A Proposed Regulatory Model for Traditional Medicines:
Guiding Assumptions and Key Components

Introduction

In the spring of 2004 a diverse group of organizations decided to initiate a cooperative process to exchange ideas about the future of traditional medicines in the United States. The result was the creation of a Traditional Medicines Congress, now sponsored by eight national organizations. Each of these either represents or is engaged in standards setting, certification or accreditation for health care practitioners who include traditional medicines in their scope of practice; educational institutions that provide training in traditional medicine; manufacturers of traditional medicines; or growers and producers of traditional medicine ingredients.

The current regulatory system in the United States does not, adequately assure continued access to and safety of traditional medicines. These products do not fit neatly into either the current "food" or "drug" categories defined by the Federal Food, Drug and Cosmetic Act. And while some traditional medicines may be marketed under the Dietary Supplement Health and Education Act, which provides a regulatory framework for dietary supplements, these may not be sold as medicines.

Representatives of each of the sponsors of the Traditional Medicines Congress have created a specific proposal for a better way to regulate traditional medicines. At the very beginning of this process a clearly specified goal was agreed upon to emphasize both the value of traditional medicines and the responsibilities that are associated with their use:

> ***The goal of the Traditional Medicines Congress is to benefit public health by ensuring access to traditional medicines in a manner that provides a reasonable expectation of public safety.***

Working from this goal, the Traditional Medicines Congress has developed "guiding assumptions" and ideas for the "key components" that are essential in a regulatory framework that would clearly define traditional medicines and ensure access to these while addressing their safety, both in the retail marketplace and in clinical settings. The results of this effort are presented in this document, which will now be broadly distributed for review and comment by practitioners and manufacturers of traditional medicines as well as other interested parties.

Comments can be submitted at any time to TMCongressFeedback@pobox.com. Comments can be general or specific.

- For specific comments, please indicate which part of the proposal you are referring to. If there's something you disagree with, please tell us why and whenever possible, please give us your specific recommendations for improvement.
- Please indicate if you can help with communicating with a member of Congress to secure support for this proposal, or raising funds to help implement the proposal.

The deadline for comments is March 31, 2006. The TM Congress will then work with received input to adjust the proposal as needed.

We believe Americans can agree that freedom of choice and public safety are important goals which need not conflict, if good judgment informs consensus. In the case of traditional medicines, people have always gained benefits according to their wisdom and stewardship. We ask that you join us in this unique opportunity to provide for the health and well being of all our fellow citizens.

Traditional Medicines Congress

Guiding Assumptions
November 2005

…remembering the agreed upon Purpose of this Congress: *To benefit public health by ensuring access to traditional medicines in a manner that provides a reasonable expectation of public safety*.

Assumptions re: reasons to act

- There is value in preserving access to a full range of traditional medicines.
- Current regulations in the United States do not adequately assure continued access to and safety of traditional medicines.

Assumptions re: reasons to create a traditional medicine category

- The current definitions of "food" and "drug" under the Federal Food, Drug and Cosmetic Act (FFDCA) do not provide an adequate regulatory category for traditional medicines.
- The Dietary Supplement Health and Education Act (DSHEA) provides a regulatory framework for dietary supplements, which may not be marketed as medicines. Thus, DSHEA does not provide a regulatory framework for traditional medicines.
- A traditional medicine category will preserve access by professionals to traditional medicines that state or federal regulatory agencies have withdrawn, or may withdraw, from the market under current regulatory frameworks.
- A traditional medicine category will support the use of traditional medicines, by both health professionals and consumers.
- A traditional medicine category will ensure the public's access to traditional medicines and to truthful information about them.
- A traditional medicine category will ensure practitioner access to traditional medicines that, for safety reasons, should not be directly accessible to the public.
- Accurate information about traditional uses and indications for traditional medicines will improve public safety.
- Distribution of restricted traditional medicines by qualified professionals will improve public safety.
- A traditional medicine category will provide a contribution to repair the U.S. health care crisis.
- Creation of a traditional medicine category in the U.S. will be harmonious with international models.

Assumptions re: an ideal regulatory model

- Establishment of a new regulatory structure for traditional medicines may require amending the Federal Food, Drug and Cosmetic Act (FFDCA).
- This TM Congress does not intend to propose amendments to the Dietary Supplement Health and Education Act (DSHEA).
- The focus for development of the envisioned ideal regulatory model is limited to the United States.
- Most traditional medicine ingredients and products will remain directly accessible to the public.
- Some traditional medicine ingredients and products will be accessible to practitioners only (and so not accessible to the public without practitioner supervision).
- Many ingredients and products that fall into a new traditional medicine regulatory category will also be able to be marketed as dietary supplements under DSHEA.
- Any regulatory structure must address safety, efficacy and product quality.

Assumptions re: the long-term process

- This may not be a short term process; it may take several years to pass legislation and to implement regulations.
- Additional losses to traditional medicine *materia medica* may be incurred in the time that it takes to create a traditional medicine category.
- Recognizing that professional practice of medicine is regulated at the state level, this TM Congress intends to maintain awareness of the potential impact on all stakeholders at state levels.
- This Congress will subject its work product to significant review by broad communities of interested persons.
- This Congress will invite and welcome significant input from sectors of the industry and professional practitioner communities.
- Some current trends in national politics create a window of opportunity favorable to creation of a traditional medicine category.

Traditional Medicines Congress

DRAFT Key Components
November 2005

…remembering the agreed upon Purpose of this Congress: *To benefit public health by ensuring access to traditional medicines in a manner that provides a reasonable expectation of public safety*.

Key Components of an Ideal Regulatory Model for Traditional Medicines

Section I. Definition of traditional medicines

a. Ingredients in traditional medicines are:
   i. Plants and parts of plants.
   ii. Animals and parts of animals.
   iii. Minerals.
   iv. Traditional preparations of any of the above.
   v. Traditionally prepared concentrations, extracts, oils, or exudates of any of the above.
   vi. Combinations of any of the above that are combined in a manner that is consistent with traditional medicine.

b. Ingredients in traditional medicines are limited to those that are identified in authoritative references, established monographs or recognized compendia, including, but not limited to:
   i. All editions of the *Pharmacopoeia of the People's Republic of China.*
   ii. All editions of the *Pharmacopoeia of the United States* (USP).
   iii. All editions of the *National Formulary.*
   iv. All editions and volumes of the *British Herbal Pharmacopoeia.*
   v. All editions and volumes of the *British Herbal Compendium.*
   vi. All editions and volumes of the *Ayurvedic Pharmacopoeia.*
   vii. All editions and volumes of the *Ayurvedic Formulary of India.*
   viii. Monographs included in the Compendium of Monographs published by Health Canada, Natural Health Products Directorate.
   ix. Monographs included in any volume of the *WHO Monographs on Selected Medicinal Plants*, published by the World Health Organization.
   x. Monographs included in the *Monographs on the Medicinal Uses of Plant Drugs*, published by ESCOP.

xi. Monographs published by the American Herbal Pharmacopoeia.
xii. Other authoritative references, established monographs or recognized compendia identified by the Traditional Medicine Advisory Board.
xiii. Additional ingredients that are approved for use in traditional medicines by the Traditional Medicine Advisory Board.

c. Ingredients in traditional medicines do not include:
   i. Isolated constituents of the ingredients identified in subparagraph (a)(i) of this section, unless such isolated constituents themselves have established traditional use (e.g., menthol).
   ii. Synthetic compounds and substances.
   iii. Any ingredient identified as a controlled substance on any schedule in 21 CFR §1308.
   iv. Species of plants or animals identified in the Appendices of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) except in accordance with the specific requirements for the species listed in those Appendices.

d. The forms in which traditional medicines are used include:
   i. Powders.
   ii. Essential oils.
   iii. Decoctions, distillations, infusions, solutions, and waters
   iv. Fluid extracts, glycerites, honeys, mucilages, oils, oxymels, spirits, tinctures, vinegars, medicated wines, and other extracts in liquid form.
   v. Aperitifs, cordials, elixirs, and syrups.
   vi. Juices of herbal ingredients.
   vii. Solid and semi-solid extracts.
   viii. Powdered extracts and granulations.
   ix. Capsules (hard shell or softgel), perles, pills, and tablets.
   x. Lozenges, pastilles, and troches.
   xi. Snuffs.
   xii. Creams, gels, lotions, ointments, and salves.
   xiii. Compresses, fomentations, liniments, plasters, poultices.
   xiv. Moxabustion.
   xv. Baths and washes.
   xvi. Steam inhalations.
   xvii. Douches and enemas.
   xviii. Suppositories and pessaries.

e. The routes of administration for traditional medicines are:
   i. any of the following for which there is traditional use:

1. Oral ingestion, including by chewing, drinking, swallowing without chewing, spraying, sublingual dissolving, or by any other means of taking into the mouth.
2. Vaginal insertion.
3. Rectal insertion.
4. External application, including application into the eyes, throat, ears or nasal cavities, or onto the skin.

f. Traditional medicines
    i. That are offered for sale to any person for resale
        1. Must either:
            A. Consist of or be prepared from a single traditional medicine ingredient; or
            B. Conform to a traditional formula; or
            C. Be a modified form of a traditional formula, such modification to be in conformity with traditional indications;
        2. And must:
            A. Be labeled with a recommended purpose or use that is consistent with the ingredient's or formula's traditional use.

    ii. That are available through the agency a qualified practitioner
        1. Must either:
            A. Consist of or be prepared from a single traditional medicine ingredient; or
            B. Conform to a traditional formula; or
            C. Be a modified form of a traditional formula, such modification to be in conformity with traditional indications; or
            D. Include or consist of ingredients or formulations that are consistent with the training or expertise of the qualified practitioner.

Section II. Manufacture of traditional medicines

a. Manufacture of traditional medicines is limited to traditional manufacturing practices.
    i. Manufacture of traditional medicines into finished forms is limited to:
        1. Cleaning, dehydration, and milling of ingredients.
        2. Extraction in conformity with subparagraph (ii) of this paragraph.
        3. Manufacturing in forms identified in paragraph (I)(d).
        4. Other traditional processing (e.g., *pao zhi* in traditional Chinese medicine, and including but not limited to: dry-frying; honey-frying; charring; etc).

5. Innovative processing approved by the Traditional Medicine Advisory Board, so long as the end product is consistent with a traditional product.

ii. Processes for manufacture of traditional medicine extracts are limited to:
    1. Decoction and infusion.
    2. Distillation.
    3. Maceration (including digestion) and percolation.
    4. Spray drying and other traditional forms of drying.

b. Solvents that are used in the manufacture of traditional medicines are consistent with traditional practices, and include:
    i. Water or steam.
    ii. Ethanolic liquids, including distilled alcohol from grains, fruits, or other plants materials; wine; or other spirits.
    iii. Vinegars.
    iv. Honey.
    v. Oils, limited to food-grade oils for products that are used internally.
    vi. Glycerin, limited to food-grade glycerin for products that are used internally.
    vii. Natural waxes.
    viii. Mineral spirits, limited to traditional medicines used externally.
    ix. Additional solvents that are approved for use in traditional medicines by the Traditional Medicine Advisory Board.

c. Additional ingredients, other than the traditional medicine ingredients defined in paragraph (I)(a) and the solvents identified in paragraph (b) of this section, may be used as appropriate for technical purposes as ingredients in traditional medicines, including, for example, excipients; emulsifiers; stabilizers; scents; flavors; colors; etc.

d. Manufacturing of traditional medicines specifically excludes:
    i. Traditional ingredients or products that have been chemically altered in a manner that is inconsistent with traditional principles.
    ii. Isolated constituents of traditional medicines or their ingredients, unless such isolated constituents themselves have established traditional use.
    iii. Traditional ingredients that are manipulated in a manner that is inconsistent with traditional practices.

e. Traditional medicines for oral use are produced with appropriate manufacturing practices, as follows:

i. Traditional medicines that are offered for sale to any person for resale are manufactured in accordance with current good manufacturing practice for dietary supplements.
ii. Facilities that prepare traditional medicines that are available only through the agency of a qualified practitioner, including, for example, a practitioner clinic; a compounding pharmacy; or a school, utilize production practices that are appropriate to the individual setting to assure that manufactured products are not adulterated. Such facilities, however, are exempt from any specifically mandated good manufacturing practice regulations.

f. Traditional medicines for non-oral use are produced with appropriate manufacturing practices to assure their safe use.

Section III. Safety of traditional medicines

a. A reasonable expectation of the safety of traditional medicines is determined by:
    i. Historical data and the references and compendia identified in paragraph (I)(b).
    ii. The reasonable expectation of safety for these ingredients established by subparagraph (i) of this paragraph is limited to their use:
        1. For a traditional indication, and
        2. In traditional dosage and for traditional duration of use, and
        3. In a manner that takes into account traditional cautions and contraindications, if any, both for the general population and for specific subpopulations (e.g., children; pregnant women; elderly; etc.).
    iii. New or emerging information that alters the understanding of the safety or use of a traditional medicinal ingredient or its processing, either by indicating that the ingredient is less safe or more safe than formerly understood, is taken into account in assessing the safety of traditional medicines.
    iv. Traditional medicine products that are offered for sale to any person for resale must include on the label any information that is material to the safe use of the product.

b. Use in traditional medicines of ingredients that are recognized as presenting a potential unreasonable risk of significant harm to consumers when used without direct supervision by a qualified health care provider or outside the agency of a qualified practitioner are subject to specified controls, as follows:
    i. Traditional medicines that contain such ingredients are labeled as “For use only under the supervision of a qualified health care provider.”

ii. Traditional medicines that contain such ingredients are not offered for general retail sale to the public, and are so labeled.
iii. Traditional medicines that contain such ingredients without conforming to the above are misbranded.
iv. The Traditional Medicine Advisory Board, as defined in section VII, provides recommendations as to the identity, dose and processing of the ingredients that are subject to this paragraph.

c. Notwithstanding the other paragraphs of this section, traditional medicines that are compounded by a qualified practitioner and are provided directly to persons under that practitioner's care, and are not offered for sale in any other channel of trade, are not subject to the restriction of this section; rather, the compounding practitioner must use only those ingredients which the practitioner can safely use based on training and experience.

Section IV. Claims for traditional medicines

a. Traditional medicines that are offered for sale to any person for resale are required to be labeled with a recommended purpose or use, in accordance with paragraphs I(f)(i)(2) and V(a)(ii)(1). The recommended purpose or use may include:
    i. Claims that a traditional medicine may treat, prevent, or mitigate a disease, disease symptom, or condition.
    ii. Claims that a traditional medicine has been traditionally used to treat, prevent or mitigate a disease, disease symptom or condition; all such claims are stated in conformity with the medical discipline in which the traditional use is established.
    iii. Claims that a traditional medicine affect the structure or function of the body;
    iv. For any claim made in conformity with the above paragraphs:
        1. Claims provided in established monographs or recognized compendia, as defined in paragraph I(b), are considered to be substantiated for traditional medicines that conform to the monograph in all particulars (dosage; form; etc).
        2. For any claim that is not substantiated by one of these identified references, the marketer must have substantiation that the claim is truthful and nonmisleading.
        3. No later than 30 days after the first marketing of a traditional medicine the manufacturer, packer, or distributor of a traditional medicine shall notify the Secretary (HHS) of the purpose or use for which the traditional medicine is recommended.

b. A recommended purpose or use is not required to be provided on the label or labeling of traditional medicines that are available only through the agency of a qualified practitioner.

c. Notwithstanding the requirements in paragraphs (a) and (b) of this section, qualified practitioners may use traditional medicines for any use or purpose that is consistent with their training and scope of practice, whether or not such use or purpose is recommended on the label or labeling of the traditional medicine.

Section V. Labeling / product information of traditional medicines offered for sale for resale

a. The labeling of traditional medicines that are offered for sale to any person for resale includes:
    i. On the label's principal display panel:
        1. The product name.
        2. The dosage form.
        3. The net amount in the immediate container (by weight, volume, or number, as appropriate).
        4. Identity of the product as a traditional medicine.
        5. For products in solid dosage form that consist of a single traditional medicine ingredient, the net quantity in weight of the ingredient per dosage unit.
    ii. Anywhere on the label:
        1. The product's recommended purpose or use, in conformity with section IV; such recommended purpose or use:
            A. Must be a traditional purpose or use; and
            B. Must be stated in a manner that is consistent with traditional indications and in conformity with the medical discipline in which the traditional purpose or use is established.
        2. The recommended dose, including the route of administration.
        3. The recommended duration of use, if any.
        4. A statement that instructs consumers to seek advice from a qualified health care provider if symptoms or conditions persist.
        5. The name and address of the marketer or manufacturer.
        6. A lot number.
        7. A shelf life date.
        8. Recommended storage conditions, if any.
    iii. Anywhere on the label or on accompanying labeling:
        1. The identity of each ingredient, including the medicinal ingredients identified in paragraph I(a), and the other ingredients identified in paragraphs II(b) and II(c).

2. For traditional medicines in a liquid form described in subparagraphs I(d)(iii), I(d)(iv), or I(d)(v):
    A. A ratio where the first number in the ratio represents the dried weight in kilograms of the total of the medicinal ingredients used to produce the liquid product, and the second number represents the volume in liters of the liquid product produced. For example, a 1:4 tincture is one in which 1 kilogram of dried herbs was used to produce 4 liters of tincture. Where fresh rather than dried starting material is used in determining the ratio, this fact must be disclosed.
    B. The proportion of the total amount of the medicinal ingredients used to produce the liquid product that is represented by each of the individual medicinal ingredients, except that if the product is made from only one medicinal ingredient this information is not required.
3. For traditional medicines in any solid dosage form:
    A. For each medicinal ingredient identified in paragraph I(a), the quantity of each ingredient per recommended dose.
    B. For concentrations and extracts identified in subparagraph I(a)(v):
        01. The ratio of concentration or extraction, where the first number in the ratio represents the amount of dried botanical starting material and the second number represents the amount of finished total extract. For example, a 4:1 extract is one in which the extractives of four kilograms (or other unit) of dried botanical starting material are represented in one kilogram (or other unit) of finished total extract. Where fresh rather than dried starting material is used in determining the ratio, this fact must be disclosed.
        02. The proportion of the total amount of the medicinal ingredients used to produce the liquid product that is represented by each of the individual medicinal ingredients, except that if the product is made from only one medicinal ingredient this information is not required.

C. For the ingredients identified in paragraphs II(b) and II(c), a sum of the quantity of those ingredients per recommended dose.

4. For ingredients that are botanicals or are derived from botanicals:
   A. The part of the plant.
   B. The scientific name of the plant in the form of the Latin binomial, in accordance with the rules of current or most recent edition of the International Code of Botanical Nomenclature.
5. For medicinal ingredients identified in I(a)i-iii that are processed, information that adequately defines the resulting processed ingredient (e.g., extract, honey-fried, etc).
6. A statement that provides information that is material to the use of the product, if any, and that includes appropriate cautions, warnings, contraindications and known adverse reactions.

b. Though no specific label or labeling is required for traditional medicines that are sold only through the agency of a qualified practitioner, such practitioner must ensure that all information that is material to the use of the traditional medicine is provided to the product's consumer.

c. Labels for traditional medicines that include botanical ingredients may include, in addition to the Latin binomial names of those ingredients, other names of the botanical ingredients (e.g., common names in any language, or pharmaceutical names).

d. Labels for traditional medicines are not required to provide nutritional information.

Section VI. Adverse event reporting

a. The manufacturer or distributor whose name appears on the label of a traditional medicine that is offered for sale to any person for resale are required to establish and maintain records and promptly report to federal health authorities all serious adverse experiences associated with the use of their product.

b. For purposes of this section, the term "serious adverse experiences" means, "Any adverse experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/ incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be

considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition."

c. The requirements and definitions for this section are based on and are significantly similar to the current federal adverse event reporting system for prescription drugs that are not new drugs. In establishing a federal requirement for submitting reports of serious adverse experiences associated with traditional medicines, this federal requirement is preemptive over state rules such that duplicative requirements may not be set by any states. In addition, regulations provide appropriate protections for marketers of traditional medicine products consistent with current protections for marketers of prescription drugs, as follows:
    i. Submission of an adverse event report shall not constitute admission that there is an actual causal relationship between the report and the product that is the subject of the report;
    ii. In providing any information about the report, for example, under a request filed by any person in conformity with the Freedom of Information Act, no information shall be disclosed that may identify any person associated with the report, including the individual who was the subject of the report; health care providers, hospitals, or emergency personnel involved; or any other person.

Section VII. Advisory body

a. A Traditional Medicine Advisory Board will be established as an expert technical and scientific committee that advises the Secretary (HHS) in discharging its responsibilities as they relate to issues of traditional medicines in any product for which the Food and Drug Administration has regulatory responsibility. The Traditional Medicine Advisory Board will be established:
    i. In conformity with the Federal Advisory Board Act and with the Draft Charter for the Traditional Medicine Advisory Board, incorporated by reference to this document.
    ii. Consisting of the following persons:
        1. Six individuals who are either certified in a traditional medicine practice† by a professional organization or who are licensed to practice a form of traditional medicine. (For purposes of the prior sentence and point 6 of this subparagraph, the term "professional organization" means one which is accredited by the National Commission for Certifying Agencies (NCCA)). Each of these persons will have a minimum of 5 years clinical experience in traditional medicine practice. At least two of these persons will be an acupuncturist with NCCAOM

Herbal Board Certification and at least two of these persons will be a naturopathic doctor who is a graduate of a college accredited by the Council on Naturopathic Medical Education (CNME) and has passed the Naturopathic Physicians Licensing Exam (NPLEX).

2. One individual who is a professional herbalist with a minimum of 5 years clinical experience in traditional medicine practice.
3. One individual with a minimum of 5 years clinical experience as a practitioner of both traditional medicine and of conventional medicine[‡].
4. One individual with dual expertise in traditional medicine and also in pharmacognosy or natural products chemistry or medicinal chemistry.
5. One individual with dual expertise in traditional medicine and also in toxicology or pharmacology.
6. One individual who is certified in a traditional medicine practice by a professional organization and who is also a faculty member or a member of the academic leadership of an institution that is accredited by an agency recognized by the U.S. Department of Education and that provides education and training in a field of traditional medicine. This person will have a minimum of 5 years clinical experience in traditional medicine practice.
7. One individual with expertise in the supply of raw materials used in traditional medicines.
8. Two individuals who own or operate companies that manufacture traditional medicine products.
9. One individual who represents consumers.

[†] The terms “traditional medicine practice” and “practitioner of traditional medicine” refer to the medical practice of an individual who is trained in the traditional knowledge, skills and practices of the medicinal uses and applications of plant, animal and/or mineral substances for the purpose of diagnosis, treatment and prevention of human and/or animal ailments.

[‡] The term “practitioner of conventional medicine” refers to the medical practice of an individual who is a licensed practitioner of any generally established “Western” medical discipline, including, for example, a medical doctor (MD); a doctor of osteopathy (DO); a doctor of chiropractic (DC); a nurse practitioner (NP); a doctor of dental surgery (DDS); a doctor of veterinary medicine (DVM); or other such licensed practitioner.

b. The Traditional Medicine Advisory Board shall advise the Secretary (HHS) on policies to:
    i. Promote the safe and appropriate use of traditional medicines;
    ii. Maintain access and freedom of choice for those using traditional medicines; and
    iii. Enhance public health through the use of traditional medicines.

c. The Secretary (HHS) shall consult with the Traditional Medicine Advisory Board in the development of any programs or the issuance of any guidelines related to:
    i. Identifying additional authoritative references, established monographs, and recognized compendia that should be added to paragraph (I)(b).
    ii. Recommending specific innovative processing or solvents that can be used, in accordance with paragraph (II)(b), in the manufacture of traditional medicines.
    iii. Identifying traditional medicines and ingredients that should be subject to restrictions on sale in accordance with paragraph (III)(b).
    iv. Recommending ways to communicate with the public on the use of traditional medicine.
    v. Making other recommendations in furtherance of traditional medicine, as appropriate.

d. Terms and operations of the Traditional Medicine Advisory Board shall include the following:
    i. Members shall be invited to serve for overlapping four-year terms; terms of more than two years are contingent upon the renewal of the Board by appropriate action prior to its termination. Members may serve after the expiration of their terms until successors have taken office. No member shall serve more than two four year terms. A Chair, Vice-Chair, and Executive Secretary will be selected by members of the Board and will serve in these positions for a period not to exceed two years.
    ii. A majority of the members of the Board shall constitute a quorum. Two-thirds of the votes cast at a meeting of the Board at which a quorum is present shall be decisive of any motion.
    iii. Management and support services shall be provided by the Food and Drug Administration.

e. Meetings of the Traditional Medicine Advisory Board:
    i. Will be held at least twice a year at the call of the chair with the advance approval of the Designated Federal Official (DFO) who shall also approve the agenda. A Government official shall be present at all meetings.

ii. Shall be open to the public except as determined otherwise by the Secretary (HHS) or other official to whom the authority has been delegated; advance notice of all meetings shall be given to the public.
iii. Shall be conducted, and records of the proceedings kept, as required by applicable laws and Department regulations.
iv. The Board shall establish a procedure for securing public input on matters pertinent to its function and responsibilities.

f. Members of the Traditional Medicine Advisory Board shall serve without compensation. While away from their homes or regular places of business on the business of the Board, members of the Board may be allowed travel expenses, including per diem in lieu of subsistence, as is authorized under section 5703 of Title 5 for persons employed intermittently in the Government service.

g. Reports of the Traditional Medicine Advisory Board:
   i. In the event a portion of a meeting is closed to the public, a report shall be prepared which shall contain, at a minimum, a list of members and their business addresses, the committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Office.
   ii. An annual report will be provided to Congress and the Secretary (HHS), summarizing the activities of the Board during the preceding year and providing recommendations.