Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 23, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–09902 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–D–1213]

Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity.'' This guidance is intended to supplement CDER's guidance for industry on ''Environmental Assessment of Human Drug and Biologics Applications,'' issued July 1998, by addressing specific considerations for drugs that have potential estrogenic, androgenic, or thyroid pathway activity (E, A, or T activity) in environmental organisms. It is intended to help sponsors of such drugs determine whether they should submit environmental assessments (EA) for new drug applications (NDAs) and certain NDA supplements, and to clarify what information such sponsors should include if they submit a claim of categorical exclusion instead of an EA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 29, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Raanan A. Bloom, Environmental Assessment Team, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2185, *CDER.EA.Team@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity.'' The National Environmental Policy Act of 1969 (Pub. L. 91–190) requires all Federal agencies to assess the environmental impact of their actions and to ensure that the interested and affected public is informed of the environmental analyses. FDA regulations at 21 CFR part 25 specify that EAs must be submitted as part of certain NDAs, abbreviated new drug applications (ANDAs), biologic license applications (BLAs), supplements to such applications, and investigational new drug applications (INDs), and for various other actions, unless the action qualifies for a categorical exclusion. Failure to submit either an EA or a claim of categorical exclusion is sufficient grounds for FDA to refuse to file or approve an application (§ 25.15(a), 21 CFR 314.101(d)(4), and 601.2(a) and (c)).

Categorical exclusions for actions related to human drugs and biologics are listed at § 25.31. This draft guidance focuses on the categorical exclusion for actions on NDAs and NDA supplements that would increase the use of an active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment would be below 1 part per billion (1 ppb) (§ 25.31(b)). Although an action that qualifies for this exclusion ordinarily does not require an EA, FDA will require ''at least an EA'' if ''extraordinary circumstances'' indicate that the specific proposed action (*e.g.,* the approval of the NDA) may significantly affect the quality of the human environment (§ 25.21). Research indicates that drugs with endocrine-related activity and, more specifically, drugs with E, A, or T activity have the potential to cause developmental or reproductive effects when present in the aquatic environment at concentrations below 1 ppb.[1]

FDA has, on a case-by-case basis, requested additional information from sponsors of NDAs and NDA supplements for drugs with E, A, or T activity to help it determine whether extraordinary circumstances exist. However, late cycle requests for additional environmental information have the potential to delay approval of applications. Accordingly, this guidance is intended to clarify that sponsors of drugs with potential E, A, or T activity should consult with the Agency early in product development concerning the information FDA may need to determine whether an EA will be required or whether a claim of categorical exclusion will be acceptable, and what information should be included in the EA or claim of categorical exclusion.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. 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.

[1] For example, see Section II.C (pp. 7–13) of USFDA, 2013, ''Response to Citizen Petition to the FDA Commissioner under the National Environmental Policy Act and Administrative Procedure Act Requesting an Amendment to an FDA Rule Regarding Human Drugs and Biologics,'' Docket No. FDA–2010–P–0377; U.S. Environmental Protection Agency (USEPA), Endocrine Disruptor Screening Program (EDSP), last accessed February 17, 2015, at *http://www.epa.gov/endo;* and Organisation for Economic Co-operation and Development (OECD), OECD Work Related to Endocrine Disrupters, last accessed February 17, 2015, at *http://www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm.*

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.*

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]

BILLING CODE 4164–01–P

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.*

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.