ATTACHMENT B:

60-Day Published Federal Register Notice

Dated: September 14, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–22648 Filed 9–18–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–09–09AD]

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 404–639–5960 or send comments to CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail 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 the Field Triage Decision Scheme: The National Trauma Triage Protocol—New—Division of Injury Response (DIR), National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Field Triage Decision Scheme: The National Trauma Triage Protocol educational initiative was developed to help emergency medical services (EMS) professionals (administrators, medical directors, trauma system leadership, and providers) learn about and implement the revised Field Triage Decision Scheme. The Decision Scheme is intended to be the foundation for the development of local and regional field triage protocols.

In the United States, injury is the leading cause of death for persons aged 1–44 years. EMS professionals have a substantial impact on care of the injured and on public health. At an injury scene, EMS professionals determine the severity of injury, initiate medical management, and identify the most appropriate facility to which the patient should be transported. This destination decision is made through a process called field triage. Certain hospitals have additional expertise, resources, and equipment to treat severely injured patients. These facilities are known as trauma centers and are classified from Level I to Level IV. The risk for death of a severely injured person is 25% lower if the patient receives care at a Level I trauma center. However, not all patients require the services of a Level I trauma center; proper triage will ensure that patients who are injured less severely will be transported to a closer emergency department that is capable of managing their injuries.

In an effort to encourage use of improved triage procedures, CDC's National Center for Injury Prevention and Control (NCIPC) worked with experts and partner organizations to develop the 2006 Field Triage Decision Scheme. In support of the 2006 Field Triage Decision Scheme, NCIPC developed a multi-media toolkit aimed at EMS professionals. The toolkit includes *A Guide to the Field Triage Decision Scheme: The National Trauma Triage Protocol,* a poster, CD–ROM, and pocket card to help EMS providers, planners, and administrators effectively train others and use the Decision Scheme criteria within their own systems.

After the national distribution, NCIPC will conduct an online survey of EMS professionals who have received a toolkit to assess the short-term impact of the communication initiative directed at EMS professionals about field triage procedures. Specifically, the survey will assess how many EMS professionals who received a copy of the Decision Scheme are using it, how EMS professionals have used the Decision Scheme and accompanying toolkit materials, how the materials have been used to educate others, what EMS professionals learned from the materials, and how the Decision Scheme changed EMS professional's triage practices. Survey results will be used to identify the impact and applicability of the Decision Scheme and toolkit materials for EMS professionals.

NCIPC will also conduct focus groups with a segment of the survey respondents in order to have them elaborate on data submitted through the survey. These group interviews will focus on the extent the Decision Scheme is being used, how it is being implemented, self-reported changes in knowledge, and perceived impact on treatment of trauma patients. There are no costs to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
EMS professionals	Online survey	3,000	1	15/60	750
	Screening and Recruitment for Focus Groups.	48	1	5/60	4
	Focus Groups	64	1	1	64
Total					818

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[FR Doc. E9–22646 Filed 9–18–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0514]

Guidance for Industry on End-of-Phase 2A Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''End-of-Phase 2A Meetings.'' This guidance provides information on end-of-phase 2A (EOP2A) meetings for sponsors of investigational new drug applications (INDs). The purpose of an EOP2A meeting is to facilitate interaction between FDA and sponsors who seek guidance related to clinical trial design employing clinical trial simulation and quantitative modeling of prior knowledge (*e.g.*, drug, disease, placebo), designing trials for better dose response estimation and dose selection, and other related issues. This guidance is intended to further FDA initiatives directed at identifying opportunities to facilitate the development of innovative medical products and improve the quality of drug applications through early meetings with sponsors.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jogarao Gobburu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3186, Silver Spring, MD 20993–0002, 301–796–2460.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''End-of-Phase 2A Meetings.'' This guidance will meet one of the performance goals agreed to under the September 27, 2007, reauthorization of the Prescription Drug User Fee Act (PDUFA IV). Under section XI of the PDUFA IV Performance Goals, Expediting Drug Development, FDA agreed to publish by the end of fiscal year 2008 a draft guidance on EOP2A meetings and to complete the final guidance within 1 year of the close of the public comment period (*see http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm* at section XI.A).

FDA has a long-standing interest in defining dose or exposure-response relationships for the effectiveness and safety of new drugs. Accurate dose-response information is important for understanding how patients should take drugs to maximize desirable effects and minimize undesirable effects. Dose selection for phase 2 and phase 3 studies is a challenge in many drug development programs and poor choice may lead to trial failure. Improving early dose selection may increase the likelihood of future trial success. FDA recognizes trial planning may be improved by clinical trial simulations that employ quantitative models of drug exposure-response, placebo effect, and disease progression. This guidance on EOP2A meetings is intended to encourage the best use of this science to facilitate the exploration of trial design alternatives to increase the likelihood for successful trials.

In the **Federal Register** of September 26, 2008 (73 FR 55851), FDA announced the availability of a draft guidance of the same title. In response to public comments on the draft version, the guidance has been revised to clarify the following topics: (1) The type of information that should be submitted with the meeting request and the background package and (2) the role of the Office of New Drugs in preparing for and conducting EOP2A meetings.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the roles of model-based drug development together with early interaction between FDA and industry to improve late phase clinical trial success. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 and the guidance on ''Formal Meetings with Sponsors and Applicants for PDUFA Products'' have been approved under OMB control numbers 0910–0014 and 0910–0429, respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: September 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–22623 Filed 9–18–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections