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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 15, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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FDA is announcing the availability of a draft guidance for industry entitled ''Testicular Toxicity: Evaluation During Drug Development.'' This draft guidance is intended to help sponsors identify nonclinical signals that raise concern regarding the potential for human testicular toxicity and to evaluate those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The draft guidance describes the standard battery of nonclinical studies that are used to assess the effects of pharmaceuticals on the male reproductive system. The draft guidance discusses findings in nonclinical studies that may increase the level of concern for drug-related testicular toxicity.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 The draft guidance then provides a general approach on how to weigh the relevance of nonclinical findings, taking into account factors that can confound the interpretation of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If a concerning nonclinical signal is identified, the draft guidance presents suggestions for clinical monitoring when the drug is initially administered to humans.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/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17557 Filed 7–16–15; 8:45 am]

BILLING CODE 4164–01–P

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

information via the internet at *http://www.regulations.gov.* Submit written comments on the collection of information to the Dockets Management Branch (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: (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.

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

OMB Control Number 0910–0641—Extension

Section 502(x) of the FD&C Act (21 U.S.C. 352(x)), which was added by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462), requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a manufacturer, packer, and distributor may receive a report of a serious adverse event associated with the product. The guidance document contains questions and answers relating to this labeling requirement and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the labeling requirements of section 502(x) of the FD&C Act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 502(x) of the FD&C Act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (pursuant to section 502(b)(1) of the FD&C Act) appears on the label of a nonprescription drug product marketed in the United States without an approved application.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Including a domestic address or phone number and a statement of its purpose on OTC drug labeling (21 U.S.C. 502(x))	300	3	900	4	3,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17558 Filed 7–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0967]

Public Meeting on Patient-Focused Drug Development for Huntington's and Parkinson's Diseases

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for Huntington's disease and Parkinson's disease. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of Huntington's disease and Parkinson's disease on daily life and patient views on treatment approaches. Although these are both neurological diseases, since they are quite distinct, FDA will structure this public meeting into two distinct sessions. The morning session, scheduled from 9 a.m. to 1 p.m., will be