

**SUBJECT:** To provide background, safety, and drug testing information about dietary/body building supplements

**DISCUSSION:**

### **Regulatory control of Supplements**

1. Prior to 1994 the Food and Drug Administration (FDA) considered dietary supplements as food and thus regulated the labeling and ensured that supplements were safe prior to being sold in the United States.
2. On October 25, 1994, President Clinton signed The Dietary Supplement Health and Education Act (DSHEA), which effectively removed dietary supplements from FDA pre-market control; supplements can be removed from the marketplace only after the FDA proves that the product is unsafe. The purpose of the DSHEA is "to improve the health status of the people of the United States and help constrain runaway health care spending by ensuring that the Federal Government erects no regulatory barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements."<sup>1</sup> In simplest terms DSHEA was enacted to reduce the bureaucratic red tape required to market supplements that could increase the overall health and reduce medical costs of the American people.
3. Public Law 108-358, the Anabolic Steroid Act of 2004, went into effect on January 20, 2005. This law reclassified several popular dietary and muscle building supplements, such as androstenedione, as Schedule III drugs on the federal schedule of controlled substances. This reclassification makes it illegal to purchase, sell, possess or consume the reclassified supplements.

### **What are Dietary Supplements?**

DSHEA defines a dietary supplement as a product intended to supplement the diet by increasing the total dietary intake that bears or contains one or more of the following dietary ingredients:

- A vitamin
- A mineral
- An herb or other botanical
- An amino acid
- Other dietary substance for use by man to supplement the diet by increasing the total dietary intake
- A concentrate, metabolite, constituent, extract, or combination of any ingredients described above

1. **Vitamins** are defined as organic compounds that are required in tiny amounts in the diet of all organisms for proper biological functioning and maintenance of health.<sup>2</sup> Vitamins are classified in two general groups, fat-soluble vitamins (A, D, E, and K) and water-soluble vitamins (C and B complex); the major difference between these groups is that the body can easily store excess fat-soluble vitamins, while excess water-soluble vitamins are more easily excreted. Taking mega doses (doses far exceeding the Recommended Daily Allowance) of ANY vitamin can produce toxic effects in the body; overdoses of Vitamins A, D and B<sub>6</sub> have produced the most deadly effects.

2. **Minerals** are defined as an inorganic substances occurring naturally in the earth and having a consistent and distinctive set of physical properties. Our bodies use small amounts of minerals for proper biological development and function. Like vitamins, taking large doses of minerals can cause deadly overdoses; the most common mineral supplement overdose probably occurs with iron. The following website provides a chart that lists natural sources of vitamins and most essential minerals, along with deficiency and overdose effects on the body: <http://www.webnat.com/hi/VitMinChart.asp>

3. **Herbs** or other botanicals are parts of seed plants, trees or shrubs used for their medicinal and/or aromatic qualities, or used for seasoning and/or food. Most people take herbal supplements for their reputed health benefits, examples include garlic for the heart, and Ginseng for the circulatory system and mental alertness. It is important that users of herbal supplements understand what they are taking, how it works, the benefits, side effects and possible interactions with other supplements or medications. Example: Someone with sleeping problems may not know that both Guarana and Kola nuts contain caffeine.

4. **Amino Acids** are any organic compound containing an amino ( $-NH_2$ ) and a carboxyl ( $-COOH$ ) group; there are 20 amino acids from which proteins are synthesized in the human body. Essential amino acids are essential for metabolism, health, and growth, but are not synthesized by the body and thus must be obtained from food. Nonessential amino acids are amino acids that are synthesized by the body and thus not specifically required in the diet. There is some controversy over whether the use of amino acids is beneficial or not to athletes and few, if any studies have been conducted to determine the benefits or side effects to average adults. Two particular amino acids are being sold as preventive health measures. L-lysine is reputed to reduce the incidence of herpes simplex virus outbreaks and L-tryptophan is used as an adjunct treatment in the management of patients suffering from depressive disorders and patients with bipolar disorder.

### **Supplement Issues Affecting Soldiers**

1. **Vitamins, minerals, protein and amino acids** – The Department of the Army has not banned the use of any of these products by soldiers. Soldiers should research available information and possibly consult with a physician prior to electing to take these supplements. Additionally, Soldiers should not exceed the manufacturers recommended dosage.

3. **Creatine** is a natural substance composed of three amino acids and is used in the body's energy producing process. Creatine is reputed to build muscle mass and boost energy. While creatine is legal to purchase and consume, Soldiers should stay informed of the risks associated with creatine use.

2. **Hemp oil** - AR 600-85 bans the ingestion of hemp oil products by soldiers. The FDA recently began regulating hemp oil products in the United States to reduce the THC content; therefore the chances of a soldier testing positive for THC using these substances is minute.

4. **Androstenedione** is a hormone that occurs naturally in the body, and is one of those responsible for male characteristics; it is a direct precursor to the male hormone testosterone. Under Public Law 108-358, which went into effect on 20 January 2005, androstenedione is considered Schedule III Controlled Substance, making the possession and use of androstenedione illegal. Prior to the law taking effect, androstenedione was used by body builders to build muscle mass and strength. The UCLA laboratory that tests Soldier urine specimens for anabolic steroids can determine if a Soldier is using androstenedione or another similar illegal anabolic steroid.

5. **Ephedra** also called Ma Huang, Chinese ephedra, Ma Huang extract, ephedra, Ephedra sinica, ephedra extract, ephedra herb powder, or epitonin, is a member of the family of herbs known as the Ephedraceae and contains two main ingredients or alkaloids, ephedrine and pseudoephedrine.

- a. The Chinese have used ephedra for thousands of years for bronchial problems.
- b. Ephedrine is used as a bronchial dilator and stimulates the nervous system, while pseudoephedrine is used as a nasal decongestant and is less stimulating to the nervous system.
- c. In accordance with the Federal Food, Drug and Cosmetic Act the sale, possession and use of dietary supplements containing ephedrine alkaloids is illegal.
- d. Exposure to ephedrine containing products as over-the-counter (OTC) cold medications (which contain mostly pseudoephedrine and small amounts of ephedrine or phenylpropanolamine) will not cause a urinalysis test conducted in a DoD/Army Forensic laboratory to be reported positive<sup>3</sup>.

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1 The Dietary Supplement Health and Education Act, 1994

2 Encyclopedia Americana, Grolier Incorporated, 1992

3 Consultant to the Surgeon General Program Manager, Forensic Drug Testing