Respiratory Viral Diseases, Division of Viral Products, Office of Vaccines Research and Review, CBER, and in closed session will discuss the reports from the laboratory site visits of December 6, 2005, January 11, 2006, and June 29, 2006.

Procedure: On November 16, 2006, from 1 p.m. to 3:55 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 9, 2006. Oral presentations from the public will be scheduled between approximately 2:55 p.m. to 3:55 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 2006 and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 16, 2006 from 3:55 p.m. to 5 p.m. the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss a review of internal research programs in the Office of Vaccines Research and Review, Division of Viral Products and Division of Bacterial Parasitic and Allergenic Products, Center for Biologics Evaluation and Research.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 26, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–18314 Filed 10–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0363]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device.'' The draft guidance describes a means by which the absorbable hemostatic device may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify the absorbable hemostatic device from class III (premarket approval) into class II (special controls). This draft guidance is not final, nor is it being implemented at this time.

DATES: Submit written or electronic comments on this draft guidance by January 29, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device'' 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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141.

SUPPLEMENTARY INFORMATION:

I. Background

Absorbable hemostatic devices are primarily applied during surgical procedures in order to control bleeding that is not readily controlled via conventional means, such as cautery or ligation. At other times, an absorbable hemostatic device may be applied due to the inaccessibility of a site to conventional hemostatic methods.

On July 24, 2003, the General and Plastic Surgery Devices Panel considered the types of information the agency should include in a class II special controls guidance document for the absorbable hemostatic device and recommended that the device be reclassified from class III into class II. FDA considered the Panel's recommendations, and elsewhere in this issue of the **Federal Register**, is proposing to reclassify the absorbable hemostatic device into class II. If this reclassification rule is finalized, FDA intends that this guidance document will serve as the special control for this device.

Following the effective date of any final reclassification rule based on this proposal, any firm submitting a premarket notification (510(k)) for an absorbable hemostatic device would need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

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 absorbable hemostatic device. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive the draft guidance document entitled ''Class II Special Controls Document: Absorbable Hemostatic Device,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document, or send a fax request to 240–276–3151 to receive a hard copy. Please use the

document number 1558 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to the review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. 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.

Dated: October 19, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–18318 Filed 10–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Cross-Site Assessment of the Residential Treatment for Pregnant and Postpartum Women (PPW) and Their Children Program—(OMB No. 0930–0269)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), is funding additional Services Grants for Residential Treatment for Pregnant and Postpartum Women (PPW). The purpose of the PPW is to expand the availability of comprehensive, high quality residential treatment services for pregnant and postpartum women who suffer from alcohol and other drug use problems, and for their infants and children impacted by the perinatal and environmental effects of maternal substance use and abuse.

Section 508 [290bb–1] of the Public Health Service Act mandates the evaluation and dissemination of findings of residential treatment programs for pregnant and postpartum women. This cross-site accountability assessment will assess project activities implemented for these services.

The grantees were brought to consensus surrounding an evaluation design and methods of data collection with accompanying instruments, via the work of the project officer and consultant experts in the field. The data collection instruments will be used for program and treatment planning, local evaluations, and for this cross-site accountability evaluation. For mothers, administration of data collection instruments will occur at intake, 6 months post-intake, discharge, and 4 months post-discharge.[1] The following four different interview instruments will be used for mothers:

1. Child Data Collection Tool, Part 1 (child's personal background) and Part 2 (child's medical background);
2. Ferrans and Powers Quality of Life Index© Generic Version—III;
3. BASIS–24® (pilot study used BASIS–32®)—behavioral health assessment; and
4. Allen Barriers to Treatment Instrument.

For all children under 18 years, program staff will collect information from observation, interview, and records review. For infants and children, data collection will occur at a time within 30 days of the mother's intake or the child's birth, 3 months post-intake/birth, 6 months post-intake/birth, discharge, and 4 months post-discharge.[1] Children's data collection tools include the following:

1. Child Well-Being Scales (staff observation and records review for all children);
2. Denver Developmental Screening Inventory II (ages 0 to 6 years, 0 days);
3. Middle Childhood Developmental Assessment Guide (ages 6 to 10);
4. Adolescent Childhood Development Assessment Guide (ages 11 to 17); and
5. CRAFFT substance abuse screening instrument (ages 11–17).

In addition, records review will be conducted by program staff on all program participants. First, at each data collection period except for 4 months post-discharge, staff will complete the Women's Medical Record Audit and the Child's Medical Record Audit (or the Newborn's Medical Record Audit at delivery.) Second, staff will complete the Women's Discharge Tool and the Children's Discharge Tool at discharge.

[1] The 4 month post-discharge administration replaces the 12-month post-admission administration approved by OMB for the pilot study. This modification was made because it is believed that post-discharge followup information will be more informative and will have more cases than 12 months post-admission.