Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Kathy Cahill, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE., M/S/ D–24, Atlanta, Georgia 30333. Telephone 404/639–7060.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 28, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–25710 Filed 10–5–00; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC): Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Healthcare Infection Control Practices Advisory Committee (Formerly Hospital Infection Control Practices Advisory Committee).

Times and Dates: 8:30 a.m.–5 p.m., November 6, 2000; 8:30 a.m.–4 p.m., November 7, 2000.

Place: Atlanta Marriott Century Center, 2000 Century Boulevard, NE, Atlanta, Georgia 30345.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Infectious Diseases (NCID), regarding (1) the practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (*e.g.,* nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare associated infections and healthcare-related conditions.

Matters to be Discussed: Agenda items will include a review of proposed revisions to the Guideline for Prevention of Healthcare-associated Pneumonia, the Guideline for Isolation Precautions in Hospitals, the Guideline for Prevention of Intravascular Device-related Infections, the Guideline for Sterilization and Disinfection, the Guideline for Hand Hygiene, and the Guideline for Environmental Controls in Healthcare Settings; a discussion of the status of Staphylococcus aureus with Reduced Susceptibility to Vancomycin (VISA) in the United States; and updates on CDC activities of interest to the committee, including nosocomial tuberculosis control, the Federal Action Plan for Antimicrobial Resistance, and bioterrorism response in healthcare facilities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michele L. Pearson, M.D., Executive Secretary, HICPAC, Hospital Infections Program, NCID, CDC, 1600 Clifton Road, NE, M/S A–07, Atlanta, Georgia 30333, telephone 404/639–6439.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 28, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–25685 Filed 10–5–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interagency Committee on Smoking and Health: Meeting

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Interagency Committee on Smoking and Health.

Date and Time: 9 a.m.–1 p.m. October 26, 2000.

Place: Secretary's Conference Room (Stonehenge) Hubert H. Humphrey Building, 200 Independence Avenue, SW, 6th Floor, Washington, DC 20201.

Status: Open to the public, limited only by the space available. Those who wish to attend are encouraged to register with the contact person listed below. If you will require a sign language interpreter, or have other special needs, please notify the contact person by 4:30 E.S.T. on October 20, 2000.

Purpose: The Interagency Committee on Smoking and Health advises the Secretary, Department of Health and Human Services, and the Assistant Secretary for Health in the: (a) Coordination of all research and education programs and other activities within the Department and with other federal, state, local and private agencies, and (b) establishment and maintenance of liaison with appropriate private entities, federal agencies, and state and local public health agencies with respect to smoking and health activities.

Matters to be Discussed: The agenda will focus on the Framework Convention on Tobacco Control.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the Internet *(www.cdc.gov/tobacco)* in mid-November or from Ms. Monica L. Swann, Interagency Committee on Smoking and Health, Office on Smoking and Health, NCCDPHP, CDC, 200 Independence Avenue, SW, Room 317B, Washington, DC, 20201, telephone (202) 205–8500.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 28, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–25689 Filed 10–5–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1534]

Agency Information Collection Activities; Proposed Collection; Comment Request; Year 2000 Continuation of National Surveys of Prescription Drug Information Provided to Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a national tracking survey, conducted every 2 years, of prescription drug information received by patients.

DATES: Submit written or electronic comments on the collection of information by December 5, 2000.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed 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.

Year 2000 Continuation of National Surveys of Prescription Drug Information Provided to Patients

FDA implements the provisions of the Federal Food, Drug, and Cosmetic Act (the act) designed to ensure the adequate labeling of prescription (Rx) drugs. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug product is misbranded if its labeling is false or misleading in any particular, and under section 201(n) of the act (21 U.S.C. 321(n)), a drug's labeling is misleading if its labeling or advertising fails to reveal material facts. FDA also has the authority to collect this information under Title VI of Public Law 104–180 (Related Agencies and Food and Drug Administration) section 601 (Effective Medication Guides), which directs the development of ''a mechanism to assess periodically * * * the frequency with which the [oral and written prescription] information is provided to consumers.''

To ensure that Rx drugs are not misbranded, FDA has historically asserted that adequate labeling requires certain information be provided to patients. In 1982, when FDA revoked a planned initiative to require mandatory patient package inserts for all Rx drugs in favor of private sector initiatives, the agency indicated that it will periodically conduct surveys to evaluate the availability of adequate patient information on a nationwide basis. In addition, FDA has been responsible for setting and tracking Healthy People 2000 goals and now for Healthy People 2010 goals for the receipt of medication information by patients.

Surveys of consumers about their receipt of Rx drug information were carried out in 1982, 1984, 1992, 1994, 1996, and 1998. This notice is in regard to conducting the survey in the year 2000.

The survey is conducted by telephone on a national random sample of adults who received a new prescription for themselves or a household member within the past 4 weeks. The interview assesses the extent to which oral and written information were received from the doctor, the pharmacist, and other sources. Survey respondents are also asked attitudinal questions, and demographic and other background characteristics are obtained. The survey enables FDA to determine the frequency with which such information is provided to consumers. Without this information, the agency would be unable to assess the degree to which adequate patient information and counseling about Rx drugs is provided.

Respondents to this collection of information are adults (18 years or older) in the continental United States who have obtained a new (nonrefill) prescription at a pharmacy for themselves or a member of their household in the last 4 weeks.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN:[1] SCREENER

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2000	9,643	1	9,643	.03	289

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ANNUAL REPORTING BURDEN:[1] SURVEY

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2000	1,000	1	1,000	.32	320

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

This total estimate of 609 total annual burden hours is based on the 1998 survey administration, in which 9,643 potential respondents were contacted to obtain 1,000 interviews.

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–25701 Filed 10–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1353]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by November 6, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practices (CGMP) and Related Regulations for Blood and Blood Components (OMB Number 0910–0116)—Extension

Under the statutory requirements contained in the Public Health Service Act (42 U.S.C. 262), no blood, blood component, or derivative may move in interstate commerce unless: (1) It is propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license; (2) the product complies with regulatory standards designed to ensure safety, purity, and potency; and (3) it bears a label plainly marked with the product's proper name, manufacturer, and expiration date. The CGMP and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections. The recordkeeping requirements serve preventative and remedial purposes. The disclosure requirements identify the various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of any deviations that occur and that may require immediate corrective action.

Section 606.100(b) (21 CFR 606.100(b)) requires that written standard operating procedures (SOP's) be maintained for the collection, processing, compatibility testing, storage, and distribution of blood and blood components used for transfusion and manufacturing purposes. Section 606.100(c) requires the review of all pertinent records to a lot or unit of blood prior to release of the lot or unit. Any unexplained discrepancy or failure of a lot or unit of final product to meet any of its specifications must be thoroughly investigated, and the investigation, including conclusions and followup, must be recorded. Section 606.110(a) (21 CFR 606.110(a)) requires a physician to certify in writing that the donor's health permits plateletpheresis or leukapheresis if a variance from additional regulatory standards for a specific product is used when obtaining the product from a specific donor for a specific recipient. Section 606.110(b) requires establishments to request prior Center for Biologics Evaluation and Research (CBER) approval for plasmapheresis of donors who do not meet donor requirements. The regulation in 21 CFR 606.151(e) requires that records of expedited transfusions in life-threatening emergencies be maintained. So that all steps in the collection, processing, compatibility testing, storage and distribution, quality control, and transfusion reaction reports and complaints for each unit of blood and blood components can be clearly traced, 21 CFR 606.160 requires that legible and indelible contemporaneous records of each significant step be made and maintained for no less than 5 years. The regulations in 21 CFR 606.165 require that distribution and receipt records be maintained to facilitate recalls, if necessary. Section 606.170(a) (21 CFR 606.170(a)) requires records to be maintained of any reports of complaints of adverse reactions as a result of blood collection or transfusion. Each such report must be thoroughly investigated, and a written report, including conclusions and followup, must be prepared and maintained. Section 606.170(b) requires that fatal complications of blood collections and transfusions be reported to FDA as soon as possible and that a written report shall be submitted within 7 days.

In addition to the CGMP's in part 606 (21 CFR part 606), there are regulations in part 640 (21 CFR part 640) that require additional standards for blood and blood components as follows: Sections 640.2(f); 640.3(a); 640.4(a); 640.25(b)(4) and (c)(1); 640.27(b); 640.31(b); 640.33(b); 640.51(b); 640.53(c); 640.56(b) and (d); 640.61; 640.63(b)(3), (e)(1), and (e)(3); 640.65(b)(2); 640.66; 640.71(b)(1); 640.72, 640.73; and 640.76(a) and (b). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described below. Respondents to this collection of information are licensed and unlicensed blood establishments inspected by FDA, and other transfusion services inspected by the Health Care Financing Administration (HCFA). Based on FDA's registration system, there are an estimated 3,032 registered blood establishments inspected by FDA of which 1,349 perform pheresis. Based on information provided by HCFA, there are an estimated 3,400 transfusion services inspected by HCFA. An estimated 27 million units of whole blood and blood components are collected annually. The recordkeeping chart reflects the estimate that 95 percent of the recordkeepers, which collect 98 percent of the blood supply, had developed SOP's as part of their customary and usual business practice. Establishments may minimize burdens associated with the CGMP and related regulations by using model SOP's developed by industries' accreditation