§ 606.110(b), licensed establishments submit supplements to their biologics license applications to request prior CBER approval of plasmapheresis donors who do not meet donor requirements. The information collection requirements for § 606.110(b) are reported under OMB control number 0910–0338. In table 2 of this document, the recordkeeping chart reflects the estimate that 95 percent of the recordkeepers, which collect 98 percent of the blood supply, had developed SOPs as part of their customary and usual business practice. Establishments may minimize burdens associated with CGMP and related regulations by using model SOPs developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 606.170(b)[2] | 70 | 1 | 70 | 20 | 1,400 |
| 610.46(a) | 1,041 | 20 | 21,000 | 0.17 | 3,570 |
| 610.46(b) | 1,041 | 20 | 21,000 | 0.17 | 3,570 |
| 610.47(b) | 166 | 0.7 | 116 | 1 | 116 |
| Total | | | | | 8,656 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Record-keepers | Annual Frequency per Record-keeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 606.100(b)[2] | 249[5] | 1 | 249 | 24 | 5,976 |
| 606.100(c) | 249[5] | 10 | 2,490 | 1 | 2,490 |
| 606.110(a)[3] | 67[6] | 5 | 335 | 0.5 | 168 |
| 606.151(e) | 249[5] | 12 | 2,988 | 0.083 | 248 |
| 606.160[4] | 249[5] | 2,169 | 540,000 | 0.5 | 270,000 |
| 606.165 | 249[5] | 2,169 | 540,000 | 0.083 | 44,820 |
| 606.170(a) | 249[5] | 12 | 2,988 | 1 | 2,988 |
| Total | | | | | 326,690 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOPs, are included in the estimate for § 606.100(b).
[3] The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).
[4] The recordkeeping requirements in §§ 640.3(a)(2); 640.3(f); 640.4(a)(2); 640.25(b)(4) and (c)(1); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (d); 640.61; 640.63(b)(3), (e)(1), and (e)(3); 640.65(b)(2); 640.71(b)(1); 640.72; and 640.76(a) and (b); which address the maintenance of various records, are included in the estimate for § 606.160.
[5] 5 percent of CMS and FDA-registered blood establishments (0.05 x 4,890).
[6] 5 percent of pheresis establishments (1,349).

Dated: October 1, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–25539 Filed 10–7–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Biological Response Modifiers Advisory Committee; Amendment of Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Biological Response Modifiers Advisory Committee. This meeting was originally announced in the **Federal Register** of September 27, 2002 (67 FR 61142). The amendment is being made to reflect a change in the *Date and Time, Agenda, Procedure, Location, and Closed Committee Deliberations* portions of the meeting. The meeting was originally scheduled as a teleconference on October 10, 2002, from 5:30 p.m. to 7:30 p.m. at the National Institutes of Health, Bldg. 29C, 29 Lincoln Dr., Bethesda, MD. FDA added a discussion topic related to

retrovirus vectors in gene therapies for the treatment of patients with severe combined immune deficiency disease to the meeting and the meeting will be held on October 10 at the Hilton DC North—Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD from 8 a.m. to 5 p.m.

**FOR FURTHER INFORMATION CONTACT:** Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314 or call the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 27, 2002 (67 FR 61142), FDA announced that a meeting of the Biological Response Modifiers Advisory Committee would be held on October 10, 2002. This amendment is to update information provided earlier pertaining to the meeting. On page 61142, beginning in the last column, the *Date and Time, Location, Agenda, Procedure, and Closed Committee Deliberations* portions of the meeting are amended to read as follows:

*Date and Time*: The meeting will be held on October 10, 2002, from 8 a.m. to approximately 5:30 p.m.

*Location*: Hilton DC North—Gaithersburg, Grand Ballrooms A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

*Agenda*: On October 10, 2002, the committee will discuss safety issues recently identified related to retrovirus vectors in gene therapies for the treatment of patients with severe combined immune deficiency disease and receive updates on individual research programs in the Division of Cell and Gene Therapies and the Division of Therapeutic Proteins.

*Procedure*: On October 10, 2002, from 8 a.m. to 5 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 October 9. Oral presentations from the public will be scheduled between approximately 11:30 a.m. to 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 9, 2002, 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 Deliberatons*: On October 10, 2002, between approximately 5 p.m. and 5:30 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 reports of individual research programs in the Center for Biologics Evaluation and Research.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 2, 2002.

**Linda Arey Skladany,**

*Senior Associate Commissioner for External Relations.*

[FR Doc. 02–25641 Filed 10–3–02; 3:17 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

*Drug Abuse Warning Network (OMB number 0930–0078, revision*—The Drug Abuse Warning Network (DAWN) is an on-going data system that currently collects information on drug abuse-related medical emergencies and deaths as reported from about 466 hospitals and 137 medical examiners/coroners (ME/C) nationwide. DAWN provides national and metropolitan estimated of substances involved with drug-related ED visits; disseminates information about substances involved in deaths investigated by participating ME/Cs; provides a means for monitoring drug abuse patterns, trends, and the emergence of new substances; assesses health hazards associated with drug use; and generates information for national and local drug abuse policy and program planning. DAWN data are used by Federal, State, and local agencies, as well as universities, pharmaceutical companies, and the press.

The current emergency department (ED) sample supports estimates for the coterminous U.S. and 21 major metropolitan areas. Beginning in 2003, the DAWN case definition will be changed to obtain more consistent and reliable data on drug abuse cases and also will capture additional cases where drug use/misuse led to ED visits or deaths for conditions such as adverse drug reactions, underage drinking and malicious poisonings. To achieve better geographic and population coverage, the ED sample will be expanded to support estimates for the full U.S. and 48 metropolitan areas. By the end of 2005, the sample will include approximately 841 hospitals. To achieve complete coverage, approximately 66 non-participating ME/C jurisdictions in the 48 metropolitan areas targeted for the ED expansion will be added in lieu of a sample. Facilities (EDs and ME/Cs) will continue to use the current forms in early 2003 to complete reporting on events occurring through December 2002, but will use the revised forms for all events occurring from 1/1/2003 forward.

TOTAL REPORTING BURDEN FOR DAWN: CLOSEOUT 2002 [1]

| | Number of respondent facilities | Estimated number of responses per respondent | Estimated time per response | Gross burden hours | IR[2] reporting hours | Total adjusted burden hours |
|---|---|---|---|---|---|---|
| **EMERGENCY DEPARTMENTS** | | | | | | |
| Current Forms | 166 | 36 | 9 min. | 896 | 448 | 448 |
| Current eHERS [3] | 300 | 36 | 9min (.15 hr) | 1,620 | 810 | 810 |