submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Scott Goldie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Multiple Endpoints in Clinical Trials.'' This guidance describes various strategies for grouping and ordering endpoints for analysis and applying some well-recognized statistical methods for managing multiplicity within a study. FDA's International Conference on Harmonization (ICH) guidance for industry ''E9 Statistical Principles for Clinical Trials'' is a broad-ranging guidance that includes discussion of multiple endpoints. This draft guidance provides greater detail on the topic of multiple endpoints. The issuance of this draft guidance represents partial fulfillment of an FDA commitment under the Food and Drug Administration Amendments Act of 2007. (Title I of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85)). Under section XI (Expediting Drug Development) of the Prescription Drug User Fee Act (PDUFA) Performance Goals, FDA agreed to develop and publish for comment draft guidance on ''Multiple Endpoints in Clinical Trials,'' and to complete the final guidance within one year of the close of the public comment period of the PDUFA Performance Goals (see *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*).

Failure to account for multiplicity when there are several clinical endpoints evaluated in a study can lead to false positive conclusions regarding the effects of the drug. The regulatory concern regarding multiplicity arises principally in the evaluation of clinical trials intended to demonstrate effectiveness and support drug approval; however, this issue is important throughout the drug development process.

The focus of this draft guidance is control of the Type 1 error rate for the planned primary and secondary endpoints of a clinical trial so that the major findings are well supported. Multiplicity adjustments provide a means for controlling Type 1 error when there are multiple analyses of the drug's effects. The issues of multiplicity and methods to address them are illustrated in the draft guidance with examples of different study endpoints. Both the issues and methods that apply to multiple endpoints also apply to other sources of multiplicity, including multiple doses, time points, or study population subgroups.

Once a trial is successful (demonstrates effectiveness or ''wins'' on the primary endpoint(s)), there are many other attributes of a drug's effects that may be described. Analyses that describe these other attributes of a drug can be informative and are often included in physician labeling. Such descriptive analyses are not the subject of this draft guidance and are not addressed in detail.

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 multiple endpoints in clinical trials. It does not establish any 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. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.regulations.gov*.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00695 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1496]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys (Generic Clearance)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 the use of rapid response surveys to obtain data on safety information to support quick turnaround decisionmaking about potential safety problems or risk management solutions from health care professionals, hospitals, and other user facilities (*e.g.,* nursing homes, etc.); consumers; manufacturers of biologics, drugs, and medical devices; distributors; and importers, when FDA must quickly determine whether or not a problem with a biologic, drug, or medical device impacts the public health.

DATES: Submit either electronic or written comments on the collection of information by March 14, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–1496 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys (Generic Clearance).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

FDA Rapid Response Surveys (Generic Collection), OMB Control Number 0910–0500—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. Under section 519 of the FD&C Act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-

related deaths, serious injuries, and malfunctions to FDA; to require user facilities to report device-related deaths directly to FDA and to manufacturers; and to report serious injuries to the manufacturer. Section 522 of the FD&C Act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the FD&C Act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the FD&C Act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for Agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently, FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA Forms 3500 and 3500A (OMB control number 0910–0291) and the vaccine adverse event reporting system.

FDA is seeking OMB clearance to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community based health care professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other health care professionals, patients, consumers, and risk managers working in medical facilities. FDA will use the information gathered from these surveys to quickly obtain vital information about medical product risks and interventions to reduce risks so the Agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

FDA projects 6 emergency risk related surveys per year with a sample of between 50 and 10,000 respondents per survey. FDA also projects a response time of 0.5 hour per response. These estimates are based on the maximum sample size per questionnaire that FDA may be able to obtain by working with health care professional organizations. The annual number of surveys was determined by the maximum number of surveys per year FDA has ever conducted under this collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA Rapid Response Survey	10,000	6	60,000	0.5	30,000

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

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00632 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1777]

Factors To Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions; Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions.'' The purpose of this guidance is to provide greater clarity for FDA staff and Investigational Device Exemptions (IDE) application sponsors and sponsor-investigators regarding the principal factors that the Agency considers when assessing the benefits and risks of IDE applications for human clinical study. The guidance also characterizes benefits in the context of investigational research, which includes direct benefits to the subjects and benefits to others.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your