

comments should be received within 30 days of this notice.

Proposed Project

National Disease Surveillance Program III—CDC Support for Case Investigation, Contact Tracing, and Case Reports—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The international outbreak of Ebola virus disease (EVD) in West Africa began March 10, 2014. The initial cases were from southern Guinea, near its rural border with Liberia and Sierra Leone. Highly mobile populations contributed to increasing waves of person-to-person transmission of EVD that occurred in multiple countries in West Africa. The CDC activated its Emergency Operations Center on July 9,

2014 to help coordinate technical assistance and control activities with international partners and to deploy teams of public health experts to the affected countries.

The operations turned to the United States (U.S.) when the first imported case of EVD was diagnosed in Texas on September 30, 2014. In response, on October 11, 2014, the CDC Quarantine Stations and the Department of Homeland Security Customs and Border Patrol mobilized to screen, detect, and refer arriving travelers who were potential persons at risk for EVD to appropriate state, territorial, and local (STL) authorities. The CDC also increased its commitment to support STL public health authorities to combat and control the spread of EVD within their jurisdictions.

Thus in 2014, the CDC requested and received an expedited emergency review and approval from OMB of an

information collection request to initiate multiple urgently needed information collections in West Africa, at U.S. ports of entry, and within STL jurisdictions. These information collections allowed the agency to accomplish its primary mission on many fronts to quickly prevent public harm, illness, and death from the uncontrolled spread of EVD.

This new collection of information is designed to allow CDC to conduct active disease surveillance in support of and at the request of STL authorities among respondents that may include the general public, workers, and STL authorities. This should cut down on the need for multiple steps in emergency requests that were experienced in the first year of the 2014 Ebola virus response.

There are no costs to the respondents other than their time. The total annualized burden requested is 14,702 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
General Public—Case	Ebola Virus Disease Case Investigation Form—United States.	15	1	30/60
General Public—Case	Symptom Monitoring Form	15	42	5/60
General Public—Person Under Investigation (PUI).	Ebola Virus Disease Person Under Investigation (PUI) Form.	300	1	10/60
General Public—Person Under Investigation (PUI).	Symptom Monitoring Form	300	42	5/60
General Public—Contact	Ebola Virus Disease Contact Tracing Form—United States.	105	1	10/60
General Public—Contact	Symptom Monitoring Form	105	42	5/60
Healthcare Workers	Ebola Virus Disease Tracking Form for Healthcare Workers with Direct Patient Contact.	600	15	10/60
Healthcare Workers	Symptom Monitoring Form	600	57	5/60
Laboratory Personnel	Ebola Tracking Form for Laboratory Personnel.	600	15	10/60
Laboratory Personnel	Symptom Monitoring Form	600	57	5/60
Environmental Services Personnel	Ebola Tracking Form for Environmental Services Personnel.	600	15	10/60
Environmental Services Personnel	Symptom Monitoring Form	600	57	5/60
State, Territorial, and Local Public Health Authorities and Their Delegates.	White House Evening Report	15	42	10/60
Total				

Leroy A. Richardson,

Chief, Information Collection Review Office,
Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2306]

Testicular Toxicity: Evaluation During Drug Development; 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 “Testicular Toxicity: Evaluation During Drug Development.” The draft guidance addresses nonclinical findings that may raise concerns of a drug-related adverse effect on the testes, clinical monitoring of adverse testicular effects early in clinical development, and the design and conduct of a safety clinical trial assessing drug-related testicular toxicity. The draft guidance is intended

to assist sponsors developing drugs to identify nonclinical signals of testicular toxicity and to evaluate the potential for such toxicity in humans.

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 October 15, 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: Eufrecina Deguia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5348, Silver Spring, MD 20993–0002, 301–796–0881.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Testicular Toxicity: Evaluation During Drug Development.” This draft guidance is intended to help sponsors identify nonclinical signals that raise concern regarding the potential for human testicular toxicity and to evaluate those signals appropriately in human studies.

The draft guidance describes the standard battery of nonclinical studies that are used to assess the effects of pharmaceuticals on the male reproductive system. The draft guidance discusses findings in nonclinical studies that may increase the level of concern for drug-related testicular toxicity. Examples of nonclinical studies that could be used to further evaluate initial signals of testicular toxicity are also described. The draft guidance then provides a general approach on how to weigh the relevance of nonclinical findings, taking into account factors that can confound the interpretation of these findings.

If a concerning nonclinical signal is identified, the draft guidance presents suggestions for clinical monitoring when the drug is initially administered to humans. These suggestions aim to minimize the hazards to men while making possible the collection of data that will assist in evaluating the potential toxicity of the drug in the target population. These early studies, however, are not intended to be a definitive evaluation of the potential for testicular toxicity of the drug. Rather, they can provide clinical information that, together with the nonclinical information, will support a judgment as to whether the testicular toxicity signal warrants indepth evaluation in a dedicated safety study.

If a reasonable basis for concern of human testicular toxicity exists, a dedicated clinical safety trial with a primary objective of evaluating drug-related testicular toxicity may be warranted. The draft guidance provides recommendations for the design of such a trial, including conduct, endpoints, and presentation of results. These are general recommendations for the purpose of defining the role of drugs in testicular injury; however, the specific details of an individual trial may vary depending on the context of use of the drug product.

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 current thinking of FDA on the evaluation of testicular toxicity during drug development. It does not establish rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft 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 have been approved under OMB control number 0910–0014.

III. 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>.

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: July 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0429 (formerly Docket No. 2007D–0496)]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

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 certain labeling statements for nonprescription human drug products marketed without an approved application.

DATES: Submit either electronic or written comments on the collection of information by September 15, 2015.

ADDRESSES: Submit electronic comments on the collection of