Food and Drug Administration
Division of Dockets Management
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration	)))	Docket No. 2006D-0480

REQUEST FOR CLARIFICATION AND EXTENSION OF COMMENT PERIOD
(April 26, 2007)

On behalf of TREA Senior Citizens League, the undersigned submits to the Commissioner of Food and Drugs this request for clarification and extension of comment period of the following matter, pursuant to 21 C.F.R. sections 10.35 and 10.40(b)(3).

A. Notice of Proposed Rulemaking Involved

The request relates to the following two documents relating to Docket No. 2006D-0480:

1. Food and Drug Administration "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation" (December 2006) (hereinafter "Draft Guidance"). http://www.fda.gov/cber/gdlns/altmed.htm.

2. Food and Drug Administration Notice of Proposed Rulemaking "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation; Availability," 72 Fed. Reg. 8756-57 (February 27, 2007).

B. Action Requested

1. TREA Senior Citizens League ("TSCL") respectfully requests that the FDA clarify that the current comment period ends on May 29, 2007 (and not on April 30, 2007, as has been previously erroneously communicated by the FDA).

2. TSCL further requests that the FDA extend this comment period until July 31, 2007.

C. Statement of Grounds

TSCL is an organization whose mission is to promote and assist members and supporters, to educate and alert senior citizens about their rights and freedoms as U.S. citizens, and to protect and defend the benefits senior citizens have earned. TSCL has more than 773,000 senior citizen members and supporters, and it has concerns about the "draft guidance" issued by the Food and Drug Administration ("FDA").

TSCL only recently learned of this proposed rulemaking, and seeks this clarification and extension in order to prepare comments on, to inform its members about, and to provide its members with an opportunity to comment on this proposed FDA rulemaking.

1. FDA Has Inconsistently Advised the Public of both an April 30, 2007, and a May 29, 2007 Deadline.

The cover page of FDA's "Draft Guidance" (December 2006) states that the deadline for the comment period is "90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance…." (Cover page attached.) Publication in the Federal Register occurred on February 27, 2007 (copy attached), and 90 days from that date is **May 29, 2007.**

Further, the FDA's docket report posted on its website (copy attached) specifies that the "comment period ends **5/29/07**"(emphasis added). http://www.accessdata.fda.gov/scripts/oc/dockets/comments/getDocketInfo.cfm?EC_DOCUMENT_ID=1451&SORT=&MAXROWS=15&START=1&CID=&AGENCY=FDA.

Nevertheless, inconsistent with this May 29, 2007 deadline, is a date buried in the Federal Register notice stating erroneously that the deadline for the comment period is **April 30, 2007**. 72 *Fed. Reg.* 8756.

Accordingly, the FDA has established a May 29, 2007 date, and the April 30, 2007 date is in error. The FDA has created confusion by including the erroneous April 30, 2007 date in the *Federal Register* notice. TSCL believes that the only way for the FDA to resolve the situation fairly is to advise the public of the error, including a notice in the *Federal Register*, that the correct date of the comment period is May 29, 2007, subject to the request for an extension, set out below.

2. TSCL Members Cannot Feasibly Respond to the Proposed Rulemaking by the May 29 Deadline.

As seniors, many TSCL members are extensive users of complementary and alternative medicine (CAM) and, having experienced the use of CAM, are in a unique position to provide the FDA with information and insight regarding the Draft Guidance. Further, while TSCL

members appreciate the expressed concerns about proliferation and confusion of CAM products and practices, they are equally concerned about their freedom of choice among these products and practices which many have found to be beneficial to their health. However, in order for TSCL to alert its members of the opportunity to submit comments — and to submit comments itself — TSCL and its members need additional time to prepare the comments in an appropriate format because, as indicated above, TSCL only recently learned of the Draft Guidance.

Once TSCL's dissemination of the information regarding the proposed rulemaking is complete, some time will be needed for TSCL and TSCL's members to prepare and submit comments. TSCL submits that it is not feasible for all of this to be accomplished in the days remaining before the current end of the comment period on May 29, 2007.

Further, the April 30, 2007 deadline which has been erroneously circulated has caused great confusion among interested parties, and an extension is thereby warranted as well.

Accordingly, TSCL requests that the comment period be extended to July 31, 2007 so that its members (and others) have the opportunity to provide to the FDA meaningful and substantive comments, which would assist the FDA in its consideration of the Draft Guidance.

Respectfully submitted,

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Guidance for Industry on

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

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CBER) Sheryl Lard-Whiteford at 301-827-0379, (CDER) Daniel Nguyen at 301-827-8971, (CDRH) Ted Stevens at 301-594-1184, or (CFSAN) Wayne Amchin at 301-827-6739.

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

December 2006

Outbreak,'' P06–131, September 14, 2006, available at *http://www.fda.gov/po/indexes/2006news.html*.

4. U.S. Centers for Disease Control and Prevention, ''Update on Multi-State Outbreak of *E. coli* O157:H7 Infections From Fresh Spinach, October 6, 2006, available at *http://www.cdc.gov/ecoli/2006/september/updates/100606.htm*.

5. U.S. Department of Health and Human Services and U.S. Department of Agriculture, ''Dietary Guidelines for Americans 2005,'' January 2005, available at *http://www.healthierus.gov/dietaryguidelines/*.

6. U.S. Food and Drug Administration, ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' October 26, 1998, available at *http://www.cfsan.fda.gov/~dms/prodguid.html*.

7. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Plant and Dairy Foods, ''Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes,'' February 5, 2004, available at *http://www.cfsan.fda.gov/~dms/prodltr.html*.

8. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Plant and Dairy Foods, ''Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce,'' November 4, 2005, available at *http://www.cfsan.fda.gov/~dms/prodltr2.html*.

9. U.S. Food and Drug Administration, ''Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables,'' March 2006, available at *http://www.cfsan.fda.gov/~dms/prodgui2.html*.

10. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, FDA Food Code, 2005, available at *http://www.cfsan.fda.gov/~dms/foodcode.html*.

11. U.S. Food and Drug Administration, ''Produce Safety from Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated With Fresh Produce Consumption,'' October 2004, available at *http://www.cfsan.fda.gov/~dms/prodpla2.html*.

12. Produce Marketing Association and United Fresh Fruit and Vegetable Association, ''Commodity Specific Food Safety Guidelines for the Melon Supply Chain,'' November 7, 2005, available at *http://www.cfsan.fda.gov/~dms/melonsup.html* or *http://www.cfsan.fda.gov/~acrobat/melonsup.pdf*.

13. International Fresh-Cut Produce Association, Produce Marketing Association, United Fresh Fruit and Vegetable Association, Western Growers Association; Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain; April 25, 2006, available at *http://www.cfsan.fda.gov/~dms/lettsup.html* or *http://www.cfsan.fda.gov/~acrobat/lettsup.pdf*.

14. North American Tomato Trade Work Group, ''Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, May 2006, available at *http://www.cfsan.fda.gov/~dms/tomatsup.html* or *http://www.cfsan.fda.gov/~acrobat/tomatsup.pdf*.

Dated: February 21, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. 07–891 Filed 2–23–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0480]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.'' In recent years, the practice of complementary and alternative medicine (CAM) has increased in the United States, and we have seen increased confusion as to whether certain products used in CAM 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, the draft guidance discusses when a CAM product is subject to the act or the PHS Act.

DATES: Submit written or electronic comments on the draft guidance by April 30, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.'' 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.

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 (see Institute of Medicine, *Complementary and Alternative Medicine in the United States*, pages 34 through 35 (2005)).

As the practice of CAM has increased in the United States, we have 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 act or the PHS Act. We have also seen an increase in the number of CAM products imported into the United States. Therefore, the draft guidance discusses when a CAM product is subject to the act or the PHS Act. (When the draft 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.) The draft guidance makes the following 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.
- Second, neither the act nor the PHS Act exempts CAM products from regulation.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the regulation of complementary and alternative medicine products by FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3259 Filed 2–26–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0020]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document; Oxygen Pressure Regulators and Oxygen Conserving Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices.'' The draft guidance document is intended to assist manufacturers in complying with minimum performance, testing, and labeling recommendations that are being proposed for these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify pressure regulators for use with medical oxygen into class II, subject to special controls. The proposal would also establish separate identification classifications for both oxygen pressure regulators and oxygen conserving devices, and would make those oxygen conserving devices that incorporate a built-in oxygen pressure regulator subject to special controls. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by May 29, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 1–800–638–2041. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 101, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christy Foreman, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0120.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides FDA's recommendations to manufacturers for labeling and for determining ignition sensitivity and fault tolerance for oxygen pressure regulators. These devices are intended to convert medical oxygen pressure from a high variable pressure to a lower, more constant working pressure. The device is affixed to a pressurized container of oxygen and the regulator controls the gas flow. These devices are currently regulated as class I devices. However, FDA has received reports of fires and explosions associated with the use of oxygen pressure regulators resulting in serious injury to a number of equipment operators, including one fatality. The draft guidance, if finalized, would serve as the special control for these devices. FDA believes that conformance with the draft special controls guidance, when combined with the general controls of the Federal Food, Drug, and Cosmetic Act (the act), would address the risks associated with oxygen pressure regulators and provide reasonable assurance of their safety and effectiveness.

The draft guidance would also serve as a special control for oxygen conserving devices with a built-in oxygen pressure regulator; a device type already classified into class II under the generic device type noncontinuous ventilator (21 CFR 868.5905). FDA believes that conformance with the draft special controls guidance, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of oxygen conserving devices with a built-in oxygen pressure regulator.

In the **Federal Register** of May 27, 2003 (68 FR 30214), FDA announced its intention to reclassify oxygen pressure regulators in its semi-annual regulatory agenda. FDA received one comment supporting the establishment of a proposed rule to reclassify these devices.

Dockets Open for Comment

If your comments are **NOT** related to a docket listed below, you can submit written comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

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