performed during the previous two years.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Emergency Epidemic Investigation Participants	Emergency Epidemic Investigation Data Collection Instruments.	12,000	1	30/60

LeRoy A. Richardson,

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

[FR Doc. 2013–27942 Filed 11–20–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–14–0910]

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 (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Message Testing for Tobacco Communication Activities (OMB No. 0920–0910, exp. 1/31/2015)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2012, CDC's Office on Smoking and Health (OSH) obtained OMB approval of a generic clearance to support the development of tobacco-related health messages (Message Testing for Tobacco Communication Activities (MTTCA), OMB No. 0920–0910, exp. 1/31/2015). A variety of information collection strategies are supported through this generic mechanism, including in-depth interviews, in-person focus groups, online focus groups, computer-assisted, in-person, or telephone interviews, and online surveys. Each project approved under the MTTCA framework is outlined in a project-specific Information Collection Request that describes its purpose and methodology.

The MTTCA clearance has been used to obtain OMB approval for a variety of message testing activities, with particular emphasis on communications supporting CDC's ''Tips from Former Smokers'' campaign. This national campaign, developed and implemented by OSH, is designed to increase public awareness of the health consequences of tobacco use and exposure to secondhand smoke. The MTTCA clearance has also supported formative research relating to the development of health messages that are not specifically associated with the national campaign.

In 2014, CDC will implement a new phase of the national tobacco education campaign and continue ongoing programmatic initiatives, such as maintaining the Media Campaign Resource Center (MCRC) and producing reports in conjunction with the Office of the Surgeon General. OSH will continue to use the MTTCA clearance to improve the quality of tobacco-related health messages associated with these activities and other tobacco control efforts of interest to CDC and its partners. OSH anticipates that a number of messages will be developed or refined for subpopulations as well as the general public. For example, screening activities may be conducted to involve individuals who are Lesbian, Gay, Bisexual, and Transgender (LGBT); individuals who are active military or veterans; individuals who suffer from depression and/or anxiety, and individuals who are English-speaking Hispanics. CDC may also request information about smoking status (e.g., current non-smoker, current smoker, ex-smoker).

CDC is requesting OMB approval to revise the generic MTTCA clearance, which was initially approved with the following estimates: 5,775 annualized burden hours and 14,974 annualized responses. The initial estimates were based on the number of respondents who were likely to participate in information collection activities such as focus groups, interviews, and surveys. The initial estimates did not specifically account for screening activities that are necessary to identify respondents from key target audiences. As a result, the initial MTTCA clearance underestimated the total number of responses needed to support data collection conducted in 2012 and 2013. The planned revision will adjust for screening and recruitment by allocating 20,000 additional respondents, and 667 additional burden hours, to the annualized estimates. To accommodate both planned activities and potential new initiatives or collaborations, CDC is also requesting modest increases in the number of respondents and burden hours associated with survey activities.

CDC's authority to collect information for public health purposes is provided by the Public Health Service Act (41 U.S.C. 241) Section 301.

The revision request does not affect the current expiration date of January 31, 2015. The estimated annualized number of responses will increase from 14,974 to 36,847 and the total estimated annualized burden hours will increase from 5,775 to 7,219. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Data collection method	Number of respondents	Number of responses per respondent	Average burden per response
General Public and Special Populations	Screening and Recruitment	20,000	1	2/60
	In-depth Interviews (In Person, telephone, etc.).	67	1	1
	Focus Groups (In Person)	160	1	1.5
	Focus Groups (Online)	120	1	1
	Short Surveys	6,500	1	10/60
	(Online, Bulletin Board, etc.)			
	Medium Surveys	8,500	1	25/60
	(Online)			
	In-depth Surveys (Online)	1,500	1	1

Leroy A. 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. 2013–27928 Filed 11–20–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0573]

Determination That BANZEL (Rufinamide) Tablet, 100 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 BANZEL (rufinamide) tablet, 100 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 rufinamide tablet, 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Olivia Morris, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6260, Silver Spring, MD 20993–0002, 301–796–3601.

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 (§ 314.162 (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.

BANZEL (rufinamide) tablet, 100 mg, is the subject of NDA 21–911, held by Eisai Inc., and initially approved on November 14, 2008. BANZEL is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and adults.

Eisai Inc., has never marketed BANZEL (rufinamide) tablet, 100 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.

Lupin Pharmaceuticals, Inc., submitted a citizen petition dated May 9, 2013 (Docket No. FDA–2013–P–0573), under 21 CFR 10.30, requesting that the Agency determine whether BANZEL (rufinamide) tablet, 100 mg, was withdrawn or discontinued from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that BANZEL (rufinamide) tablet, 100 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BANZEL (rufinamide) tablet, 100 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BANZEL (rufinamide) tablet, 100 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list BANZEL (rufinamide) tablet, 100 mg, 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 BANZEL (rufinamide) tablet, 100 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised