DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DP 17
Display Date 4-22-08
Publication Date 4-25-08
Certifier

[Docket No. FDA–2008–N–0234]

Developing Guidance on Conducting Scientifically Sound Pharmacoepidemiologic Safety Studies Using Large Electronic Healthcare Data Sets; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) are announcing a public workshop entitled "Developing Guidance on Conducting Scientifically Sound Pharmacoepidemiologic Safety Studies Using Large Electronic Healthcare Data Sets." The purpose of the public workshop is to solicit information and views from interested persons on best practices and principles for the design and evaluation of pharmacoepidemiologic safety studies using large electronic healthcare data sets. The input from this workshop will be used to develop a draft Guidance to Industry, and to provide consistent review criteria for FDA to use in evaluating protocols and study reports submitted to the agency.

DATES: The public workshop will be held on Wednesday, May 7, 2008, from 8:30 a.m. to 5 p.m. See section III of this document for information on the deadline and on how to attend or present at the meeting. Written or electronic comments must be submitted to the docket by June 7, 2008.

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ADDRESSES: The public workshop will be held in the Ballroom at the Crowne Plaza Hotel Washington DC-Silver Spring, MD at 8777 Georgia Ave., Silver Spring, MD 20910.

Regardless of attendance at the public workshop, interested persons may submit written electronic comments 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*. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lana Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, rm. 6196, Silver Spring, MD 20903, 301–796–0518, FAX: 301–847–8753, e-mail: *lana.pauls@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA IV), FDA committed to certain performance goals (see *http://www.fda.gov/oc/pdufa4/pdufa4goals.html*). In one of these goals, FDA agreed to identify, with input from academia, industry, and others from the general public, epidemiology best practices and to develop guidance(s) describing these practices. In addition, in the Food and Drug Administration Amendments Act of 2007 (FDAAA, Public Law 110–85, 121 Stat. 823 *et seq.*), Congress directed FDA to develop and implement a postmarket risk identification and analysis system that would include, among other things, advanced analysis of drug safety data (FDAAA, section 905, 121 Stat. 944). This workshop

represents the first step in meeting the PDUFA goal and will provide valuable information as we build our active postmarket surveillance system.

New technologies and the ability to assemble large data sets for use in epidemiologic research of drug safety issues have precipitated a great deal of discussion over the appropriate use of these data in conducting pharmacoepidemiologic studies. FDA is committed to developing guidance to identify and encourage the use of best practices in the conduct of epidemiologic studies of drug safety issues by industry, FDA, and academic researchers. Experts from industry, academia, and the general public are invited to contribute ideas and concepts for consideration.

The workshop objectives are as follows: (1) Initiate constructive dialogue and information-sharing among regulators, researchers, the pharmaceutical industry, health organizations, and individuals about the design, conduct and interpretation of pharmacoepidemiologic safety studies using electronic healthcare data sets; (2) share current FDA experiences regarding the evaluation of protocols and study reports submitted to the agency; and (3) obtain input on developing consistent review criteria for FDA to use in evaluating protocols and study reports submitted to the agency.

Two panel discussions will focus on areas in which the agency requests input.

Panel 1 will focus on characteristics of electronic data used to conduct pharmacoepidemiologic studies for use in regulatory assessment of product safety. Topics include: differences in health care coverage, determinants of enrollment, country or region of data collection, characteristics of various healthcare systems and how these might impact on the interpretation and the

generalizability of the results to the U.S. patient population. Specific questions include:

1. What information and what level of detail are needed for FDA to ensure the appropriateness of the data source to address the product safety questions being asked? How does this differ by type of data source (electronic medical records (EMR) vs. claims)?

2. What are the challenges of using enrollment data for defining study populations in claims databases? Describe effective strategies for addressing the absence of formal enrollment data in some EMR systems.

3. Under what circumstances should FDA consider studies using non-U.S. electronic data sources in its assessment of product safety questions?

Panel 2 will focus on characteristics related to study design, conduct and interpretation of pharmacoepidemiologic safety studies, specifically those using electronic healthcare data sources. Topics include issues pertinent to definition of exposure, ascertainment of outcome, analysis of data, and interpretation of study findings and will address the following questions:

1. How can FDA assure that the study design accurately captures the clinical events, exposures of interest, and confounding factors needed to answer the product safety question under investigation?

2. What are effective strategies to address confounding by indication and the effect of measured and unmeasured confounders?

3. What are other challenges to internal and external validity in studies using EMR and claims databases? What are the best practices for addressing them?

FDA is working to refine the workshop agenda and to invite panel members. We are seeking broad participation by safety researchers, health system officials, the pharmaceutical industry, and others. We anticipate issuing

a summary of the workshop, including a discussion of implications and next steps for further development.

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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov.*

III. Attendance and Registration

The Workshop facility, the Ballroom in the Crowne Plaza Hotel at 8777 Georgia Ave. in Silver Spring, MD is not a secure facility. Seating will be made available on a first-come basis. Individual interested in attending the workshop need not register.

Individuals who wish to speak during the public workshop must register on or before April 7, 2008. You should identify the subject matter you wish to address during the public workshop. Please specify Panel 1, or Panel 2 (see **I. Background**). To register to speak, contact *lana.pauls@fda.hhs.gov* or call 301–796–0518.

Ample time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage written comments to the docket.

If you need special accommodations because of disability, please contact Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

IV. Workshop Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

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Dated: APR 17 2008

April 17, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

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