Promotion, Office of Public Health and Science, Office of the Secretary.

At its first meeting, the membership will establish procedures for conducting the business of the Council and for reporting the results of its meetings to the Secretary. Other items on the agenda include consideration of reports from Healthy People 2000 Consortium focus groups, discussion of data developments relevant to Healthy People 2010, and strategies for engaging the business community in the Department's prevention efforts. During its tenure, the Council will oversee the development of Healthy People 2010, the third generation of a national initiative to prevent disease and promote the health of the American people. It is anticipated that a call for submission by the public of health promotion/disease prevention objectives for 2010 will be published in the fall of 1997. At a second meeting proposed for spring of 1998, the Council will consider the resulting submissions as the basis for a draft of the 2010 objectives to be published in the fall of 1998.

If time permits at the conclusion of the formal agenda of the Council, the Chair may allow brief oral statements from interested parties and persons in attendance. The meeting is open to the public; however, seating is limited. If you will require a sign language interpreter, please call Gloria Robledo (202) 401–7736 by 4:30 p.m. E.S.T on April 7, 1997.

Dated: March 27, 1997.

Susanne A. Stoiber,

Acting Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion).

[FR Doc. 97–8598 Filed 4–3–97; 8:45 am]

BILLING CODE 4160–17–M

Notice of a Meeting of the National Bioethics Advisory Commission (NBAC); Human Subjects Subcommittee

On Saturday, April 12, 1997, in conjunction with National Bioethics Advisory Commission's April 13 meeting, the Human Subjects Subcommittee is now scheduled to meet from 2:00 to 5:00 p.m. at the Crystal City Marriott, Salon E, Jefferson Davis Highway, Arlington, VA. 22202. The meeting is open to the public. For public statements, please contact the person listed below.

For Further Information Contact: Ms. Henrietta D. Hyatt-Knorr, National Bioethics Advisory Commission, MSC–7508, 6100 Executive Boulevard, Suite 3C01, Rockville, Maryland 20892–7508, telephone 301–402–4242, fax number 301–480–6900.

Dated: March 31, 1997.

Henrietta D. Hyatt-Knorr,

Deputy Executive Director (Acting), National Bioethics Advisory Commission.

[FR Doc. 97–8596 Filed 4–3–97; 8:45 am]

BILLING CODE 4160–17–P

National Committee on Vital and Health Statistics; Meetings

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meetings.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Health Data Needs, Standards, and Security.

Times and Dates: 9:30 a.m.–6 p.m., April 15, 1997; 9 a.m.–5:30 p.m., April 16, 1997.

Place: Room 503A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open.

Purpose: Under the Administrative Simplification provisions of Pub. L. 104–191, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Secretary of Health and Human Services is required to adopt standards for specified transactions to enable health information to be exchanged electronically. The law requires that, within 24 months of adoption, all health plans, health care clearinghouses, and health care providers who choose to conduct these transactions electronically must comply with these standards. The law also requires the Secretary to adopt a number of supporting standards including standards for code sets and classifications systems. The Secretary is required to consult with the National Committee on Vital and Health Statistics (NCVHS) in complying with these provisions. The NCVHS is the Department's federal advisory committee on health data, privacy and health information policy.

To assist in the development of the NCVHS recommendations to HHS, the NCVHS Subcommittee on Health Data Needs, Standards, and Security has been holding a series of public meetings to obtain the views, perspectives and concerns of interested and affected parties. On the morning of April 15, the Subcommittee's Working Group on Data Standards and Security will hold a public meeting at which they will be briefed by HHS on the status of and plans for unique identifiers for providers and payers.

On the afternoon of April 15th and all day on April 16th, the full Subcommittee will consider and discuss perspectives on medical and clinical coding and classification issues in the implementation of Pub. L. 104–191. For the meeting, the Subcommittee is inviting specific organizations representing both the users and developers of medical and clinical classification systems to address the following questions in writing, to make brief oral presentations of their answers, and to answer further questions from the Subcommittee. Other organizations that would also like to submit written statements on these issues are invited to do so.

Questions to be Addressed:

1. What medical/clinical codes and classifications do you use in administrative transactions now? What do you perceive as the main strengths and weaknesses of current methods for coding and classification of encounter and/or enrollment data?

2. What medical/clinical codes and classifications do you recommend as initial standards for administrative transactions, given the time frames in the HIPAA? What specific suggestions would you like to see implemented regarding coding and classification?

3. Prior to the passage of HIPAA, the National Center for Health Statistics initiated development of a clinical modification of ICD–10 (ICD–10–CM) and the Health Care Financing Administration undertook development of a new procedure coding system for inpatient procedures (called ICD–10–PCS), with a plan to implement them simultaneously in the year 2000. On the pre-HIPAA schedule, they will be released to the field for evaluation and testing by 1998. If some version of ICD is to be used for administrative transactions, do you think it should be ICD–9–CM or ICD–10–CM and ICD–10–PCS, assuming that field evaluations are generally positive?

4. Recognizing that the goal of Pub. L. 104–191 is administrative simplification, how, from your perspective, would you deal with the current coding environment to improve simplification and reduce administrative burden, but also obtain medically meaningful information?

5. How should the ongoing maintenance of medical/clinical code sets and the responsibility, intellectual input and funding for maintenance be addressed for the classification systems included in the standards? What are the arguments for having these systems in the public domain versus in the private sector, with or without copyright?

6. What would the resource implications be of changing from the coding and classification systems that you currently are using in administrative transactions to other systems?

7. A Coding and Classification Implementation Team has been established within the Department of Health and Human Services to address the requirements of Pub. L. 104–191. Does your organization have any concerns about the process being undertaken by the Department to carry out the requirements of the law in regard to coding and classification issues? If so, what are those concerns and what suggestions do you have for improvements?

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey building by non-government employees. Thus, persons without a government identification card will need to have the guard call for an escort to the meeting.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from James Scanlon, NCVHS Executive Staff

Director, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, telephone (202) 690–7100, or Marjorie S. Greenberg, Acting Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 436–7050. Information also is available on the NCVHS home page of the HHS website: http://aspe.os.dhhs.gov/ncvhs.

Dated: March 26, 1997.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 97–8597 Filed 4–3–97; 8:45 am]

BILLING CODE 4151–04–M

Centers for Disease Control and Prevention

[30 DAY–3–97]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

1. Congenital Syphilis Case Investigation and Report Form (CDC 73.126 REV 09–91)–(0920–0128). This request is for a 3-year extension of clearance. Reducing congenital syphilis (CS) is a national objective in the DHHS Report entitled *Healthy People 2000: Midcourse Review and 1995 Revisions.* Objective 19.4 of this document states the goal: ''reduce congenital syphilis to an incidence of no more than 40 cases per 100,000 live births'' by the year 2000. In order to meet this national objective, an effective surveillance system for CS must be continued in order to monitor current levels of disease and progress towards the year 2000 objective. This data will also be used to develop intervention strategies and to evaluate ongoing control efforts. The total annual burden hours are 500.

Respondents	Number of respondents	Number of responses/respondent (in hrs.)	Average burden/response (in hrs.)
State and local health department ..	2000	1	0.25

Dated: March 28, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–8618 Filed 4–3–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96E–0503]

Determination of Regulatory Review Period for Purposes of Patent Extension; XALATAN™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XALATAN™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product XALATAN™ (latanoprost). XALATAN™ is indicated for the reduction of elevated intraocular pressure in patents with open-angle glaucoma and ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XALATAN™ (U.S. Patent No. 4,599,353) from the Trustees of Columbia University in the City of New York, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 18, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of XALATAN™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for XALATAN™ is 1,875 days. Of this time, 1,519 days occurred during the testing phase of the regulatory review period, while 356 days occurred during the approval phase. These periods of time were derived from the following dates: