years. Committee members receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business in the interest of the Committee. Interested applicants may self-nominate. Nominations may be retained and considered for future vacancies.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that individuals from a broad representation of geographic areas, women and men, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of SACHRP.

Dated: October 25, 2013.

Jerry Menikoff,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2013–26291 Filed 11–1–13; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–14–14BB]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project:

Evaluation of Rapid HIV Home-Testing among MSM Trial—New—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Innovative testing strategies are needed to reduce levels of undiagnosed Human immunodeficiency virus (HIV) infection and increase early access to treatment. Rapid home HIV tests may play an important role in efforts to reduce both HIV morbidity and mortality. Given the unrelenting HIV crisis among men who have sex with men (MSM) and the release into the market of a rapid HIV test for at-home use, it is necessary to evaluate the impact of providing rapid HIV home-test kits on repeat HIV testing, linkage to care, partner testing, serosorting, and HIV sexual risk behaviors among MSM. This information will assist the Division of HIV/AIDS Prevention (DHAP) in developing recommendations, future research and program needs concerning home-testing for MSM.

Specific Aims

This study is a randomized trial which aims to evaluate the use and effectiveness of home-test kits as a public health strategy for increasing testing among MSM. A secondary aim of the randomized trial is to evaluate the extent to which MSM (both HIV-negative and HIV-positive) distribute HIV home-test kits to their social and sexual networks.

The population for the randomized trial will be men over the age of 18 years who self-report that they have had anal sex with at least one man in the past year. We will recruit approximately 3,200 men who report their HIV status to be negative or who are unaware of their HIV status and 300 men who self-report that they are HIV-positive. Men will be recruited from the 12 cities: Atlanta, Georgia; Baltimore, Maryland; Chicago, Illinois; Dallas, Texas; District of Columbia; Houston, Texas; Los Angeles, California; Miami, Florida; New York City, New York; Philadelphia, Pennsylvania; San Francisco, California; and San Juan, Puerto Rico. We will ensure that at least 20% of participants are black and at least 15% are Hispanic. Recruitment will be conducted through banner advertisements displayed on social networking sites such as Facebook and dating and sex-seeking sites such as Manhunt and Adam4Adam.

This study also has a qualitative component that aims to examine the experiences of participants in the randomized control trial (RCT). Participants for the qualitative data collection will be drawn from the randomized control trial. Two data collection techniques will be used: focus group discussions (FGD) (both online and in-person) and individual in-depth interviews (IDIs).

CDC is requesting approval for a 3-year clearance for data collection. All participant consenting and data collection for the RCT will be completed using an online reporting system. Data will be collected using an eligibility screener, an online study registration process, a baseline survey, HIV test results reporting system, and follow-up surveys. Men will be asked to use the study Web site or download and access a secure cell phone application prior to enter results of their rapid HIV home-tests that they receive and conduct at home and to take the follow-up surveys which will collect information on HIV

testing results and behaviors and sexual activities. Focus group discussions and in-depth interviews will be used to examine experiences of participants in the RCT.

The duration of the eligibility screener is estimated to be 5 minutes; the study registration process 5 minutes; the baseline survey 15 minutes; the reporting of home-test results 5 minutes; the follow-up surveys 10 minutes; the focus group discussion 1 hour and 30 minutes; and the in-depth interviews 1 hour and 15 minutes.

There is no cost to participants other than their time.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
Prospective Participant	Eligibility Screener	24,000	1	3/60	1,200
Enrolled participant	Study Registration	14,000	1	5/60	1,167
Enrolled participant	Baseline Survey for RCT	3,200	1	15/60	800
Enrolled participant	Baseline Survey for HIV-positive group.	300	1	15/60	75
Enrolled participant	Reporting of Home-test Results during study.	1,600	3	5/60	400
Enrolled participant	Follow-up Surveys for RCT	3,200	4	10/60	2,133
Enrolled participant	Follow-up Surveys for HIV positive group.	300	2	10/60	100
Enrolled participants	Reporting of Home-test Results at completion of study.	3,200	1	5/60	267
Enrolled participant	Focus group discussion	216	1	1.5	324
Enrolled participant	Individual in-depth interview guide	30	1	1.5	45
Total					6,511

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–26277 Filed 11–1–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0775]

Determination That INVEGA (Paliperidone) Extended-Release Tablet, 12 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that INVEGA (paliperidone) extended-release tablet, 12 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for paliperidone extended-release tablet, 12 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–3977.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

INVEGA (paliperidone) extended-release tablet, 12 mg, is the subject of NDA 21–999, held by Janssen Pharmaceuticals, Inc., and initially approved on December 19, 2006. INVEGA extended-release tablets are indicated for the treatment of schizophrenia and the treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants.

Janssen Pharmaceuticals, Inc., has never marketed INVEGA (paliperidone) extended-release tablet, 12 mg. In previous instances (see, e.g., 72 FR 9763, 61 FR 25497), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. The other strengths of INVEGA (paliperidone) that are approved under NDA 21–999 are being marketed.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated June 25, 2013 (Docket No. FDA–2013–P–0775), under 21 CFR 10.30, requesting that the Agency determine whether