

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

## III. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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 part 25 have been approved under OMB control number 0910–0322 and the collections of information in part 314 have been approved under OMB control number 0910–0001.

## 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: April 23, 2015.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

[FR Doc. 2015–09869 Filed 4–28–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–N–0001]

#### Addressing Inadequate Information on Important Health Factors in Pharmacoepidemiology Studies Relying on Healthcare Databases; Public Workshop; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled “Addressing Inadequate Information on Important Health Factors in Pharmacoepidemiology Studies Relying on Healthcare Databases; Public

Workshop” that appeared in the **Federal Register** of April 17, 2015 (80 FR 21248). The document announced a public workshop. The document was published with the incorrect title. This document corrects that error.

#### **FOR FURTHER INFORMATION CONTACT:**

Leslie Wheelock, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4345, Silver Spring, MD, 301–796–8450, FAX: 301–847–8106, [leslie.wheelock@fda.hhs.gov](mailto:leslie.wheelock@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 17, 2015, in FR Doc. 2015–08846, on page 21248 the following correction(s) is/are made:

1. On page 21248, in the second column, starting at the sixth sentence of the first paragraph, the title “Methodological Considerations to Address Unmeasured Information About Important Health Factors in Pharmacoepidemiology Studies that Rely on Electronic Healthcare Databases to Evaluate the Safety of Regulated Pharmaceutical Products in the Postapproval Setting” is corrected to read “Inadequate Information on Important Health Factors in Pharmacoepidemiology Studies Relying on Healthcare Databases.”

Dated: April 23, 2015.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

[FR Doc. 2015–09966 Filed 4–28–15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–N–0280]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the

notice. This notice solicits comments on information collection on financial disclosure by clinical investigators.

**DATES:** Submit either electronic or written comments on the collection of information by June 29, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Financial Disclosure by Clinical Investigators**

(OMB Control Number 0910-0396)—  
Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial

arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

Under § 54.6, the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records with regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates that an average of

15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that it will take clinical investigators 15 minutes to submit such records to the sponsor.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification—54.4(a)(1) and (a)(2)— Form FDA 3454 .....	1,000	1	1,000	1	1,000
Disclosure—54.4(a)(3)—Form FDA 3455 .....	100	1	100	5	500
Total .....					1,500

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping—54.6 .....	1,000	1	1,000	0.25 (15 minutes)	250

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
54.4(b)—Clinical Investigators .....	7,106	1	7,106	0.17 (10 minutes)	1,208

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 23, 2015.

**Peter Lurie,**

*Associate Commissioner for Public Health  
Strategy and Analysis.*

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Neurological  
Disorders and Stroke; Amended Notice  
of Meeting**

Notice is hereby given of a change in the meeting of the National Institute of Neurological Disorders and Stroke Special Emphasis Panel, April 22, 2015, 08:00 a.m. to April 23, 2015, 06:00 p.m., Lorien Hotel & Spa, 1600 King Street,

Alexandria, VA, 22314 which was published in the **Federal Register** on April 3, 2015, 80FRN18241.

The meeting notice is amended to change the location of the meeting from the Lorien Hotel & Spa to the Hotel Monaco Alexandria. The date and time remain the same. The meeting is closed to the public.