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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13–13RE]

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 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Public Health Systems, Mental Health and Community Recovery Project—New—Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project stems from, and aligns with, publication of the Office of Public Health Preparedness and Response's (OPHPR) ''National Strategic Plan for Public Health Preparedness and Response'' which provides overall direction for Centers for Disease Control and Prevention's (CDC) preparedness and response portfolio, including programmatic direction across OPHPR's four divisions. The focus of this project is to generate findings useful for future preparedness planning and response in order to develop strategies and interventions aimed at mitigating the impact of adverse events. In April 2011, one of the largest tornado outbreaks ever recorded, a ''Super Outbreak,'' occurred in the southeastern United States, resulting in more than 300 deaths and an estimated $10 billion in damages. This large-scale multistate tragedy offers a unique opportunity to study how communities with similar cultural and geographic features yet different public health and mental health emergency response systems could provide access to care around the same crisis. The outcomes of these efforts can inform the field of what effect these differences had on the recovery patterns of each of these communities. By doing so, we can begin to elucidate best practices for robust community preparedness and recovery with attention to types of services that most effectively promote the natural resilience of survivors. Two primary research questions will guide the proposed study:

1. How did the Alabama and Mississippi State and local public health and mental health (PH/MH) systems prepare for, respond to, and support recovery after the April 2011 tornados?

2. To what extent have these communities recovered and what is the overall health and quality of life of individuals affected by these events?

CDC requests OMB approval to collect information for two years.

To address these questions, CDC, in collaboration with ICF International, will conduct a mixed method evaluation utilizing key informant interviews of public health and mental health agency staff and other leaders from the community and household survey data in each of the four regions in Mississippi and Alabama to assess community recovery. Specifically, the study design includes two main components (qualitative and quantitative) designed to comprehensively examine the PH/MH system response to and community recovery and resilience from disasters.

The total estimated burden for the 98 one-time qualitative interviews for public health/mental health professionals and community leaders is 98 hours (98 respondents × 1 hour/response). Interviews will be conducted during an in-person site-visit to the region to reduce travel and time burdens on the respondents. Respondents unable to participate during the site visit may participate via telephone. In addition, the total estimated burden for the quantitative computer-assisted interviews are based on 1,313 screener respondents and 860 survey respondents in each of the four tornado effected regions; the screener will take approximately 2 minutes to complete and the survey will take approximately 25 minutes to complete.(Study Screener: 4 counties × 1,313 study screeners = 5,252 participants screened; 5,252 participants × 2/60 minutes = 175 hours; Household Survey for General Public: 4 counties × 860 respondents = 3,440 respondents; 3,440 respondents × 25/60 minutes = 1,433 hours).

There are no costs to respondents other than their time.

The total estimated annual burden hours are 1,706.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Mental Health/Public Health Agency Staff	Key Informant Interview Guide_PH/MH Agency Staff & Key Informant Interview Guide_Consent Form.	53	1	1
Community Organization Leaders	Key Informant Interview Guide_Community Organization Respondents & Key Informant Interview Guide_Consent Form.	45	1	1
General public from disaster affected communities.	Household Survey for General Public and Consent.	3,440	1	25/60
General public from disaster affected communities.	Household Survey for General Public_Study Screener.	5,252	1	2/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0450]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Abbreviated New Animal Drug Applications

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 September 25, 2013.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0669 and title ''Abbreviated New Animal Drug Applications.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Abbreviated New Animal Drug Applications—Section 512(b)(2) and (n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2) and (n)(1)) (OMB Control Number 0910–0669)—Extension

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA) (Pub. L. 100–670). Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by GADPTRA, any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an abbreviated application is described in section 512(n)(1) of the FD&C Act. Among other things, an abbreviated application is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved drug referenced in the abbreviated application. FDA allows applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review followed by the submission of an Administrative ANADA when FDA finds that all the applicable technical sections for an ANADA are complete. FDA requests that an applicant accompany ANADAs and requests for phased review of data to support ANADAs with the Form FDA 356v to ensure efficient and accurate processing of information to support approval of the generic new animal drug.

In the **Federal Register** of April 30, 2013 (78 FR 25279), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however the comment was not responsive to any of the four topics solicited by the notice. Therefore, FDA does not address the comment here.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ANADAS: ESTIMATED ANNUAL REPORTING BURDEN

FD&C act section 512 (b)(2)	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA	356v	18	1	18	159	2,862
Phased Review With Administrative ANADA	356v	3	5	15	31.8	477
Total						3,339

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

ANADA paperwork burden (section 512(b)(2) of the FD&C Act). Over the past 5 fiscal years, from October 2007 through September 2012, FDA has received an average of 21 ANADAs per year. FDA estimates that preparing the paperwork required under 21 U.S.C. 360b(n)(1) to be contained in an ANADA, whether all of the information is submitted with the ANADA or the applicant submits information for phased review followed by an Administrative ANADA that references that information, will take approximately 159 hours. (FDA is estimating that each ANADA that uses the phased review process will have approximately five phased reviews per application. Therefore, assuming that three respondents will take advantage of the phased review option per year and an average of five phased reviews are submitted per application, times 31.8 hours per phased review, equals 477 total hours per year or 159 hours per application.)

Although over the last 5 fiscal years all sponsors chose to submit traditional ANADAs, some sponsors did indicate an interest in using the phased review option in the future. FDA believes that, with time, more and more sponsors will take advantage of the phased review option as it provides greater flexibility and estimates that there will be three respondents for the phased review option. FDA also estimates that sponsors of ANADAs take approximately 25 percent less time to put together the information to support an ANADA than a new animal drug application (NADA) because they only need to provide evidence of bioequivalence and not the data required in a NADA to support a full demonstration of safety and effectiveness.