The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 of FAA Order 7400.9G, *Airspace Designations and Reporting Points*, dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be revised and published subsequently in the Order.

The FAA has determined that these proposed regulations only involve an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9G, *Airspace Designations and Reporting Points*, dated September 1, 1999, and effective September 16, 1999, is to be amended as follows:

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Yukon-Kuskokwim Delta, AK [New]

That airspace extending upward from 1,200 feet above the surface within the area bounded by lat. 58°25′36″ N long. 158°00′ W, to lat. 57°50′ N. long. 158° 00′ W, to lat. 57°50′ N long. 156°00′ W, to lat. 64°00′ N long. 156°00′ W, to lat. 64°00′ N long. 161°41′24″ W, then via the 12 nautical mile limit to the point of beginning.

* * * * *

Issued in Anchorage, AK, on February 9, 2000.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 00–3699 Filed 2–23–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 April 24, 2000, from 9 a.m. to 5 p.m. Submit written comments by April 24, 2000.

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 April 24, 2000. 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.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–4276 Filed 2–18–00; 10:05 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

RIN 1010–AC66

Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Update of International Organization for Standardization Documents Incorporated by Reference

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: The MMS is proposing to remove API Specification 14A and replace it with a new document incorporated by reference in regulations governing oil and gas and sulphur operations in the Outer Continental Shelf (OCS). The addition of this document incorporated by reference will ensure that lessees use the best available and safest technologies while operating in the OCS. The proposed new document has been issued by the International Organization for Standardization (ISO) and is an international standard titled: ''Petroleum and natural gas industries—Downhole equipment—Subsurface safety valve equipment'' (ISO 10432:1999, otherwise known as API/ISO 10432:1999).

DATES: We will consider all comments we receive by May 24, 2000. We will begin reviewing comments then and may not fully consider comments we receive after May 24, 2000.

ADDRESSES: Mail or hand-carry comments (three copies) to the Department of the Interior; Minerals Management Service; Mail Stop 4024; 381 Elden Street; Herndon, Virginia 20170–4817; Attention: Rules Processing Team. The Rules Processing Team' e-mail address is: rules.comments@mms.gov.

FOR FURTHER INFORMATION CONTACT: Fred Gray, Operations Analysis Branch, at (703) 787–1027.

SUPPLEMENTARY INFORMATION: We use standards, specifications, and recommended practices developed by standard-setting organizations and the oil and gas industry for establishing requirements for activities in the OCS. This practice, known as incorporation by reference, allows us to incorporate the provisions of technical standards into the regulations without increasing the volume of the Code of Federal Regulations (CFR). The legal effect of incorporation by reference is that the material is treated as if it was published in the **Federal Register**. This material, like any other properly issued regulation, then has the force and effect of law. We hold operators/lessees accountable for complying with the documents incorporated by reference in our regulations. We currently incorporate by reference 85 private sector consensus standards into the offshore operating regulations.

The regulations found at 1 CFR part 51 govern how we and other Federal agencies incorporate various documents by reference. Agencies can only incorporate by reference through publication in the **Federal Register**. Agencies must also gain approval from the Director of the Federal Register for each publication incorporated by reference. Incorporation by reference of a document or publication is limited to the specific edition or specific edition and supplement or addendum cited in the regulations.

ISO is a worldwide federation of national standards bodies (ISO member bodies). Founded in the mid 1940s, ISO is a non-profit agency based in Geneva, Switzerland, whose purpose is to promote the development of international standards and related activities to facilitate the global exchange of goods and services. The American National Standards Institute (ANSI) is the official United States member body to ISO.

The work of preparing international standards is normally carried out through an ISO technical committee (TC). Each member body interested in a subject for which a TC has been established has the right to be represented on that committee. ANSI relies on various United States trade and industry associations, such as the American Petroleum Institute (API), for support on industry specific standards. This standard was developed by ISO/TC 67, ''Materials, equipment and offshore structures for petroleum and natural gas industries.'' API has been appointed by ANSI to administer the U.S. ISO/TC 67 delegation, known as the U.S. Technical Advisory Group (U.S.TAG). MMS has been an active participant in the U.S. TAG since August 1998.

This second edition of the international standard cancels and replaces the first edition (ISO 10432:1993) and includes the changes in the similar API standard, API Specification 14A, Ninth edition, 1994, and its supplement dated December 15, 1997. ISO 10432:1999 was released as a Final Draft International Standard (FDIS) on June 3, 1999. Voting to advance the FDIS to a full international standard occurred on August 3, 1999, and the standard was published as an international standard in November 1999.

This standard was formulated to provide the minimum acceptable requirements for subsurface safety valve (SSSV) equipment—the SSSV is a downhole safety device used to shut off flow of hydrocarbons in the event of an emergency. MMS views this important piece of equipment as the last line of defense in securing the well and/or preventing pollution of the environment. The standard covers SSSVs, safety valve locks, safety valve landing nipples, and all components that establish tolerances and/or clearances that may affect performance or interchangeability of the SSSV equipment.

We have reviewed this document and have determined that the new edition should be incorporated into the regulations to ensure the use of the best and safest technologies. We currently incorporate by reference the ninth edition (July 1994) of API Specification 14A, without Supplement 1. Until now we have not included API Specification 14A, Supplement 1, in the documents incorporated by reference in our regulations. API Specification 14A, Supplement 1, includes editorial corrections, changes, and revisions approved by the API Subcommittee on Valves and Wellhead Equipment. The revisions strengthened guidelines for