
Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
Food and Drug Administration**

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Guidance for Industry:
Complementary and
Alternative Medicine
Products and Their
Regulation by the Food and
Drug Administration

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Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration¹

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Why Are We Issuing This Guidance?

The term “complementary and alternative medicine” (CAM) encompasses a wide array of health care practices, products, and therapies that are distinct from practices, products, and therapies used in “conventional” or “allopathic” medicine. Some forms of CAM, such as traditional Chinese medicine and Ayurvedic medicine, have been practiced for centuries, whereas others, such as electrotherapy, are more recent in origin.

In the United States, the practice of CAM has risen dramatically in recent years. In 1992, Congress established the Office of Unconventional Therapies, which later became the Office of Alternative Medicine (OAM), to explore “unconventional medical practices.” In 1998, OAM became the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM is a center within the National Institutes of Health. The Institute of Medicine, in its book entitled, *Complementary and Alternative Medicine in the United States*, stated that more than one-third of American adults reported using some form of CAM and that visits to CAM providers each year exceed those to primary care physicians.²

As the practice of CAM has increased in the United States, the Food and Drug Administration (“FDA”, “we”) has seen increased confusion as to whether certain products used in CAM (which, for convenience, we will refer to as “CAM products”) are subject to regulation under the Federal Food, Drug, and Cosmetic Act (“the Act”) or Public Health Service Act (“PHS Act”). We have also seen an increase in the number of CAM products imported into the United States. Therefore, we are providing guidance as

¹ This guidance was prepared by the Office of Policy and Planning, Office of the Commissioner, Food and Drug Administration, with assistance from the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Food Safety and Applied Nutrition.

² See Institute of Medicine, *Complementary and Alternative Medicine in the United States*, pages 34-35 (2005).

to when a CAM product is subject to the Act or the PHS Act.³ This guidance makes two fundamental points:

- First, depending on the CAM therapy or practice, a product used in a CAM therapy or practice *may* be subject to regulation as a biological product, cosmetic, drug, device, or food (including food additives and dietary supplements) under the Act or the PHS Act. For example, the PHS Act defines “biological product,” and the Act defines (among other things):
 - Cosmetic;
 - Device;
 - Dietary supplement;
 - Drug, as well as “new drug” and “new animal drug;”
 - Food; and
 - Food additive.These statutory definitions cover some CAM products.
- Second, neither the Act nor the PHS Act exempts CAM products from regulation. This means, for example, if a person decides to produce and sell raw vegetable juice for use in juice therapy to promote optimal health, that product is a food subject to the requirements for foods in the Act and FDA regulations, including the hazard analysis and critical control point (HACCP) system requirements for juices in 21 CFR part 120. If the juice therapy is intended for use as part of a disease treatment regimen instead of for the general wellness, the vegetable juice would also be subject to regulation as a drug under the Act.

We explain these two points in greater detail later in this document.

II. What Is Complementary and Alternative Medicine (CAM)?

NCCAM defines CAM as “a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine.”⁴ It interprets “complementary” medicine as being used together with conventional medicine, whereas “alternative” medicine is used in place of conventional medicine.

NCCAM classifies CAM therapies into four categories or “domains.” These are:

- Biologically-based practices;
- Energy therapies;

³ When this guidance mentions a particular CAM therapy, practice, or product, it does so in order to provide background information or to serve as an example or illustration; any mention of a particular CAM therapy, practice, or product should *not* be construed as expressing FDA’s support for or endorsement of that particular CAM therapy, practice, or product or, unless specified otherwise, as an agency determination that a particular product is safe and effective for its intended uses or is safe for use.

⁴ See NCCAM, “Get the FACTS – What Is Complementary and Alternative Medicine (CAM)?” available at <http://nccam.nih.gov/health/whatiscam> (accessed on November 22, 2005).

- Manipulative and body-based methods; and
- Mind-body medicine.

NCCAM once had a fifth domain, “Alternative medical systems,” but now considers “alternative medical systems” (now known as “whole medical systems”) to be a separate category rather than another domain because alternative medical systems use practices from the four domains listed above. For purposes of this guidance, we adopt the same domains and “whole medical systems” category that NCCAM uses.

A. What Are “Biologically Based Practices?”

According to NCCAM, the domain called “biologically based practices” includes, but is not limited to, botanicals, animal-derived extracts, vitamins, minerals, fatty acids, amino acids, proteins, prebiotics⁵ and probiotics,⁶ whole diets, and “functional foods”.⁷

Many biologically-based products within this domain are subject to statutory and regulatory requirements under the Act or the PHS Act. The intended use of a product plays a central role in how it is regulated. For example:

- Botanical products, depending on the circumstances, may be regulated as drugs, cosmetics, dietary supplements, or foods.⁸ All four types of

⁵ Prebiotics have been defined as nondigestible food ingredients that beneficially affect the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon (see Gibson, G.R. and Roberfroid, M.B., “Dietary Modulation of the Human Colonic Microbiota: Introducing the Concept of Prebiotics,” *Journal of Nutrition*, 125: 1401-1412 (1995)). Oligosaccharides are commonly used as prebiotics.

⁶ “Probiotics” have been defined as live microbial food supplements which beneficially affect the host animal by improving its intestinal microbial balance (see Fuller, R., “Probiotics in Man and Animals,” *Journal of Applied Bacteriology*, 66: 365-378 (1989)) and as live microorganisms which, when consumed in adequate amounts of food, confer a health benefit on the host (see Food and Agriculture Organization and World Health Organization, “Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria” (1-4 October 2001)). For purposes of this document, we will consider probiotics to refer to whole, live microorganisms that are ingested with the intention of providing a health benefit (such as supporting digestion and nutrient adsorption in the intestine). Our Center for Food Safety and Applied Nutrition, simply refers to such bacteria as “live microorganisms.”

“Probiotics” are not defined as a regulatory product category under the Act or the PHS Act, and products that may be considered to be “probiotics” may be foods or drugs under the Act, depending on the intended use of the product.

⁷ See NCCAM, “BACKGROUND: Biologically Based Practices: An Overview” (October 2004), at page 1 (available at <http://nccam.nih.gov/health/backgrounds/biobasedprac.pdf>) (accessed on November 22, 2005)). NCCAM interprets “functional foods” as “components of the usual diet that may have biologically active components (e.g., polyphenols, phytoestrogens, fish oils, carotenoids) that may provide health benefits beyond basic nutrition” (id. at page 3). However, “functional foods” are not defined as a regulatory product category, and products that NCCAM would interpret to be “functional foods” would either be foods or drugs to FDA, depending on the claims associated with the product.

⁸ Although dietary supplements are a type of food (see section 201(ff) of the Act (last sentence)), for ease of reference, we will use the term “food” to refer to foods other than dietary supplements (e.g., conventional foods, food additives, or GRAS substances intended for use in food) throughout the remainder of this guidance. We may discuss specific types of “foods,” such as “food additives,” separately

products are subject to the Act. For example, a botanical product intended for use in treating a disease would generally be regulated as a drug; a botanical product taken by mouth, labeled as a dietary supplement, and intended for use to affect the structure or function of the body would generally be regulated as a dietary supplement; a raw or dried botanical intended for use as an ingredient to flavor food would generally be regulated as a food or as a food additive, depending on whether the botanical was generally recognized as safe for its intended use in food; and a lotion containing botanical ingredients and intended for use in moisturizing the skin would generally be regulated as a cosmetic.

- Probiotics may be regulated as dietary supplements, foods, or drugs under the Act, depending on the product's intended use. Other factors may also affect the classification of the product, e.g., whether the product contains a "dietary ingredient" as defined in section 201(ff)(1) of the Act (21 U.S.C. 321(ff)(1)), whether it is represented as a conventional food or as a meal replacement (see section 201(ff)(2)(B) of the Act), and, for probiotics used as ingredients in a conventional food, whether the ingredient is generally recognized as safe for its intended use (see section 201(s) of the Act (21 U.S.C. 321(s)). In addition to any requirements that apply based on the product's classification under the Act, probiotics may also be subject to the PHS Act's provisions concerning the prevention of communicable disease, due to potential disease-causing microorganisms that might be contained in such products. Finally, if a probiotic is a drug under the Act, it may be subject to regulation as a biological product under the PHS Act as well.
- Products that NCCAM would consider to be "functional foods" may be subject to FDA regulation as foods, dietary supplements, or drugs under the Act. As with botanicals and probiotics, the classification of a "functional food" under the Act is based primarily on the product's intended use and may also involve other factors, depending on the elements of the statutory definition of a particular product category.

B. What Is "Energy Medicine?"

NCCAM considers energy medicine to involve energy fields of two types:

- Veritable energy fields, which can be measured and use either mechanical vibrations (such as sound) or electromagnetic forces, including visible light, magnetism, monochromatic radiation (such as laser light), and other light rays; and
- Putative energy fields (or biofields) that have defied measurement to date by reproducible methods. According to NCCAM, therapies involving putative energy fields "are based on the concept that human beings are

to explain additional statutory or regulatory requirements or concepts, but those products are still "foods" under the Act.

infused with a subtle form of energy” and therapists “claim that they work with this subtle energy, see it with their own eyes, and use it to effect changes in the physical body and influence health.”⁹

In a sense, “conventional” medicine already uses various forms of “energy” medicine. For example, a magnetic resonance imaging (MRI) device uses electromagnetic waves to create images of internal body organs and tissues. As another example, an ultrasound machine uses sound waves to create images of body organs, tissues, and fetuses. Given their intended uses, we regulate these products as medical devices under the Act.

CAM products that use veritable energy fields in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals may be medical devices under the Act.¹⁰ Additionally, if the product is electronic and emits radiation, it may be subject to additional requirements to ensure that there is no unnecessary exposure of people to radiation.

CAM products that use putative energy fields in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or animals may be medical devices under the Act. For example, we regulate acupuncture needles as “class II” medical devices.¹¹

C. What Are “Manipulative and Body-Based Practices?”

According to NCCAM:

Under the umbrella of manipulative and body-based practices is a heterogeneous group of CAM interventions and therapies. These include chiropractic and osteopathic manipulation, massage therapy, Tui Na, reflexology, rolfing, Brown technique, Trager bodywork, Alexander technique, Feldenkrais method, and a host of others....

Manipulative and body-based practices focus primarily on the structures and systems of the body, including the bones and joints, the soft tissues, and the circulatory and lymphatic systems....¹²

To the extent that manipulative and body-based practices involve practitioners physically manipulating a patient’s body, without using tools or machines, we do not

⁹ See NCCAM, “BACKGROUND – Energy Medicine: An Overview (August 2005), at page 1 (available at <http://nccam.nih.gov/health/backgrounds/energymed.pdf>) (accessed on November 22, 2005).

¹⁰ See section 201(h)(2) and (h)(3) of the Act (21 U.S.C. 321(h)(2) and (h)(3)) (definition of “device”).

¹¹ See 21 CFR 880.5580.

¹² See NCCAM, “BACKGROUND: Manipulative and Body-Based Practices: An Overview” (December 2004), at page 1 (available at <http://nccam.nih.gov/health/backgrounds/manipulative.pdf>) (accessed on November 22, 2005).

believe that such practices are subject to regulation under the Act or the PHS Act. If, however, the manipulative and body-based practices involve the use of equipment (such as massage devices) or the application of a product (such as a lotion, cream, or oil) to the skin or other parts of the body, those products may be subject to regulation under the Act, depending on the nature of the product and its intended use..

D. What Is “Mind-Body Medicine?”

NCCAM describes mind-body medicine as focusing on “the interactions among the brain, mind, body, and behavior, and the powerful ways in which emotional, mental, social, spiritual, and behavioral factors can directly affect health.”¹³ It states that mind-body medicine “typically focuses on intervention strategies that are thought to promote health, such as relaxation, hypnosis, visual imagery, meditation, yoga, biofeedback, tai chi, qi gong, cognitive-behavioral therapies, group support, autogenic training, and spirituality.”¹⁴

In general, CAM practices in this domain would *not* be subject to our jurisdiction under the Act or the PHS Act. As with the manipulative and body-based practices domain, however, any equipment or other products used as part of the practice of mind-body medicine may be subject to FDA regulation, depending on the nature of the product and its intended use. For example, biofeedback machines intended to help a patient learn to affect body functions, such as muscle activity, are regulated as class II devices.¹⁵

E. What Are “Whole Medical Systems?”

NCCAM describes whole medical systems as involving “complete systems of theory and practice that have evolved independently from or parallel to allopathic (conventional) medicine.”¹⁶ These may reflect individual cultural systems, such as traditional Chinese medicine and Ayurvedic medicine. Some elements common to whole medical systems are a belief that the body has the power to heal itself, and that healing may involve techniques that use the mind, body, and spirit.

Although it is unlikely that a whole medical system itself would be subject to regulation under the Act or the PHS Act, products used as *components* of whole medical systems may be subject to FDA regulation for the reasons described above.

¹³ See NCCAM, “BACKGROUND: Mind-Body Medicine: An Overview” (August 2005), at page 1 (available at <http://nccam.nih.gov/health/backgrounds/mindbody.pdf>) (accessed on November 22, 2005).

¹⁴ Id.

¹⁵ See 21 CFR 882.5050.

¹⁶ See NCCAM, “BACKGROUND: Whole Medical Systems: An Overview” (October 2004), at page 1 (available at <http://nccam.nih.gov/health/backgrounds/wholemed.pdf>) (accessed on November 22, 2005).

III. How Do CAM Domains Relate to Products That We Regulate?

Given the vast array of CAM products, practices, and therapies, it is impractical for us to describe in detail how each one might be subject to regulation under the Act or the PHS Act. Our intent, in part IV of this document, is two-fold:

- To indicate which CAM domains might be subject to regulation under the Act or the PHS Act; and
- To show that neither the Act nor the PHS Act contains any exemption for CAM products. In other words, if a product meets the statutory definition of drug, device, biological product, food, etc., it will be subject to regulation under the Act and/or the PHS Act.

IV. What FDA Authority Might Apply to CAM Products?

A. What Statutory Definitions Might Apply?

To understand how the Act or the PHS Act might apply to CAM products, we begin by understanding the Act's statutory definitions or, in the case of the PHS Act, our authority regarding biological products.

1. "Drug" and "New Drug"

Section 201(g)(1) of the Act (21 U.S.C. 321(g)(1)) defines the term "drug," in relevant part, to mean:

(A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C).

Section 201(p) of the Act (21 U.S.C. 321(p)) defines the term "new drug" to mean:

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective¹⁷ for use under the conditions prescribed, recommended, or suggested in

¹⁷ In *Weinberger v. Hynson, Westcott and Dunning*, 93 S.Ct. 2469, 2483 (1973), the Supreme Court stated that "general recognition" of effectiveness "requires at least 'substantial evidence' of effectiveness for approval" of a new drug application (NDA). (An NDA is the marketing application for a new drug.)

the labeling thereof, except that such a drug not so recognized shall not be deemed to be a “new drug” if at any time prior to the enactment of this Act, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

To illustrate how these definitions might apply, consider an herbal product that is intended to treat arthritis in humans. The herbal product, which would be a “biologically based practice” insofar as CAM domains are concerned, would be a “drug” under section 201(g)(1)(B) of the Act because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (arthritis) in man. The same herbal product would also be a “new drug” under section 201(p)(1) of the Act unless it is generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. “New drug” status triggers the Act’s requirements for premarket review and approval by FDA.¹⁸

A detailed discussion of the Act’s drug provisions is beyond the scope of this guidance document. Note, however, that the Act imposes certain requirements (including requirements pertaining to establishment registration and product listing, pre-market approval, labeling, postmarket reporting, and good manufacturing practices) on those who manufacture and distribute drugs. The Act and our drug regulations can be found at our website at <http://www.fda.gov/opacom/laws>.

2. “Device”

In general, section 201(h) of the Act (21 U.S.C. 321(h)) defines the term “device” as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is –

Section 505(d) of the Act (21 U.S.C. 355(d)) defines “substantial evidence” as “evidence consisting of adequate and well-controlled investigations, including clinical investigations conducted by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.” Thus, “general recognition” is a high standard.

¹⁸ Under section 505(a) of the Act (21 U.S.C. 355(a)), “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [section 505(b) or 505(j) of the Act] is effective with respect to such drug.”

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) 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, or
- (3) intended to affect the structure or any function of the body of man or other animals, and
which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

To illustrate how a CAM product might be a “device” under the Act, acupuncture is a CAM therapy that seeks to stimulate energy pathways (“meridians”) by puncturing, pressing, heating, using electrical current, or using herbal medicines. Fine needles are often used, and these acupuncture needles are “devices” under section 201(h) of the Act because they are intended for use in the cure, mitigation, treatment, or prevention of disease in man or are intended to affect the structure or function of the body of man. We regulate acupuncture needles (see 21 CFR 880.5580), but not the practice of acupuncture itself.

A detailed discussion of the Act’s device provisions is beyond the scope of this guidance document. Note, however, that the Act establishes classifications for devices (class I, II, or III) that affect how they are regulated. The Act also imposes certain requirements on those who manufacture devices (including requirements pertaining to establishment registration and product listing, pre-market review, labeling, postmarket reporting, and good manufacturing practices). Certain requirements also apply to device distributors. The Act and our device regulations can be found at our website at www.fda.gov/opacom/laws.

3. “Food”

Section 201(f) of the Act (21 U.S.C. 321(f)) defines the term “food” to mean “articles used for food or drink for man or other animals,” chewing gum, and articles used for components of any such article.

To illustrate how a CAM practice might involve “foods,” juice therapy uses juice made from vegetables and fruits. Absent any claims that would make the juice subject to the drug definition, the juice would be a “food” under section 201(f) of the Act because it is an article used for food or drink for man.

A detailed discussion of the Act’s food provisions is beyond the scope of this guidance document. However, anyone who intends to market CAM products that might be subject to regulation under these provisions should familiarize himself/herself with the Act’s requirements for foods, particularly with respect to safety and labeling. The Act and our food regulations can be found at our website at www.fda.gov/opacom/laws.

4. “Food Additive”

Section 201(s) of the Act (21 U.S.C. 321(s)) defines the term “food additive” to mean, in part, “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food...if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use....”¹⁹

To illustrate how a CAM product might involve “food additives” under section 201(s) of the Act, some CAM practices involve dietary modifications where substances such as botanicals or enzymes are added to foods in the diet. If a manufacturer adds such a substance to a food, the substance may fall within the “food additive” definition at section 201(s) of the Act. A food additive is subject to premarket approval by FDA under section 409 of the Act (21 U.S.C. 348). Food additives that we have not approved or that do not comply with applicable FDA regulations prescribing safe conditions of use are deemed to be unsafe under section 409(a) of the Act, and foods that contain such additives are adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)). The Act provides that a substance is exempt from the definition of a food additive and thus, from pre-market approval, if, among other reasons, it is generally recognized as safe (GRAS) by qualified experts under the conditions of intended use. Whether a substance added to a food is considered to be a food additive or is GRAS, any claims associating the substance with the reduction of a disease risk are “health claims” (defined in 21 CFR 101.14(a)(1)) that require premarket review by FDA.²⁰

A detailed discussion of the Act’s food additive provisions is beyond the scope of this guidance document. However, anyone intending to market CAM products that are or contain substances that might be subject to regulation as food additives should familiarize himself/herself with the Act’s food additive requirements. The Act and our food additive regulations can be found at our website at www.fda.gov/opacom/laws.

5. “Dietary Supplement”

Section 201(ff) of the Act (21 U.S.C. 321(ff)) defines the term “dietary supplement” as follows:

The term “dietary supplement” -

¹⁹ The statutory definition of “food additive” exempts certain substances, such as pesticide chemical residues in or on a raw agricultural commodity or processed food, pesticide chemicals, color additives, dietary ingredients in or intended for use in a dietary supplement (as defined in section 201(ff) of the Act), and new animal drugs.

²⁰ See 21 CFR 101.70.

- (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
- (A) a vitamin;
 - (B) a mineral;
 - (C) an herb or other botanical;
 - (D) an amino acid;
 - (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
- (2) means a product that
- (A) (i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or
 - (ii) complies with section 411(c)(1)(B)(ii);
 - (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
 - (C) is labeled as a dietary supplement; and
- (3) does--
- (A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and
 - (B) does not include—
 - (i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or
 - (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,
 which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, under notice and comment, finding that the article would be lawful under this Act.

Except for purposes of section 201(g) [of the Act], a dietary supplement shall be deemed to be a food within the meaning of this Act.

To illustrate how a CAM product might be a “dietary supplement” under section 201(ff) of the Act, consider botanical products used in naturopathy. (Naturopathy is a CAM whole medical system that views disease as a manifestation of alterations in the

processes by which the body heals itself.²¹) For example, naturopathic cranberry tablets might be labeled for use to maintain the health of the urinary tract. In this example, the cranberry tablets generally would be regulated as “dietary supplements” under section 201(ff)(1) of the Act if they were labeled for use to “maintain the health of the urinary tract” rather than “prevent urinary tract infections.” The cranberry tablets would be regulated as “drugs” under section 201(g) of the Act if they were labeled for use to “treat urinary tract infections” even if they were labeled as dietary supplements.

A detailed discussion of the Act’s dietary supplement provisions is beyond the scope of this guidance document. However, anyone intending to market CAM products that might be subject to regulation as a dietary supplement should familiarize himself/herself with the Act’s dietary supplement requirements, particularly with respect to safety and labeling. The Act and our dietary supplement regulations can be found at our website at www.fda.gov/opacom/laws.

6. “Cosmetic”

Section 201(i) of the Act defines the term “cosmetic” to mean “(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.”

It is possible that certain products used in conjunction with CAM practices may be “cosmetics” under the Act. For example, if a CAM practice involves massage with a moisturizer, the moisturizer could be a “cosmetic” to the extent that it is “rubbed, poured, sprinkled, or sprayed on” the body for beautification or appearance-altering purposes. However, if the moisturizer’s intended use is also for the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, then it may also be subject to regulation as a drug. Other examples of drug/cosmetic combinations are deodorants that are also antiperspirants, moisturizers and makeup marketed with sun-protection claims, and shampoos that also treat dandruff.

The Act does not require premarket approval for cosmetics, but it does prohibit the marketing of adulterated or misbranded cosmetics in interstate commerce. Anyone intending to market CAM products that might be subject to regulation as cosmetics should familiarize himself/herself with the safety and labeling requirements for these products in the Act and our regulations. The Act and our cosmetic regulations can be found at our website at www.fda.gov/opacom/laws.

²¹ See NCCAM, “BACKGROUND: Whole Medical Systems: An Overview” (October 2004) at pages 3-4.

7. “Biological Product”

Section 351(a)(1) of the PHS Act (42 U.S.C. 262(a)(1)) states, in part, that no person “shall introduce or deliver for introduction into interstate commerce any biological product” unless that product has an effective license and its package is plainly marked with the product’s proper name, the name, address, and applicable license number of the biological product’s manufacturer, and the product’s expiration date. Section 351(a)(2) of the PHS Act gives us the authority to establish requirements for the approval, suspension, and revocation of biological product licenses.

Section 351(i) of the PHS Act defines “biological product” as “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition in human beings.” The term “virus” captures a broad spectrum of microorganisms that cause an infectious disease and includes, but is not limited to, filterable viruses, bacteria, rickettsia, fungi, and protozoa (see 21 CFR 600.3(h)(1)).

It is conceivable that some “biologically based practices” (as defined by NCCAM) could involve the use of “biological products” as defined by section 351(i) of the PHS Act. For example, the bacteria used in a probiotic product could make the product a “biological product” subject to the PHS Act.

A detailed discussion of biological product regulation under the PHS Act is beyond the scope of this guidance document. Note, however, that in addition to our authority under section 351 of the PHS Act, section 361 of the PHS Act (42 U.S.C. 264) authorizes us to make and enforce regulations “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.” If a CAM product manufacturer attempted to use a live, disease-causing virus as a component of a CAM product, we could exercise our authority under section 361 of the PHS Act and 21 CFR 1240.30 to take action against the product, in addition to consider the applicability of section 351 of the PHS Act. The PHS Act and FDA’s regulations for biological products can be found at our website at www.fda.gov/opacom/laws.

V. Whom Do You Contact For More Information?

For more information about how we regulate drugs, devices, cosmetics, foods (including food additives and dietary supplements), and biological products, visit our website at www.fda.gov. We also have many other guidance documents that present our current thinking on a particular topic.

For more information about products that we regulate, and how they might relate to CAM, please contact:

- For biological products, the Manufacturers Assistance and Technical Training Branch, Office of Communication, Training & Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 1-800-835-4709 or 301-827-1800.
- For cosmetics, the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 301-436-1130.
- For devices, the Office of Communication, Education, and Radiation Programs (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Drive, Rockville, MD 20850, 1-800-638-2041 or 301-827-3990.
- For dietary supplements, the Division of Dietary Supplement Programs (HFS-810), Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 301-436-2375.
- For foods and food additives, the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food And Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835, 301-436-1200
- For human drugs, the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4570 or 1-888-463-6332. You can also send electronic mail inquiries to druginfo@cder.fda.gov.