other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR 1320(a)(2)(ii). This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures due to an unexpected event as stated in 5 CFR 1320.13(a). The Centers for Medicare and Medicaid Services (CMS) is requesting that an information collection request (ICR) for Consumer Research on Public Reporting of Hospital Outpatient Measures be processed under the emergency clearance process. Approval of this package is essential in order to comply with Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)(17)).

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Consumer Research on Public Reporting of Hospital Outpatient Measures *Use:* The Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act (MIEA–TRHCA) of 2006, enacted in December of 2006, made changes in the Outpatient Prospective Payment System (OPPS). Consequently, CMS is now statutorily required to establish a program under which hospitals will report data on the quality of hospital outpatient care using standardized measures to receive the full annual update to the OPPS payment rate. This will be effective for payments beginning in calendar year (CY) 2009. The program established under these amendments is the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The measures will expand as additional priority areas for quality improvement in hospital outpatient settings are identified and will be designed to evaluate the diversity of services and clinical topics provided to adult patients in hospital outpatient settings.

The Centers for Medicare & Medicaid Services contracted with L&M Policy Research, LLC (L&M) and its subcontractors, Mathematica Policy Research, Inc. (MPR) and McGee & Evers Consulting (M&E), to conduct exploratory or formative research around the new Hospital Outpatient Measures. Concepts and topics were presented to groups of consumers and caregivers, and to individual physicians. Subsequent to this exploratory or formative research, the research team designed mock-ups of the planned measures, utilizing feedback from the measure developers, the website programmers, plain language experts, and other CMS staff and contractors. The goals of the mock-ups were to integrate the measures into an existing website using the display devices similar to those used for extant measures, but presenting the measures clearly and in such a way that consumers and professionals could draw accurate and useful inferences from the data. The research team and CMS remain concerned about a number of issues in the displays and would like to conduct additional Web site research with consumers, caregivers and professionals to fine tune the recommendations to the website owners and programmers. The team proposes to conduct cognitive interviews with mock-ups and protocols in January 2010 in order to meet Agency deadlines for presentation of the data by June 2010. *Form Number:* CMS–10310 (OMB#: 0938–New); *Frequency:* Once; *Affected Public:* Individuals or Households; *Number of Respondents:* 104; *Total Annual Responses:* 104; *Total Annual Hours:* 41. (For policy questions regarding this collection contact David Miranda 410–786–7819. For all other issues call 410–786–1326.)

CMS is requesting OMB review and approval of this collection by *January 15, 2010,* with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by January 13, 2010.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by January 13, 2010.

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

3. *By Facsimile or E-mail to OMB.* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, E-mail: *OIRA_submission@omb.eop.gov.*

Dated: December 22, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–31298 Filed 1–4–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–09AY]

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 Officer at (404) 639–5960 or send an e-mail 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

Laboratory Response Network (LRN)—Existing Data Collection in use without an OMB Control Number—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. The LRN's mission is to maintain an integrated national and international network of laboratories that can respond to suspected acts of biological, chemical, or radiological terrorism and other public health emergencies.

When Federal, State and local public health laboratories voluntarily join the LRN, they assume specific responsibilities and are required to provide information to the LRN Program Office at CDC. Each laboratory must submit and maintain complete information regarding the testing capabilities of the laboratory. Biannually, laboratories are required to review, verify and update their testing capability information. Complete testing capability information is required in order for the LRN Program Office to determine the ability of the Network to respond to a biological or chemical terrorism event. The sensitivity of all information associated with the LRN requires the LRN Program Office to obtain personal information about all individuals accessing the LRN Website. In addition, the LRN Program Office must be able to contact all laboratory personnel during an event so each laboratory staff member that obtains access to the restricted LRN Web site must provide his or her contact information to the LRN Program Office.

As a requirement of membership, LRN Laboratories must report all biological and chemical testing results to the LRN Program at CDC using a CDC developed software tool called the LRN Results Messenger. This information is essential for surveillance of anomalies, to support response to an event that may involve multiple agencies and to manage limited resources. LRN Laboratories must also participate in and report results for Proficiency Testing Challenges or Validation Studies. LRN Laboratories participate in multiple Proficiency Testing Challenges, Exercises and/or Validation Studies every year consisting of five to 500 simulated samples provided by the LRN Program Office. It is necessary to conduct such challenges in order to verify the testing capability of the LRN Laboratories. The rarity of biological or chemical agents perceived to be of bioterrorism concern prevents some LRN Laboratories from maintaining proficiency as a result of day-to-day testing. Simulated samples are therefore distributed to ensure proficiency across the LRN. The results obtained from testing these simulated samples must also be entered into Results Messenger for evaluation by the LRN Program Office.

During a surge event resulting from a bioterrorism or chemical terrorism attack, LRN Laboratories are also required to submit all testing results using LRN Results Messenger. The LRN Program Office requires these results in order to track the progression of a bioterrorism event and respond in the most efficient and effective way possible and for data sharing with other Federal partners involved in the response. The number of samples tested during a response to a possible event could range from 10,000 to more than 500,000 samples depending on the length and breadth of the event. Since there is potentially a large range in the number of samples for a surge event, CDC estimates the annualized burden for this event will be 3,000,000 hours or 625 responses per respondent.

Semiannually the LRN Program Office may conduct a Special Data Call to obtain additional information from LRN Member Laboratories in regards to biological or chemical terrorism preparedness. Special Data Calls are conducted using the LRN Web site.

Respondents are public health laboratorians. There are no costs to respondents other than their time. The total estimated annualized burden for this information collection is 3,176,400 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Forms	Respondents	Number of respondents	Average number of responses per respondent	Average burden per response (in hours)
Biennial Requalification	Public Health Laboratorians	100	1	2
General Surveillance Testing Results	Public Health Laboratorians	200	25	24
Proficiency Testing/Validation Testing Results	Public Health Laboratorians	200	5	56
Surge Event Testing Results	Public Health Laboratorians	200	625	24
Special Data Call	Public Health Laboratorians	200	2	30/60

Dated: December 30, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–31368 Filed 1–4–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0263]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer Television and Print Advertisements for Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by February 4, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–New and title Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Liz Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

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.

Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs—(OMB Control Number 0910–New)

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks.[1] By its nature, the presentation of this information is likely to evoke active trade-offs by consumers, i.e., comparisons with the perceived risks of not taking treatment, and comparisons with the perceived benefits of taking a treatment (Ref. 1). FDA has an interest in fostering safe and proper use of prescription drugs, an activity that engages both risks and benefits. Therefore, an examination of ways to improve consumers' understanding of this information is central to this regulatory task.

Under the act, FDA engages in a variety of communication activities to ensure that patients and health care providers have the information they need to make informed decisions about treatment options, including the use of prescription drugs. FDA regulations (21 CFR 201.57) describe the content of required product labeling, and FDA reviewers ensure that labeling contains accurate and complete information about the known risks and benefits of each drug.

FDA regulations require that prescription drug advertisements that make (promotional) claims about a product also include risk information in a ''balanced'' manner (21 CFR 202.1(e)(5)(ii)), both in terms of the content and presentation of the information. This balance applies to both the front, display page of an advertisement, as well as including information ''in brief summary'' about the advertised product's ''side effects, contraindications, and effectiveness''[2] usually, but not always, on a separate page. However, beyond the ''balance'' requirement there is limited guidance and research to direct or encourage sponsors to present benefit claims that are informative, specific, and reflect clinical effectiveness data.

FDA has recently provided guidance to sponsors about ways to present risk information in prescription drug advertisements (Ref. 2). This guidance notwithstanding, research addressing specifically how to present benefit and efficacy information in prescription drug advertisements is limited. For example, ''benefit claims,'' broadly defined, appearing in advertisements are often presented in general language that does not inform patients of the likelihood of efficacy and are often simply variants of an ''intended use'' statement. One content analysis of DTC advertising by Woloshin and Schwartz (2001) (Ref. 3) found that information about product benefits and risks is often presented in an unbalanced fashion. The researchers classified the ''promotional techniques'' used in the advertisements. Emotional appeals were observed in 67 percent of the ads while vague and qualitative benefit terminology was found in 87 percent of the ads. Only 9 percent contained data. However, for risk information, half the advertisements used data to describe side-effects, typically with lists of side-effects that generally occurred infrequently. Similarly, a content analysis by Frosch et al. (2007) (Ref. 4) found that only a small proportion of product-claim ads gave specific information about the population prevalence of the medical condition being advertised. The authors criticize DTC for presenting ''best-case scenarios that can distort and inflate consumers' expectations about what prescription drugs can accomplish'' (see p. 12 of Frosch et al.) (Ref. 4) without disclosing how many consumers are likely to experience that benefit.

Some research has proposed that providing quantitative information about product efficacy enables consumers to make better choices about potential therapy. One possible format (termed the ''drug facts'' box by its creators) for this information has recently received attention (Refs. 5, 6, and 7). In these studies, the drug facts box format contained information about the product's efficacy and safety in terms of rate (how many people in the clinical trial experienced a benefit or side effect compared to placebo). As expected, this study showed that consumers who were provided efficacy information used it. Participants receiving efficacy information (without other potentially valuable information about the drug) were more likely to correctly choose the product with the higher efficacy than consumers who saw

[1] For prescription drugs and biologics, the act requires advertisements to contain ''information in brief summary relating to side effects, contraindications, and effectiveness'' (section 502(n) of the act (21 U.S.C. 352(n)).

[2] See section 502(n) of the act.