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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 101

[Docket No. 00N-0506]

Safety Issues Associated With Dietary Supplement Use During Pregnancy; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on safety issues associated with dietary supplement use during pregnancy. The purpose of this meeting is to obtain public comment on safety concerns that have been raised regarding structure/function claims for dietary supplements used during pregnancy. On January 6, 2000, FDA published a final rule on statements that may be made for dietary supplements concerning the effect of the product on the structure or function of the body. FDA has since received comments from public health professionals and others concerned about the safety of using dietary supplements during pregnancy. The public meeting is intended to give the public an opportunity to comment on these issues.

DATES: The meeting will be held on March 30, 2000, from 9 a.m. to 5 p.m. Submit written comments by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: The public meeting will be held in the Crystal Ballroom at the Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877. Submit written comments to the Dockets Management Branch (DMB) (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that

individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane (HFD-6), Rockville, MD 20857, 301-594-5468, FAX 301-594-5493, e-mail: sfp15reg@cder.fda.gov.

See **SUPPLEMENTARY INFORMATION** for electronic access addresses.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this announcement for a public meeting on safety issues associated with dietary supplement use during pregnancy apply to me?

This announcement is directed to the general public. It may, however, be of particular interest to individuals or organizations concerned with public health, pregnancy, or dietary supplements. Specific groups that may want to attend include: Consumers; public health professionals, including obstetricians, gynecologists, neonatologists, pediatricians, and pediatric and obstetric nurses; dietary supplement producers, processors, distributors, and retailers; academia; and State, Tribal, and local public health agencies. Other entities or individuals may also be interested in attending.

B. Where will this meeting be held?

This meeting will be held in the Crystal Ballroom at the Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

C. When will this meeting be held?

This meeting will be held on March 30, 2000, from 9 a.m. to 5 p.m.

D. How can I participate?

1. In person. Anyone interested in dietary supplement use during pregnancy is encouraged to attend the public meeting. Persons who wish to speak during the public meeting must file an

electronic, written, or facsimile notice of participation with Rose Cunningham by March 17, 2000. To ensure timely handling, the outer envelope or facsimile cover sheet should be clearly marked with Docket No. 00N-0506. Groups should submit two copies. The notice of participation should contain the speaker's name, address, telephone number, FAX number, title, business affiliation, if any, a brief summary of the presentation, and approximate amount of time requested for the presentation. The notice of participation form is available on the Internet and can be e-mailed to sfp15reg@cder.fda.gov or printed and faxed to 301-594-5493.

Individuals and organizations with common interests are encouraged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA may require joint presentations by persons with common interests. Participants may request a specific amount of time for their presentation. After registration has closed, FDA will inform participants of the amount of time available for their presentation.

Persons requiring a sign language interpreter or other special accommodations should notify Rose Cunningham at 301-594-5468 by March 21, 2000.

2. In writing. FDA has established a public docket for comments. Comments should be submitted by [*insert date 60 days after date of publication in the Federal Register*]. It is important that comments submitted to the docket are identified with Docket No. 00N-0506. Submit written comments to DMB (address above).

E. Is there a registration fee for this meeting?

There is no registration fee for this meeting.

F. How can I get additional information, including copies of this document or other related documents?

1. Electronically. You may obtain electronic copies of this document and other related documents on the Internet at <http://www.fda.gov/ohrms/dockets/default.htm>. The notice of participation form, information about the meeting, and other related documents are available at

<http://www.fda.gov/cder/calendar/meeting/pregsup2000/default.htm>. Additional information regarding dietary supplements is available at <http://vm.cfsan.fda.gov/dms/supplmnt.html>.

2. By phone. If you have any questions about the public meeting, please consult the person listed under “**FOR FURTHER INFORMATION CONTACT.**”

G. Can I get a transcript of this meeting?

A transcript of the public meeting will be available from DMB (address above), approximately 15 business days after the meeting at a cost of 10 cents per page. The transcript of the public meeting will also be available for public examination at the office above between the hours of 9 a.m. and 4 p.m., Monday through Friday.

II. Background Information

A. Why is FDA holding this meeting?

FDA is holding this meeting in response to comments it received after publishing a final rule regarding claims that may be made for dietary supplements concerning the effect of the product on the structure or function of the body (65 FR 1000, January 6, 2000).

In that final rule, FDA announced that it would not treat as diseases common conditions associated with natural states or processes that do not cause significant or permanent harm and that claims about beneficial effects on such conditions would not be treated as disease claims. In the preamble to the final rule, FDA noted that pregnancy is associated with common and mild conditions such as morning sickness and leg edema that cause no permanent harm if left untreated, as well as with such serious conditions as hyperemesis gravidarum, toxemia of pregnancy, and acute psychosis of pregnancy, which can be life-threatening if not effectively treated. FDA stated that claims about common, mild conditions related to pregnancy such as morning sickness and leg edema would be considered structure/function claims. FDA also noted that claims to treat some conditions related to pregnancy would remain disease claims that could not be made without prior

review, for example, toxemia of pregnancy, hyperemesis gravidarum, and acute psychosis of pregnancy.

After FDA published the final rule, it received additional comments raising safety concerns about dietary supplement use during pregnancy. As a result, on February 9, 2000, FDA issued a statement concerning the structure/function rule and pregnancy claims. That statement said:

To ensure that careful consideration is given to concerns recently raised regarding how the structure/function rule relates to pregnancy, FDA today is advising dietary supplement manufacturers not to make any claims related to pregnancy on their products based on the agency's recently issued structure/function rule. FDA will issue a **Federal Register** Notice shortly describing these concerns in more detail, stating the agency's intention to fully review these concerns, hold a public meeting related to potential pregnancy related safety concerns, and then issue further guidance. FDA urges all pregnant women to consult their health care provider before taking any dietary supplements or medications.

FDA is issuing this **Federal Register** notice in accordance with that statement.

B. What concerns have been raised to FDA in recent letters?

FDA has received three letters from medical doctors, one letter from a law professor, and one letter from a citizen's group. Several newspapers have also run articles regarding the marketing of dietary supplements to pregnant women. All the incoming letters indicate opposition to classifying "ordinary morning sickness" and "leg edema associated with pregnancy" as non-diseases and express concern that use of dietary supplements during pregnancy may adversely affect the fetus. They strongly urge revising the rule so it does not allow these claims to be made in the absence of evidence of fetal safety. Several letters argue that FDA should treat as disease claims all conditions associated with pregnancy. In addition, similar safety concerns were raised about the safety of dietary supplement use in other vulnerable populations such as infants, who may be exposed thru nursing and children.

C. On what issues does FDA seek comment?

The Dietary Supplement Health and Education Act (DSHEA) allows manufacturers of dietary supplements to claim effects on the “structure or function” of the body, but not to make claims to mitigate, treat, prevent, cure, or diagnose disease (21 U.S.C. 343(r)(6)). The structure/function rule focuses on the distinction between disease claims, which require evidence of safety and efficacy to be presented to the agency before marketing, and structure/function claims. In contrast, the comments received by the agency focus primarily on the safety issues that may result from the use of dietary supplements during pregnancy. The purpose of this meeting is to obtain public comment on safety concerns that have been raised regarding structure/function claims for dietary supplements used during pregnancy. Although FDA welcomes comments on all of the issues discussed in the letters mentioned previously and on all aspects of dietary supplement use during pregnancy, FDA specifically seeks comment on the following points.

1. What are the potential hazards that may be associated with use of dietary supplements for conditions associated with pregnancy, both to the pregnant woman and the fetus? Should these hazards be considered to be different than hazards to other potential users of dietary supplements? If so, why and on what basis under DSHEA?
2. Are there certain conditions associated with pregnancy (in addition to those already identified in the final rule) for which structure/function claims should not be permitted? If so, why and on what basis?
3. What is the potential for harm that may be associated with the use of dietary supplements during pregnancy for conditions unrelated to pregnancy?
4. Are there means to address safety concerns associated with dietary supplement use during pregnancy, for example, a requirement to conduct animal studies or collect human safety information?

5. Should dietary supplements with a specific recommended use during pregnancy be required to bear specific warnings about use during pregnancy? Should all dietary supplements be required to bear such warnings?

FDA will post any additional questions to be addressed on the Internet at <http://www.fda.gov/cder/calendar/meeting/pregsup2000/default.htm>.

Dated: February 16, 2000

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
Jen Williams

William K. Hubbard

William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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