge nutrients necessary for brain function and health.

Provides the vitamins and minerals they need for proper health, growth and development.

Focus Factor safely and naturally enhances memory, mood, mental alertness, energy and concentration.

Improved my ability to focus and concentrate tremendously.

Focus Factor gives you the ability to think with more clarity, to perform tedious tasks, to improve your attention to detail...

I feel much more focused; I can concentrate longer.

We've seen their ability to concentrate improve.

Once you get the nutrients your brain needs, which Focus Factor does, the thinking is more clear.

The body is more in balance and able to do more.

With regular multi-vitamins, you don't really notice the mental clarity that you get with Focus Factor.

But my memory is wonderful since I've started taking Focus Factor.

It has given me the energy I need, and has also sharpened my memory significantly.

You can really reduce those sluggish feelings that so many people complain about.

There was a major difference in my energy level and concentration level.

I'm alert, I'm awake, I have more energy.

I've already noticed a difference in my memory and concentration.

Since taking Focus Factor my mental clarity has improved.

My mental and physical energy is tremendous.

I'm remembering things and I feel better.

I have totally regained my mental capability and capacity.

Focus Factor has truly helped me think better and feel better.

We were more focused on what we were doing.

I'm taking up other interests and getting focused on it.

I find that I am in a better mood, I have more enthusiasm and I have more patience.

I feel much more alert and alive all day long.

My concentration – that's the most important thing for me because I am a musician – is so much better.

I have more energy.

I have a more stabilized mood.

I feel like my brain functions better.

I am on top of my game.

I have noticed my mood swings are not the highs and lows that they used to be.

I am a much more steady clam person.

I noticed a marked improvement in my energy level and the way I felt.

I have noticed such a difference in my energy level while at work – in the air as well as home.

I can think more clearly.

I can concentrate better.

My energy level is steady.

My mind is absolutely clear.

My mood is higher than it's been in my whole life.

This product has absolutely brought my body back into balance and helped me feel like a normal, healthy, vibrant individual.

It also gave me more stamina and helps me focus and concentrate better.

Helps ensure that we regain some of the loss to our memories that we didn't think we would be able to get back.

Has just improved my energy and my mood so much.

Our ability to concentrate on our work has increased.

Our energy level has greatly increased.

Now we feel refreshed in the morning and have enough energy after a long day of work to exercise.

It keeps me focused on what I need to do.

Now my focus is there.

I don't lose the energy.

I just keep going and going.

I think it is great for older folks who need to be able to think and concentrate better.

Effective for calming the mind and for enhancing brain function in children as well as adults.

Significant improvement in memory, concentration and overall well-being.

This program is a home run for helping a variety of mental concerns.

When your mind is right, you can think better, feel better and perform better.

Focus Factor is what your brain needs to think more clearly.

Focus Factor has helped me reduce that stress.

I found that I have the ability, particularly in the evening, to concentrate on my reading material, whether it's pleasure reading or technical material.

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I can absorb what I'm reading and concentrate and retain the information more completely.

Stimulate the brain to help it think, focus and recover facts, numbers, words, definitions etc.

It helped with my memory and concentration.

Improved my concentration level and energy.

I felt much better and I was getting more done.

I just feel really focused.

Focus Factor has given me more sustained energy throughout the day.

It has allowed me to focus on goals and achieve those goals.

It just helps me to concentrate and just be more conscious of my surroundings... to things that are going on around me.

Focus Factor is clearly the supplement that really helps me stay focused.

I know it's feeding my brain because I'm a lot more focused and I make more sound decisions.

My memory is getting sharper and sharper, my mood stays upbeat all the time and my attitude is unbelievable.

I'm way more energetic than I ever was.

Helping me out on my energy level and multi-tasking, which is a normal day-to-day operation for any business.

My mood is better; I have more clarity.

I attribute that extra focus I've gotten to Focus Factor.

This has definitely lifted my mood.

It's given me more concentration.

I have more energy.

My mood is more stable.

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I think much more clearly.

It has made a significant difference in my concentration – staying on the task at hand.

It has significantly helped me to grab not only long-term memories but short-term memory whenever I am in the field.

After taking Focus Factor, my son Brian showed a marked improvement in his ability to focus and concentrate.

I've noticed a significant improvement in my level of energy and my ability to concentrate in the afternoon.

I noticed a difference in my concentration level.

Things that I could not comprehend in the books seemed clearer to me.

We noticed remarkable improvement in her ability to concentrate.

My mood has improved dramatically.

I'm better able to focus and to communicate with other people.

My ability to concentrate has improved dramatically.

Focus Factor helps me concentrate.

I don't feel tired, I have more energy and I'm a much happier person.

I would highly recommend it for children or adults who need that mental alertness and brain power.

Within a week we saw major differences with Blake's ability to focus.

My 10-year old daughter Deborah was having trouble with concentration.

Noticed a difference in her memory, concentration, mood and energy just like the product said she would.

I saw a significant difference in his concentration.

He can concentrate, he has confidence.

Now we are just so happy.

The improvement has been immense in my children's ability to concentrate.

I enjoy the energy that I get from Focus Factor.

It helps me to concentrate a little better too.

He's remembering things so much better.

He was able to sit down and concentrate and be able to focus and he really felt better about himself.

I don't have the mood swings that I did and I feel calmer.

People are saying he's more settled and focused.

It helps me focus.

It really helps me concentrate more.

Gives me enough energy to go on with my life with more energy.

It helps me concentrate on my work and focus on the questions and stuff.

I can listen and understand more.

I feel more upbeat now.

And it really affected me because it made me more focused.

Focus Factor also helps me feel confident and that helps me accomplish things a lot faster.

This has helped me stay on-task

A fast, easy and natural way to improve focus, memory, mood, concentration and energy.

Focus Factor is a superior natural supplement that enhances brain function.

The nutrients selected for this unique formula are the most absorbable, biologically active ingredients available, and were chosen for their ability to feed and nourish the brain.

These nutrients are combined with natural antioxidants and plant extracts that protect and support neurotransmitters (natural chemicals in the brain that regulate mood, memory and concentration).

Focus Factor provides a full spectrum of ingredients that feed your brain what it needs to keep you focused, mentally sharp, positive, and energetic everyday.

We've chosen specific forms of nutrients that assist the brain in the process of energy production.

Improved oxygen utilization.

Increased blood circulation.

Enhanced neurotransmitter formation.

You'll feel the difference in your focus, memory, mood concentration and energy.

When taken as directed, it will make you feel refreshed, alert and focused.

However, one of the natural benefits is a healthy increase in energy.

Providing superior nutritional support for optimal brain function in adults and children.

A nutritional supplement that promotes, maintains and supports optimal brain function.

Specifically, it gives you essential nutrients needed to promote optimal brain function.

Compared to other supplements on the market, the constituent nutrients of Focus Factor are present at better levels, and in the ideal forms more likely to enhance brain function.

Focus Factor results in a significant improvement in memory, concentration and overall well-being.

Here's a product that can increase your mental clarity, that can help you physically feel better, and can increase your memory.

It can make a significant difference for your kids in terms of their concentration.

I think there's a significant advantage with Focus Factor in our senior citizens, and their ability to increase their memory and mental clarity to improve their quality of life.

I have more energy.

I have a more stabilized mood.

It has helped significantly increase concentration, and dramatically decrease mood swings, which helps to improve social skills and self esteem.

I feel really refreshed and rejuvenated throughout the day.

With Focus Factor I noticed an improvement in my energy level within a few days.

Phosphatidyl Serine enhances your brain's output of acetylcholine, the neurotransmitter associated with our ability to think, reason and concentrate.

Phosphatidyl Serine improves short-term and long-term memory recall.

It also stimulates the creation and release of dopamine, a substance related to heightened states of attention and awareness.

DHA – an essential omega-3 fatty acid that your brain uses for growth and function.

DHA is an essential component to optimal brain and memory function, and maintaining a positive mental state.

L-pyroglutamic Acid – plays a vital role in brain chemistry and enhances the ability to focus, remember, concentrate, and learn.

GABA – the chief relaxing neurotransmitter of the human brain which works to clam your mind and enhance mental focus and concentration.

DMAE – a natural substance which promoted increased levels of choline in the brain.

Choline is essential for storage and recall of memories, and is important for concentration and learning.

Magnesium – from citrate, malate, and taurinate, three superior forms which support the proper function of neurons in the brain.

It can easily take the place of your multivitamin.

Men and women feel more focused and alert throughout the day.

Women report relief from irritability and mood swings.

Seniors say they feel an improvement in memory, mental clarity, and energy.

Children and teens love the effect on focus and concentration.

I have absolutely found new respect for treating my brain and feeding my brain, because I have improved my ability to focus and concentrate tremendously with Focus Factor.

My memory is wonderful since I've started taking Focus Factor.

It has given me the energy I need, and has also sharpened my memory significantly.

You can really reduce those sluggish feelings.

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There was a major difference in my energy level and concentration level.

I've noticed a difference in my memory and concentration.

I find that I'm in a better mood, I have more enthusiasm, and I have more patience.

My concentration and energy levels on my new job seem never ending and my mood swings are much better.

We have noticed an increase in memory and our ability to concentrate on our work has increased.

The Focus Factor formula is extremely effective for calming the mind and for enhancing brain function in children, as well as adults.

When your mind is right, you can think better, feel better, and perform better.

Focus Factor has helped me reduce that stress to practically nothing.

I feel much better and I just feel really focused.

I would highly recommend it for children or adults who need the mental alertness and brain power.

He was able to sit down and concentrate and be able to focus and he really felt better about himself.

The exclusive Focus Factor formula was developed to support healthy brain function.

Focus factor contains specific forms of nutrients that assist the brain in the process of energy production.

Provides the building blocks for energy.

You'll feel the difference in your focus, memory, mood, concentration and energy.

Decreased irritability.

Increased motivation.

Improved patience.

Focus Factor quickly improves brain function by providing the nutrients your brain needs to produce important neurotransmitters, the natural materials your brain makes from food and nutrients that are natural building blocks for mental focus, concentration and memory.

Focus Factor is formulated to feed your brain what it needs to enhance neurotransmitter production.

Support healthy brain function.

Focus Factor is a comprehensive nutritional supplement designed to provide superior support for the brain and body.

As a result it makes a noticeable, healthy improvement in your mental energy and your overall well-being.

As a matter of fact, ensuring that your children receive all the nutrition that they need in their diet every day is critical for optimal mental and physical development.

In addition, the nutrients in Focus Factor are essential not only for optimal brain function but also optimal health throughout the body.

It keeps me alert and has given me more energy to handle all the facts and figures that my job demands.

Focus Factor provides all the nutrients that the brain and body need for energy production.

Focus Factor gives me the mental clarity to deal with the 101 things that occur in everyday life.

Focus Factor has made my family happier, less stressed, and we have more energy since we started taking it.

Focus Factor feeds your brain the nutrition it needs to balance out your mood, relieve stress and enhance mental clarity, energy and alertness.

Focus Factor restores energy and vitality to a tired, underfed brain in children and adults.

Focus Factor is a unique, all-natural nutritional supplement designed to “feed the brain” nutrients needed for enhanced focus, concentration, memory, and attentiveness.

It helps both adults & children to stay on task as well as support a positive attitude.

Focus Factor was developed to help the brain work more efficiently by providing nutritional ingredients that support energy production and neurotransmitter synthesis.

Focus Factor provides over 57 major nutritional and dietary supplement ingredient sources that support, protect, and enhance brain function.

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Eliminates mental fatigue or foginess.

Heightens sense of mental alertness.

## **2. Supplement Brand Name**

V-Factor System I and II

### **Supplement Ingredients**

L-Arginine, Proprietary blend: saw palmetto extract (berry), standardized ginkgo biloba extract (leaf) (24% flavone glycosides and 6% terpene lactones).

### **Text of Statements of Nutritional Support**

All-natural sexual enhancer.

Prostate support.

Memory booster.

Emotional well-being.

V-Factor is a revolutionary new approach to solving some of today's most talked about health issues, including sexual performance, poor memory, concerns about prostate health, and emotional well-being.

To enhance sexual function and provide relief for other common health issues, including memory function, prostate health, and emotional well-being.

Helps maintain healthy nitric oxide levels that are necessary for vasodilation (blood flow) and important for healthy sexual function.

Supports healthy prostate function.

Improves memory function by promoting micro-circulation in the brain.

Eliminates mental fatigue or "foginess."

Promotes feelings of well-being.

Helps maintain healthy nitric oxide levels that are necessary for vasodilation (blood flow), and important for achieving erections.

Promotes healthy genital tissue and function.

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Ginkgo is a potent antioxidant that supports healthy micro-circulation.

Ginkgo promotes healthy blood flow in the brain, genital area and other bodily tissues.

Ginkgo enhances cognitive function and memory.

Promotes healthy lower urinary tract function in men.

Enhanced sexual response.

Improved sexual satisfaction.

Healthy sexual function.

### **3. Supplement Brand Name**

V-Factor Natural Pack

### **Supplement Ingredients**

V-Factor proprietary blend: L-arginine, yohimbe (standardized yohimbe extract), standardized ginkgo biloba extract (leaf).

### **Text of Statements of Nutritional Support**

V-Factor Natural Pack is a revolutionary, natural formula that enhances sexual response, improves sexual satisfaction and supports healthy sexual function.

In addition to other important scientific evidence, a recent clinical trial of V-Factor has indicated a statistically significant increase in sexual satisfaction.

V-Factor promotes healthy sexual function.

Yohimbe is a potent substance that has been shown to support blood flow into the genital area and enhance the male sexual response.

This stimulus effect improves sexual satisfaction.

L-arginine triggers a desired buildup of nitric oxide.

Certain studies on l-arginine have identified noticeable improvements in the study subjects' physical sexual reactions as well as increased sexual satisfaction.

Ginkgo biloba is known to support and encourage increased peripheral blood flow, including circulation to the reproductive organs.

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This type of blood flow, known as microcirculation, is essential for sexual arousal.

V-Factor is the easy way for men to improve sexual satisfaction and enhance sexual function.

Now these natural ingredients are combined in a new, advanced formula that improves sexual response and satisfaction.

V-Factor contributes to a satisfying sex life which helps create a foundation for physical health and an overall sense of well-being.

Yohimbe helps intensify the quality of male sexual response so you can enjoy full satisfaction.

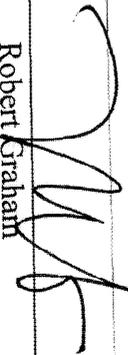
In accordance with 21 U.S.C. § 343(r)(6) and 21 CFR § 101.93(c), each of the above statements is followed by an asterisk that is cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

Respectfully submitted,

Jonathan W. Emord  
Christopher A. Brown

Certification

I, Robert Graham, Co-CEO of Vital Basics, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Vital Basics has substantiation that the statements are truthful and not misleading.

Executed on: 11/15/01  Robert Graham