October 12, 2010

VIA UPS

In reply refer to Warning Letter SEA 11-01

WARNING LETTER

James G. Cole, CEO
Maxam Nutraceutics/Maxam Laboratories
1020-D Wasco Street
Hood River, Oregon 97031

Re: PCA-Rx, PC3x, AFX, AD-Rx, AN-Rx, Anavone, AV-Rx, BioGuard, BSAID, CF-Rx, CreOcell, Dermatotropin, Endotropin, GTF-Rx, IM-Rx, Keto-Plex, Natural Passion, NG-Rx, NX-Rx, OR-Rx, Oxy-Charge, PN-Rx, Ultra-AV, Ultra Pure Yohimbe, and the Heavy Metal Screening Test

Dear Mr. Cole:

This letter concerns your firm's marketing of your products: PCA-Rx, PC3x, AFX, AD-Rx, AN-Rx, Anavone, AV-Rx, BioGuard, BSAID, CF-Rx, CreOcell, Dermatotropin, Endotropin, GTF-Rx, IM-Rx, Keto-Plex, Natural Passion, NG-Rx, NX-Rx, OR-Rx, Oxy-Charge, PN-Rx, Ultra-AV, Ultra Pure Yohimbe, and the Heavy Metal Screening Test on your website, www.maxamlabs.com. These products are marketed in violation of provisions of the Federal Food, Drug, and Cosmetic Act (the Act) as described below.

According to labeling, your products are intended to affect the structure or function of the body of man or other animals and/or intended to cure, mitigate, treat, or prevent disease conditions. Statements documenting these intended uses include, but are not limited to, the following:

PCA-Rx

• “Try our oral chelation therapy called clathration for autism, Alzheimers, allergies, heavy metal detox and more.”

• “Removes heavy metals, toxins, mycoplasmas and cardio and cerebral vascular plaque.”

• “Some older users of PCA-Rx have remarked a definite improvement in thought process and recall ability ....”

• "Strong Relief For Uterine Fibroids ... After 3 months of using PCA-Rx from Maxam, the growths resolved completely."
PC3x

- "I have been giving this to a friend of mine that has lung problems from chemical exposure and had to use an inhaler to breathe [sic] when out in the heat. After just two months of use ... he showed a 51% increase in lung capacity."

- "Aids in and accelerates the cellular detoxification process."

AFX (Autism Factor)

- "Restructures and repairs all pathways, including the brain, nervous system, thyroid, growth hormone and immune function."

- "Maxam constantly fine-tuned AFX to enhance its efficacy, addressing all aspects of Autism Spectrum/ADD/ADHD/RS or any other neural developmental disorders...."

AD-Rx

- "AD-Rx enhances serotonin (5-HT) function in the body."

- "[N]atural treatment for mood disorders, anxiety, fatigue, insomnia, eating disorders, Post-Traumatic Stress Disorder (PTSD), Premenstrual Syndrome (PMS) and Obsessive-compulsive disorder (OCD)."

AN-Rx (Pain Relief Anti-Anxiety Formula)

- "Relieves pain and anxiety, helps balance mood and has a calming effect."

- "[H]elps with insomnia and interrupted sleep patterns."

Anavone

- "Suppresses the catabolic hormone cortisol."

- "[I]ncreases protein synthesis."

- "Prevents muscle breakdown."

AV-Rx

- "Diseases such as herpes, AIDS, the flu, mad cow disease and various types of cancer are all of viral or prion origin.... AV-Rx will help protect the body against diseases of viral or prion origin, as well assisting the body in the healing of these types of diseases."

- "Herpes Relief - At Last!! ... Within 24 hours of starting to take AV-Rx, Maxam Lab's antiviral formula, he symptoms began to respond.... The client ... even sprayed it externally on the vaginal membranes.... As a clinician, it is so wonderful to have clients get such an immediate response when the body has not been able to respond to any other treatment."

BioGuard

- "Clean(s) and enhance(s) the immune system."

- "Beneficial for intestinal bacteria and fungus, such as Candida yeast overgrowth."

BSAID (Broad Spectrum Anti-Infective Disease)

- "Shown effective against latent residual viruses from old inoculations, measles, mumps, small pox, as well as HPV, EBV, CMV, HIV, etc.""
• "My son who is now 18 has had severe large clusters of cold sore breakouts since he was about 2 years old ... I thought I would try BSAID for my son. IT WORKED WONDERS!!!He has not had a breakout in 2 years now."

**CF-Rx (Cellaflex Anti-Inflammatory Anti-Arthritic)**

• "Anti-arthritic which stimulates regeneration and repair of all soft tissue, tendons, ligaments, muscle, skin (bruises). Cellaflex is also an anti-inflammatory which reduces pain in joint structures."

• "It is useful to nebulize the Cellaflex for lung diseases, especially asthma and other related pulmonary diseases."

**CreOcell (Creatinine Phosphokinase)**

• "Enhances Endurance and Muscular Growth."

• "Increased muscle nitrogen levels with lower protein intake, increased ATP level recovery and many of the positive benefits of a true anabolic compound without any of the negative side effects associated with toxic loading or anabolic steroid use."

• "CreOcell is reported to give higher energy and endurance levels, harder more defined muscles, an increase in mental awareness and the most incredible "pump" users say they have ever experienced."

**Dermatropin**

• "Dermatropin stimulates collagen, elastin regeneration, activates scar tissue repair, and reduces wrinkling and sun damage."

**Endotropin**

• "Endotropin has been created to stimulate release of human growth hormone, stimulates full pituitary and hypothalamic function, luteinizing and follicle stimulating hormones, which, in turn, will stabilize estrogen and testosterone production."

• "Endotropin will also stimulate adrenocorticotropic hormone (acth), which increases energy. Melanin, dopamine, serotonin, melatonin, and oxytocin are all stimulated as well.... Your entire endocrine system is covered. Endotropin may have just made growth hormone obsolete!"

**GTF-Rx (Glucose Tolerance Factor)**

• "GTF-Rx increases insulin sensitivity of cells, lowers insulin requirements, normalizes glucose levels, ameliorates symptoms of diabetes and accompanying chronic tissue degeneration."

**IM-Rx (Immune System Enhancement)**

• "IM-Rx is an immune system modifier that down-regulates autoimmune dysfunction, to help alleviate symptoms of arthritis, lupus, multiple sclerosis and enhances T & B cell activity in response to infection."

**Keto-Plex**

• "Increases Immunity/Assists in Weight Loss"

• "Keto-Plex ... has measurable effects on increasing muscular density and hardness and promoting a defined, lean appearance. It also assists in weight loss and minimizes catabolism (break down) of muscle tissue."

**Natural Passion**

• "Natural Passion Helps Increase:
  - Libido
  - Virility
  - Sensitivity
  - Desire for sexual intimacy"
NG-Rx (Neural Regeneration)

• "[D]esigned to ... balance and correct the brain chemistry ... and induce the formation and activation of neuro-pathways."

• "NG-Rx ... can help to reduce memory loss."

• "It can stimulate your immune system."

• "NG-Rx can also assist with weight loss, and can improve your mood when you are feeling a little down."

• "I have had paralysis of the left side of my face for many years. I began using your NG-Rx on the advice of your friendly customer service staff. I am happy to report that after only ten days of being on your product, I am seeing changes in the amount of facial paralysis."

NX-Rx (Neural Enhancer)

• "Stimulates nerve cell regeneration and repair in both the central and peripheral nervous system by encouraging the production of nerve growth factor."

OR-Rx (Osteo Regeneration Hard Tissue Support)

• "This product assists your body with hard tissue repair of teeth and bones; up-regulates calcium and calcium absorption."

• "Also beneficial for gum infections, soft teeth, broken bones, osteoporosis and osteoarthritis."

• "OR-RX has the capability to pull bacterial infections from the oral cavity."

Oxy-Charge

• "Oxy-Charge effectively increases muscle energy on a cellular level, oxygenates the hemoglobin in blood and eliminates carbon monoxide."

PN-Rx (Pineal Stimulating Peptides)

• "PN-Rx stimulates pineal hormone production, up-regulates melatonin and sleep while down-regulating Premenstrual Syndrome (PMS) and pain."

Ultra-AV

• "A powerful growth hormone stimulant that effectively suppresses production of the hormone somatostatin (which inhibits growth-hormones) and has life extension and anti-aging properties."

• "A 'Fountain of Youth' of sorts, that helps reverse biological aging, assists in regeneration of all tissues, is anabolic and aids in weight loss."

Ultra Pure Yohimbe

• "Used in the treatment of male impotence."

• "Promotes the stimulation of testosterone."

Your firm markets the above-listed products as dietary supplements. However, your products are labeled as transmucosal sprays for sublingual administration. You also recommend that "It is also beneficial to nebulize many of the Maxam products." In addition, your firm markets your products AV-Rx, BSAID, an CF-Rx for topical administration. Because these products are not intended for ingestion, they are not dietary supplements as defined by section 201(ff) of the Act, 21 U.S.C. § 321(ff). Rather, these products are drugs, as defined by section 201(g)(1) of the Act, 21 U.S.C. § 321(g)(1), because they intended to affect the structure or function of the body and/or intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man.
Moreover, all of the above-listed products are "new drugs" as defined by section 201(p) of the Act, 21 U.S.C. § 321 (p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of your above-listed products, without an approved application, violates these provisions of the Act.

Furthermore, your above-listed products are offered for conditions which are not amendable to self-diagnoses and treatment by individuals who are not medical practitioners such as, but not limited to, autism, Alzheimer's disease, heavy metal toxicity, uterine fibroids, mood disorders, impotence, asthma, diabetes, and infections including herpes HIV (human immunodeficiency virus), and EBV (Epstein-Barr virus). Therefore, adequate directions cannot be written so that laymen can use your products safely for their intended uses. Thus, the labeling of your above-listed products fail to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1). The above-listed products are not exempt, under 21 C.F.R. §§ 201.100(c)(2) and 201.115, from the requirement that their labeling bear adequate directions for use because they lack approved applications. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act, 21 U.S.C. § 331(a).

In addition to the new drugs that you market and sell on your website, www.maxamlabs.com, in violation of the Act, you also market and sell the Heavy Metal Screening Test in violation of the Act. The Heavy Metal Screening Test is a device because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. The Heavy Metal Screening Test, used to detect heavy metals in human urine, saliva and/or hair, is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because an approved application for premarket approval (PMA) pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360(g), are not in effect for it. The Heavy Metal Screen Test is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), in that it was manufactured, prepared, propagated, compounded or processed in an establishment not duly registered under section 510 of the Act, 21 U.S.C. § 360; not included in a list required by 510(j), 21 U.S.C. § 360(j); and notification or other information respecting the device was not provided to the FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action, without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Furthermore, please advise this office what actions you will take to address product that you have already distributed. Additionally, if another firm manufactures these products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Address your reply to the Food and Drug Administration, 10903 New Hampshire Avenue, WO51-2201, Silver Spring, Maryland 20993-0002.

A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm. In addition, information regarding approval or clearance for devices is described at http://www.fda.gov/cdrh/devadvice/3122.html. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, WO51-2201, Silver Spring, Maryland 20993-0002.

Sincerely,
/SA/  
Charles M. Breen  
District Director  

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