

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0480]

DDM Immediate Display

Display Date 5-22-07 @ 3:21pm

Publication Date 5-25-07

Certifier N. Hawkins

Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration; Availability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and Drug Administration (FDA, we) is announcing that it will consider comments submitted through May 29, 2007, for a draft guidance for industry entitled "Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration."

Although the comment period for the draft guidance ended on April 30, 2007, we will consider comments submitted through May 29, 2007, due to confusion as to the closing date for comments on the draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance, submit written or electronic comments on the draft guidance by May 29, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration,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

oc07137

2006D-0480

NEC 1

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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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

In the **Federal Register** of February 27, 2007, (72 FR 8756), FDA announced the availability of a draft guidance for industry entitled “Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.”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 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.

The notice announcing the availability of the draft guidance provided a 60-day comment period, so the comment period for the draft guidance was

scheduled to end on April 30, 2007. Unfortunately, due to a typographical error in the draft guidance itself (which stated that the comment period would be 90 days from the date of the notice's publication in the **Federal Register**), we became aware that some members of the public believed that the comment period would or should end on May 28 or May 29, 2007. This confusion was compounded by another error that appeared at one section of FDA's Web site; the error, which appeared at the "Dockets Open for Comment" portion of the Web site where electronic comments are submitted, stated that the comment period would end on May 29, 2007. (In contrast, other sections of FDA's Web site retained the April 30, 2007, date.)

Given the amount of confusion as to the comment period, we are announcing that we will consider all comments on this draft guidance that are submitted through May 29, 2007. Previously submitted comments do not need to be resubmitted.

Additionally, we are aware of considerable confusion about the content of the draft guidance, which has been widely misinterpreted. Therefore, we want consumers and CAM practitioners to understand that the draft guidance does *not* contain or propose any new regulatory requirements for any complementary and alternative medicine CAM product marketed in the United States and does *not* affect any state licensing requirements for any CAM practitioner or any consumer's ability to buy or receive a CAM product or be treated by any CAM practitioner.

Public concern based on misinterpretations of the draft guidance has generated a large volume of comments to the docket. The large volume of comments has impeded our ability to identify and respond to extension

requests. Consequently, we are addressing those unanswered extension requests by considering comments submitted through May 29, 2007.

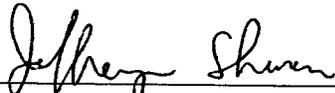
II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. 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 draft guidance at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: MAY 22 2007
May 22, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

