sections of the existing ''Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems'' guidance.

In the **Federal Register** on August 30, 2013 (78 FR 53773), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 30, 2013. Four sets of comments were received and, in general, were supportive of the guidance. There were multiple comments regarding the need for clarification of acceptance criteria and the desire for a flow chart to visualize the overall testing paradigm described in the guidance update. In response to these comments, FDA revised the guidance document to include more specific information on acceptance criteria for pitting corrosion and surface oxide properties, as well as a flow chart. General concerns were noted that the guidance modifications might be interpreted to be more burdensome. However, the addition of the flowchart is intended to clarify when testing beyond pitting corrosion testing should be considered, and based on prior experience, it is anticipated that few stents will need further assessment. In addition, there were several comments regarding the lack of utility of post-fatigue pitting corrosion assessment. In response to these comments, as well as discussions at the March 2012 workshop, FDA has removed the suggestion to consider post-fatigue pitting corrosion testing when damage to samples is noted due to fatigue testing. There was also a comment that the 60-day suggested duration for nickel release may be unnecessarily long and burdensome, and in response, FDA has reduced the minimum duration to 30 days if the release rate falls below a predetermined level based on toxicological risk assessment.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on certain non-clinical testing for coronary and peripheral stents. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems '' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1826 to identify the guidance you are requesting.

IV. 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 814 have been approved under OMB control number 0910–0231.

V. 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.*

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20308 Filed 8–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0640]

Uncomplicated Gonorrhea: Developing Drugs for Treatment; 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 guidance for industry entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of uncomplicated gonorrhea. This guidance finalizes the draft guidance of the same name issued on June 19, 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 guidance document.

Submit electronic comments on the 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: Maria Allende or Joseph Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of uncomplicated gonorrhea.

This guidance describes approaches for trial designs for the evaluation of new drugs for the treatment of uncomplicated gonorrhea. The guidance focuses on the noninferiority trial design and describes an efficacy endpoint for which there is a well-defined treatment effect. The guidance also provides the justification for the noninferiority margin. After careful consideration of comments received in response to the draft guidance issued on June 19, 2014 (79 FR 35172), we added a brief discussion of the potential for pregnant women to be included in specific populations for drug development. In addition, this guidance

reflects recent developments in scientific information that pertain to drugs being developed for the treatment of uncomplicated gonorrhea.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on developing drugs for the treatment of uncomplicated gonorrhea. 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. The Paperwork Reduction Act of 1995

This 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 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

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: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20306 Filed 8–17–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2918]

Pilot Program for Medical Device Reporting on Malfunctions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is soliciting nominations for participation in a pilot program for the submission of medical device reports for malfunctions of class I devices and certain class II devices in summary format on a quarterly basis. Under the Medical Device Reporting on Malfunctions pilot program, FDA intends to work with manufacturers to identify candidates for the pilot program and intends to continue to accept nominations until candidates for the pilot program have been selected.

DATES: FDA will begin accepting nominations for participation in the voluntary pilot program on September 1, 2015, and intends to continue to accept nominations until candidates for the pilot program have been selected. See section II for instructions on how to participate in the voluntary pilot program.

FOR FURTHER INFORMATION CONTACT: William C. Maloney, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 3236, Silver Spring, MD 20993–0002, *227pilot@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), amended section 519(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(a)), relating to the reporting of device malfunctions to FDA under part 803 (21 CFR part 803). Specifically, FDAAA amended the FD&C Act to require that medical device reports of malfunctions for class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining—with the exception of any type of class I or II device which FDA has, by notice, published in the **Federal Register** or by letter to the person who is the manufacturer or importer of the device, indicated should be subject to part 803 in order to protect the public health—be submitted in accordance with the criteria established by FDA (section 519(a)(1)(B)(ii) of the FD&C Act).[1] The criteria must require the reports to be in summary form and made on a quarterly basis (section 519(a)(1)(B)(ii) of the FD&C Act).

FDA is considering the development of malfunction reporting criteria for devices subject to section 519(a)(1)(B)(ii) of the FD&C Act. In the interim, FDA clarified that all manufacturers of class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining, must continue to report in full compliance with part 803 (76 FR 12743 at 12744, March 8, 2011).

The malfunction reporting requirements for class III devices and those class II devices that are permanently implantable, life supporting, or life sustaining were not altered by FDAAA. Under the amended section 519(a) of the FD&C Act, device manufacturers are to continue to submit malfunction reports in accordance with part 803 for all class III devices and for those class II devices that are permanently implantable, life supporting, or life sustaining, unless FDA grants an exemption or variance from, or an alternative to, a requirement under such regulations under § 803.19 (section 519(a)(1)(B)(i) of the FD&C Act).

In addition, under section 519(a) of the FD&C Act, as amended by FDAAA, there is no change to the obligation for an importer to submit malfunction reports to the manufacturer in accordance with part 803 for devices that it imports into the United States (section 519(a)(1)(B)(iii) of the FD&C Act).

FDA intends to use the information learned and experiences gained from the pilot program to develop the malfunction reporting criteria for devices subject to section 519(a)(1)(B)(ii) of the FD&C Act.

II. Pilot Program for Medical Device Reporting (MDR) on Malfunctions

FDA has developed this pilot program for manufacturers interested in submitting malfunction reports for certain devices in a summary format on a quarterly basis. This notice provides:

[1] In light of section 1003(d) of the FD&C Act (21 U.S.C. 393(d)) and the Secretary of Health and Human Services' (the Secretary's) delegation to the Commissioner of Food and Drugs, statutory references to ''the Secretary'' have been changed to ''FDA'' or the ''Agency'' in this document.