Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, is the subject of approved NDA 21–492 held by Sanofi-Aventis. Oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, is a chemotherapeutic agent indicated for adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor. Sanofi-Aventis ceased manufacturing ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, in June 2006.

FDA received five citizen petitions, submitted under 21 CFR 10.30, requesting that the agency determine whether oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, was withdrawn from sale for reasons of safety or effectiveness. The petitions were submitted as follows:

- Sicor Pharmaceuticals, Inc., submitted a citizen petition dated July 24, 2006 (Docket No. 2006P–0291/CP1).
- Rothwell, Figg, Ernst & Manbeck, P.C., submitted a citizen petition dated July 24, 2006 (Docket No. 2006P–0299/CP1).
- AAC Consulting Group submitted a citizen petition dated July 25, 2006 (Docket No. 2006P–0298/CP1).
- Frommer Lawrence & Haug LLP submitted a citizen petition dated August 4, 2006 (Docket No. 2006P–0309/CP1).
- Regulus Pharmaceutical Consulting, Inc., submitted a citizen petition dated February 20, 2007 (Docket No. 2007P–0062/CP1).

The agency has determined that ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant information has uncovered no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing agency records, FDA determines that for the reasons outlined previously, ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. If FDA determines that the labeling of this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: November 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22973 Filed 11–23–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Questionnaire Cognitive Interview and Pretesting (ARP/DCCPS/NCI)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Questionnaire Cognitive Interview and Pretesting. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The purpose of the data collection is to conduct cognitive interviews, focus groups, Pilot household interviews, and experimental research in laboratory and field settings, both for applied questionnaire evaluation and more basic research on response errors in surveys. The most common evaluation method is the cognitive interview, in which a questionnaire design specialist interviews a volunteer participant. The interviewer administers the draft survey questions as written, but also probes the participant in depth about interpretations of questions, recall processes used to answer them, and adequacy of response categories to express answers, while noting points of confusion and errors in responding. Interviews are generally conducted in small rounds of 10–15 interviews. When possible, cognitive interviews are conducted in the survey's intended mode of administration. Cognitive interviewing provides useful information on questionnaire performance at minimal cost and respondent burden. Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations. There are no costs to respondents other than their time. The total estimated annualized burden hours are 600.

Frequency of Response: Once. *Affected Public:* Individuals or households.

Type of respondents	Projects	Number of respondents	Frequency of responses/ participant	Average hours per response	Response burden
Questionnaire Development Volunteers.	(1) Survey questionnaire development.	200	1	1.25 (75 minutes)	250.0
General Volunteers	(2) Research on the cognitive aspects of survey methodology.	100	1	1.25 (75 minutes)	125.0
Computer User Volunteers	(3) Research on computer-user interface design.	100	1	1.25 (75 minutes)	125.0
Household Interview Volunteers	(4) Pilot Household interviews	200	1	0.5 (30 minutes)	100.0
Total		600			600.0

The estimated total annual burden hours requested is 600. There are no annualized costs to respondents. The annualized costs to the Federal Government are estimated at $264,000 and include cost of NCI staff to plan, conduct, and analyze outcomes of questionnaire development, $50 payment of pretest participants, contracting for pretesting activities and research, travel costs, and additional materials needed to conduct and recruit participants for the research.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Gordon Willis, PhD., Cognitive Psychologist, Applied Research Program, DCCPS, NCI/NIH, 6130 Executive Blvd, MSC 7344, EPN 4005, Bethesda, MD 20892 or call non-toll-free number 301–594–6652 or e-mail your request, including your address to: *willis@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: November 13, 2007.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E7–22905 Filed 11–23–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Consensus Development Conference: Hydroxyurea Treatment for Sickle Cell Disease; Notice

Notice is hereby given of the National Institutes of Health (NIH) ''NIH Consensus Development Conference: Hydroxyurea Treatment for Sickle Cell Disease'' to be held February 25–27, 2008, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on February 25 and 26, at 9 a.m. on February 27, and will be open to the public.

Sickle cell disease is an inherited blood disorder that affects between 50,000 and 75,000 people in the United States. It is most common among people whose ancestors come from sub-Saharan Africa, South and Central America, the Middle East, India, and the Mediterranean basin. Sickle cell disease occurs when an infant inherits the gene for sickle hemoglobin from both parents (Hb SS, or sickle cell anemia) or the gene for sickle hemoglobin from one parent and another abnormal hemoglobin gene from the other parent. Each year, approximately 2,000 babies with sickle cell disease are born in the United States. The condition is chronic and lifelong and is associated with a decreased lifespan. In addition, approximately 2 million Americans carry the sickle cell trait, which increases the public health burden as this disorder is passed on to future generations.

The red blood cells in people with sickle cell disease become deoxygenated (or depleted of oxygen) and crescent-shaped or ''sickled.'' The cells become sticky and adhere to blood vessel walls, thereby blocking blood flow within limbs and organs. These changes lead to acute painful episodes, chronic pain, and chronic damage to the brain, heart, lungs, kidneys, liver, and spleen. Infections and lung disease are leading causes of death.

Pain crises are responsible for most emergency room visits and hospitalizations of people with sickle cell disease. Standard treatments for acute pain crises include painkilling medications, fluid replacement, and oxygen. In the mid-1990s, researchers began investigating the potential of hydroxyurea to reduce the number and severity of pain crises in sickle cell patients. Hydroxyurea is in a class of anticancer drugs and it acts to increase the overall percentage of normally structured red blood cells in the circulation. By diluting the number of cells that ''sickle,'' it may, if taken on a daily basis, reduce their damaging effects. Hydroxyurea was approved by the Food and Drug Administration for use in adults with sickle cell anemia in 1998. However, there are a number of unresolved issues about the use of hydroxyurea, including a lack of knowledgeable providers who treat sickle cell disease, and patient and practitioner questions about safety and effectiveness, including concerns regarding potential long-term carcinogenesis.

In order to take a closer look at this important topic, the National Heart, Lung, and Blood Institute and the Office of Medical Applications of Research of