collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Biological Products: Reporting of Biological Product Deviations in Manufacturing (OMB Control Number 0910–0458)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be licensed and meet standards designed to ensure the continued safety, purity, and potency of such products. In addition, the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with Current Good Manufacturing Practice (CGMP) assuring that they meet the requirements of the act. All establishments manufacturing human blood and blood components are required to register with FDA, and comply with the CGMP regulations for human blood and blood components (parts 211 and 606 (21 CFR parts 211 and 606)). Transfusion services are required under 42 CFR 493.1273(a) to comply with part 606 and 21 CFR 640 as they pertain to the performance of manufacturing activities. FDA regards biological product deviation reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

Section 600.14 (21 CFR 600.14) requires the licensed manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over the product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171 requires a licensed manufacturer of human blood and blood components, including Source Plasma; an unlicensed registered blood establishment; or a transfusion service who had control over the product when the deviation occurred, to report to CBER as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred.

Respondents to this collection of information are the licensed manufacturers of biological products other than human blood and blood components, unlicensed registered blood establishments, and transfusion services. Based on information from CBER's databases for fiscal year (FY) 2002, the agency estimates that 115 licensed manufacturers of biological products other than human blood and blood components submitted 476 error and accident reports under § 600.14. FDA also estimates 207 licensed manufacturers of human blood and blood components, including Source Plasma, submitted 27,000 error and accident reports under § 606.171. In addition, FDA estimates 2,800 unlicensed registered blood establishments and 3,221 transfusion services submitted a total of 6,446 error and accident reports. The number of total annual responses is based on the number of biological product deviation reports CBER received in FY 2002. 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 FDA Form 3486, and the ability to submit this report electronically further streamlines the report submission process. Activities such as investigating, changing SOP's or processes, and follow-up are currently required under parts 211 (approved under OMB control numbers 0910–0139 and 0910–0353), 606 (approved under OMB control number 0910–0116), and 21 CFR part 820 (approved under OMB control number 0910–0073) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

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

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
600.14	3486	115	4.1	476	2	952
606.171[2]	3486	207	130.4	27,000	2	54,000
606.171[3]	3486	6,021	1.1	6,446	2	12,892
Total	3486	6,343		33,922		67,844

[1] There are no capital costs or operating and 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 (2,800+3,221=6,021).

Dated: June 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16495 Filed 6–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management 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). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management 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 on September 18, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, e-mail at: topperk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting. Background materials for this meeting, when available, will be posted on the Web one business day before the meeting at: www.fda.gov/ohrms/dockets/ac/acmenu.htm.

Agenda: The committee will discuss medication errors relating to the labeling and packaging of various drug products in low-density polyethylene plastic vials.

Procedure: 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 September 12, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 12, 2003, 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.

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 Kimberly Topper 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: June 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16358 Filed 6–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs 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). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs 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 on July 15, 2003, from 8 a.m. to 4:30 p.m.

Location: Center for Drug Evaluation and Research (CDER) Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Thomas H. Perez, CDER (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6758, e-mail: *PerezT@cder.fda.gov*, or the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting. Background materials for this meeting, when available, will be posted on FDA's Web site 1-business day before the meeting at *www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

Agenda: The subcommittee will discuss the following topics: (1) Pharmacogenetic testing for thiopurine methyltransferase deficiency in patients for whom treatment with 6-mercaptopurine is being considered; and (2) overcoming challenges in pediatric oncology product development: regulatory oversight of multinational clinical studies.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by July 7, 2003. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. and 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 7, 2003, 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.

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 notify Thomas Perez 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: June 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16359 Filed 6–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995: