

BPD reports FDA received in fiscal year 2005. The rate of submission is not expected to change significantly in the next few years. Based on information from industry, the estimated average time to complete a deviation report is 2 hours. The availability of the standardized report form, Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER is developing an addendum to Form FDA 3486. The web-based addendum (Form FDA 3486A) would request additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested would include information not contained in

the Form FDA 3486 such as: (1) Distribution pattern, (2) method of consignee notification, (3) consignee(s) of products for further manufacture, (4) additional product information, and (5) updated product disposition. This information would be requested by CBER through e-mail notification to the submitter of the BPD report. This information would be used by CBER for purposes of recall classification. We plan to use Form FDA 3486A for only biological products regulated by CBER. We do not plan to use this form for biological products regulated by CDER because they receive very few BPD reports and do not accept electronic filings. CBER estimates that 5 percent of the total BPD reports submitted to CBER would need additional information submitted in the addendum. CBER

estimates it would take between 15 to 45 minutes to complete the addendum. For calculation purposes, CBER is using one-half hour.

Activities such as investigating, changing standard operating procedures or processes, and followup are currently required under 21 CFR parts 211 (approved under OMB control no. 0910-0139, expires September 30, 2008), 606 (approved under OMB control no. 0910-0116, expires December 31, 2008), and 820 (approved under OMB control no. 0910-0073, expires September 30, 2007) and, therefore, are not included in the burden calculation for the separate requirement of submitting a BPD report to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | FDA Form Number | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Responses | Total Hours |
|----------------------|--------------------|--------------------|-------------------------------|------------------------|---------------------|-------------|
| 600.14 | 3486 | 147 | 2.73 | 401 | 2.0 | 802 |
| 606.171 ² | 3486 | 194 | 169.89 | 32,958 | 2.0 | 65,916 |
| 606.171 ³ | 3486 | 6,210 | 1.50 | 9,311 | 2.0 | 18,622 |
| | 3486A ⁴ | 6,551 | 0.33 | 2,133 | 0.5 | 1,067 |
| Total | | | | | | 86,407 |

¹ There are no capital costs or maintenance costs associated with this collection of information.

² Licensed manufacturers of human blood and blood components, including Source Plasma.

³ Unlicensed registered blood establishments and transfusion services (1,230 + 4,980 = 6,210).

⁴ Five percent of the total annual responses to CBER (42,653 x 0.05 = 2,133).

Dated: October 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee

General Function of the Committee:

To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held via teleconference on November 16, 2006 from 1 p.m. to 5 p.m.

Location: NIH campus, Food and Drug Administration Bldg. 29B, Conference Room C, 8800 Rockville Pike, Bethesda, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the above location. A speakerphone will be provided at the specified location for public participation in this meeting. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the internet at <http://www.nih.gov/about/visitor/index.htm>. Visitors must show two forms of identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Drive entrance of the campus

which is located on Wisconsin Ave. (the medical center metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at <http://www.nih.gov/about/visitorssecurity.htm>. Due to the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314 or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear an overview on the operations of the Laboratory of Bacterial Toxins, Division of Bacterial, Parasitic, and Allergenic Products; and the Laboratory of Vector Borne Virus Diseases, the Laboratory of Hepatitis Viruses, and the Laboratory of

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.

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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