E. Duplicative, Overlapping, or Conflicting Federal Rules

The Commission has not identified any other federal statutes, rules, or policies that would duplicate, overlap, or conflict with the proposed amendments. The Commission invites comment and information on this issue.

F. Significant Alternatives to the Proposed Amendments

The Commission has not proposed any specific small entity exemption or other significant alternatives, as the proposed amendments simply clarify and update the Rules' guaranty provisions by, among other things, replacing the requirement that suppliers that provide a guaranty sign under penalty of perjury with a certification requirement. Under these limited circumstances, the Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the proposed amendments. As discussed above, adopting NRF's proposed changes is unnecessary to allow electronic compliance with the Fur Rules.

Nonetheless, the Commission seeks comment and information on the need, if any, for alternative compliance methods that would reduce the economic impact of the Fur Rules on small entities. If the comments filed in response to this document identify small entities that would be affected by the proposed amendments, as well as alternative methods of compliance that would reduce the economic impact of the proposed amendments on such entities, the Commission will consider the feasibility of such alternatives and determine whether they should be incorporated into the final Rules.

VII. Paperwork Reduction Act

The Rules contain various ''collection of information'' (*e.g.,* disclosure and recordkeeping) requirements for which the Commission has obtained OMB clearance under the Paperwork Reduction Act (''PRA'').[35] As discussed above, the Commission proposes amending sections 301.47 and 301.48 to clarify and update the Rules' guaranty provisions by, among other things, replacing the requirement that suppliers provide a guaranty signed under penalty of perjury with a certification requirement for continuing guaranties that must be renewed every year.

The proposed amendments to the guaranties would impose no additional collection of information requirements. The proposal that continuing guaranty certifications expire after one year would likely impose minimal additional costs on businesses that choose to provide a guaranty.

VIII. Proposed Rule

List of Subjects in 16 CFR Part 301

Furs, Labeling, Trade practices.

For the reasons discussed in the preamble, the Federal Trade Commission proposes to amend title 16, Chapter I, Subchapter C, of the Code of Federal Regulations, part 301, as follows:

PART 301—RULES AND REGULATIONS UNDER THE FUR PRODUCTS LABELING ACT

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 15 U.S.C. 69 et seq.

■ 2. Revise § 301.47 to read as follows:

§ 301.47 Form of separate guaranty.

The following is a suggested form of separate guaranty under section 10 of the Act which may be used by a guarantor residing in the United States, on and as part of an invoice or other document in which the merchandise covered is listed and specified and which shows the date of such document and the signature and address of the guarantor:

We guarantee that the fur products or furs specified herein are not misbranded nor falsely nor deceptively advertised or invoiced under the provisions of the Fur Products Labeling Act and rules and regulations thereunder.

Note: The printed name and address on the invoice or other document will suffice to meet the signature and address requirements.

■ 3. Amend § 301.48 by revising paragraphs (a)(2) and (b) to read as follows:

§ 301.48 Continuing guaranty filed with Federal Trade Commission

(a) * * *

(2) Continuing guaranties filed with the Commission shall continue in effect for one year unless revoked earlier. The guarantor shall promptly report any change in business status to the Commission.

* * *

(b) Any person who has a continuing guaranty on file with the Commission may, during the effective dates of the guaranty, give notice of such fact by setting forth on the invoice or other document covering the marketing or handling of the product guaranteed the following: ''Continuing guaranty under the Fur Products Labeling Act filed with the Federal Trade Commission.''

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2013–14671 Filed 6–18–13; 8:45 am]

BILLING CODE 6750–01–P

[35] 44 U.S.C. 3501 *et seq.* The Commission recently published its PRA burden estimates for the current information collection requirements under the Fur Rules. *See Federal Trade Commission: Agency Information Collection Activities; Proposed Collection; Comment Request,* 76 FR 77230 (Dec. 12, 2011) and *Federal Trade Commission: Agency Information Collection Activities; Submission for OMB Review; Comment Request,* 77 FR 10744 (Feb. 23, 2012). On March 26, 2012, OMB granted clearance through March 31, 2015, for these requirements and the associated PRA burden estimates. The OMB control number is 3084–0101.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2013–N–0544]

Microbiology Devices; Reclassification of Nucleic Acid-Based Systems for *Mycobacterium tuberculosis* Complex in Respiratory Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify nucleic acid-based in vitro diagnostic devices for the detection of *Mycobacterium tuberculosis* complex in respiratory specimens from class III (premarket approval) into class II (special controls). FDA is also issuing the draft special controls guideline entitled ''Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens.'' These devices are intended to be used as an aid in the diagnosis of pulmonary tuberculosis.

DATES: Submit either electronic or written comments on the proposed rule by August 19, 2013. See section XIII for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0544, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0544 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), 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:

Janice A. Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5554, Silver Spring, MD 20993–0002, 301–796–6207

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the FD&C Act, FDA clears or approves the three classes of medical devices for commercial distribution in the United States through three regulatory processes: Premarket approval (PMA), product development protocol, and premarket notification (a premarket notification is generally referred to as a ''510(k)'' after the section of the FD&C Act where the requirement is found). The purpose of a premarket notification is to demonstrate that the new device is substantially equivalent to a legally marketed predicate device. Under section 513(i) of the FD&C Act, a device is substantially equivalent if it has the same intended use and technological characteristics as a predicate device, or has different technological characteristics but data demonstrate that the new device is as safe and effective as the predicate device and does not raise different issues of safety or effectiveness.

FDA determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807). Section 510(k) of the FD&C Act and the implementing regulations in part 807, subpart E, require a person who intends to market a medical device to submit a premarket notification submission to FDA before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use.

In accordance with section 513(f)(1) of the FD&C Act, devices that were not in commercial distribution before May 28, 1976, the date of enactment of the 1976 amendments, generally referred to as postamendment devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA classifies the device into class I or class II by issuing an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval or the device is reclassified into class I or class II. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 of FDA's regulations.

Section 513(f)(2) of the FD&C Act establishes procedures for ''de novo'' risk-based review and classification of postamendment devices automatically classified into class III by section 513(f)(1). Under these procedures, any person whose device is automatically classified into class III by section 513(f)(1) of the FD&C Act may seek reclassification into class I or II, either after receipt of an order finding the device to be not substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval, or at any time after determining there is no legally marketed device upon which to base a determination of substantial equivalence. In addition, under section 513(f)(3) of the FD&C Act, FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a device classified into class III under section 513(f)(1).

II. Regulatory Background of the Device

A nucleic acid-based in vitro diagnostic device for the detection of M. tuberculosis complex in respiratory specimens is a postamendment device classified into class III under section 513(f)(1) of the FD&C Act in 1995. Consistent with the FD&C Act and FDA's regulations in 21 CFR 860.130(a), FDA believes that these devices should be reclassified from class III into class II because there is sufficient information from FDA's accumulated experience with these devices to establish special controls that can provide reasonable assurance of the device's safety and effectiveness.

III. Identification

Nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens are qualitative nucleic acid-based in vitro diagnostic devices intended to detect *M. tuberculosis* complex nucleic acids extracted from human respiratory specimens. These devices are non-multiplexed and intended to be used as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings. These devices do not include devices intended to detect the presence of organism mutations associated with drug resistance. Respiratory specimens may include sputum (induced or expectorated), bronchial specimens (e.g., bronchoalveolar lavage or bronchial aspirate), or tracheal aspirates.

IV. Background for Proposed Reclassification Decision

At an FDA/Centers for Disease Control (CDC)/National Institute of Allergy and Infectious Diseases public

workshop entitled ''Advancing the Development of Diagnostic Tests and Biomarkers for Tuberculosis'', held in Silver Spring, MD, on June 7 and 8, 2010, the class III designation for nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens was raised as a barrier to advancing *M. tuberculosis* diagnostics (Ref. 1). Based on discussion at the public workshop, FDA agreed to consider this issue further and subsequently convened a meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee on June 29, 2011. Panel members were asked to discuss if sufficient risk mitigation was possible for FDA to initiate the reclassification process from class III to class II devices for this intended use through the drafting of a special controls guidance. All panel members expressed the opinion that sufficient data and information exist such that the risks of false positive and false negative results can be mitigated to allow a special controls guideline to be created that would support reclassification from class III to class II for nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens (Ref. 2). All outside speakers at the open public hearing session during the meeting also spoke in favor of reclassification.

V. Classification Recommendation

FDA is proposing that nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens be reclassified from class III to class II. FDA believes that class II with special controls (guideline document) would provide reasonable assurance of the safety and effectiveness of the device. Section 510(m) of the FD&C Act provides that a class II device may be exempt from the premarket notification requirements under section 510(k), if the Agency determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this device, FDA believes that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, does not intend to exempt the device from the premarket notification requirements.

VI. Risks to Health

After considering the information discussed by the Microbiology Devices Panel during the June 29, 2011, meeting, the published literature, and the Medical Device Reporting system reports, FDA believes the following risks are associated with nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens: (1) False positive test results may lead to incorrect treatment of the individual with possible adverse effects. The patient may be subjected to unnecessary isolation and/or other human contact limitations. Unnecessary contact investigations may also occur; (2) False negative test results could result in disease progression and the risk of transmitting disease to others; and (3) Biosafety risks to health care workers handling specimens and control materials with the possibility of transmission of tuberculosis infection to health care workers.

VII. Summary of the Reasons for Reclassification

FDA, consistent with the opinions expressed by the Microbiology Devices Panel of the Medical Devices Advisory Committee, believes that the establishment of special controls, in addition to general controls, provides reasonable assurance of the safety and effectiveness of nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens.

1. The safety and effectiveness of nucleic acid-based systems for *M. tuberculosis* complex have become well-established since approval of the first device for this use in 1995.

2. The risk of false positive test results can be mitigated by specifying minimum performance standards in the special controls guideline and including information regarding patient populations appropriate for testing in the device labeling. Additional risk mitigation strategies include the indication for use that the device be used as an aid to the diagnosis of pulmonary tuberculosis in conjunction with other clinical and laboratory findings. The device also should be accurately described and have labeling that addresses issues specific to these types of devices.

3. The risk of false negative test results can be mitigated by specifying minimum performance standards for test sensitivity in the special controls guideline and ensuring that different patient populations are included in clinical trials. Additional risk mitigation strategies include the indication for use that the device be used as an aid to the diagnosis of pulmonary tuberculosis in conjunction with other clinical and laboratory findings. The device also should be accurately described and have appropriate labeling that addresses issues specific to these types of devices.

4. Biosafety risks to health care workers handling specimens and control materials with the possibility of transmission of tuberculosis infection to health care workers could be addressed similarly to existing devices of this type that we have already approved. It is believed there are no additional biosafety risks introduced by reclassification from class III to class II. The need for appropriate biosafety measures can be addressed in labeling recommendations that are included in the special controls guideline and by adherence to recognized laboratory biosafety procedures.

Based on FDA's review of published literature, the information presented by outside speakers invited to the Microbiology Devices meeting, and the opinions of panel members expressed at that meeting, FDA believes that there is a reasonable basis to determine that nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens can provide the significant benefit of rapid detection of infection in patients with suspected tuberculosis as compared to traditional means of diagnosis. For patients with acid-fast smear negative tuberculosis, nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens are currently the only laboratory tests available for rapid detection of active pulmonary tuberculosis. Rapid identification of patients with active tuberculosis may have significant benefits to the infected patient by earlier diagnosis and management as well as potentially significant effects on the public health by limiting disease spread.

Nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens have been approved for marketing by FDA for over 15 years. There is substantial scientific and medical information available regarding the nature, complexity, and problems associated with these devices. Revised public health recommendations for use, published by CDC on January 16, 2009, recommended the use of nucleic acid amplification testing in conjunction with acid-fast microscopy and culture and specifically states that ''Nucleic acid amplification testing should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary [tuberculosis] for whom a diagnosis of [tuberculosis] is being considered but has not yet been established, and for whom the test result would alter case

management or [tuberculosis] control activities'' (Ref 3).

VIII. Special Controls

FDA believes that the measures set forth in the special controls guideline entitled ''Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens'' are necessary, in addition to general controls, to mitigate the risks to health described in section VI in this document. As seen in table 1, the special controls set forth in the guideline for this device address each of the identified risks.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES

Identified risks	Recommended mitigation measures
False positive test results may lead to incorrect treatment of the individual with possible adverse effects. The patient may be subjected to unnecessary isolation and/or other human contact limitations. Unnecessary contact investigations may also occur.	Device Description. Performance Studies. Labeling.
False negative test results could result in disease progression, and the risk of transmitting disease to others.	Device Description. Performance Studies. Labeling.
Biosafety risks to health care workers handling specimens and control materials with the possibility of transmission of tuberculosis infection to health care workers.	Labeling.

If this proposed rule is finalized, nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens will be reclassified into class II. As discussed in this document, the reclassification will be codified in 21 CFR 866.3372. Firms submitting a 510(k) for a nucleic acid-based in vitro diagnostic devices for the detection of *M. tuberculosis* complex in respiratory specimens will need either to: (1) Comply with the particular mitigation measures set forth in the special controls guideline or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. Adherence to the criteria in the guideline, when finalized, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of the devices.

IX. Electronic Access to the Special Controls Guideline

Persons interested in obtaining a copy of the draft guideline may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidelines and guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. The guideline is also available at *http://www.regulations.gov*.

To receive ''Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1788 to identify the guideline you are requesting.

X. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this proposed reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Paperwork Reduction Act of 1995

This proposed rule 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 56.115 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

XII. Clarifications to Special Controls Guidelines

This special controls guideline reflects changes the Agency is making to clarify its position on the binding nature of special controls. The changes include referring to the document as a ''guideline,'' as that term is used in section 513(a) of the FD&C Act, which the Secretary has developed and disseminated to provide a reasonable assurance of safety and effectiveness for class II devices, and not a ''guidance,'' as that term is used in 21 CFR 10.115. The guideline clarifies that firms will need either to: (1) Comply with the particular mitigation measures set forth in the special controls guideline or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. Finally, the guideline uses mandatory language to emphasize that firms must comply with special controls to legally market their class II devices. These revisions do not represent a change in FDA's position about the binding effect of special controls, but rather are intended to address any possible confusion or misunderstanding.

XIII. Proposed Effective Date

FDA proposes that any final regulation based on this proposed rule become effective 30 days after its date of publication in the **Federal Register**.

XIV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a

significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed reclassification would relieve manufacturers of premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e) it would not create new burdens. Thus, the Agency proposes to certify that the proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule, if finalized, to result in any 1-year expenditure that would meet or exceed this amount.

Our estimate of benefits annualized over 20 years is $11.85 million at a 3 percent discount rate and $7.83 million at a 7 percent discount rate. The change in pre- and post-marketing requirements between a 510(k) and a PMA lead to benefits in the form of reduced submission costs, review-related activities, and inspections. Another unquantifiable benefit from the rule is that a decrease in entry could lead to further product innovation. FDA is unable to quantify the costs that could arise if there is a change in risk which could lead to adverse events, recalls, warning letters, or unlisted letters.

The full discussion of economic impacts is available in docket FDA–2013–N–0544 at *http://www.regulations.gov*, and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 4).

XV. Comments

Interested persons may submit either electronic comments regarding this document or the associated Special Controls guideline 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*.

XVI. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov*. (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Transcript of the Tuberculosis Public Workshop, June 7, 2010, (Available at: *http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/CriticalPathInitiative/UpcomingEventsonCPI/UCM289182.doc*, accessed on January 25, 2012.)

2. Transcript of FDA's Microbiology Devices Panel Meeting, June 29, 2011. (Available at: *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MicrobiologyDevicesPanel/UCM269469.pdf.*)

3. ''Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis,'' *Morbidity and Mortality Weekly Report (MMWR),* vol. 58, pp. 7–10, January 16, 2009. (Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm*, accessed on July 26, 2011.)

4. Full Disclosure Preliminary Regulatory Impact Analysis of the proposed rule ''Microbiology Devices; Reclassification of Nucleic Acid-Based Systems for *Mycobacterium tuberculosis* Complex in Respiratory Specimens,'' Docket No. FDA–2013–N–0544.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 866.3372 to subpart D to read as follows:

§ 866.3372 Nucleic acid-based in vitro diagnostic devices for the detection of Mycobacterium tuberculosis complex in respiratory specimens.

(a) *Identification.* Nucleic acid-based in vitro diagnostic devices for the detection of *Mycobacterium tuberculosis* complex in respiratory specimens are qualitative nucleic acid-based in vitro diagnostic devices intended to detect *Mycobacterium tuberculosis* complex nucleic acids extracted from human respiratory specimens. These devices are non-multiplexed and intended to be used as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings. These devices do not include devices intended to detect the presence of organism mutations associated with drug resistance. Respiratory specimens may include sputum (induced or expectorated), bronchial specimens (e.g., bronchoalveolar lavage or bronchial aspirate), or tracheal aspirates.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA document entitled ''Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens.'' For availability of the guideline document, see § 866.1(e).

Dated: June 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14552 Filed 6–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2013–N–0581]

Cardiovascular Devices; Reclassification of Intra-Aortic Balloon and Control Systems (IABP) for Acute Coronary Syndrome, Cardiac and Non-Cardiac Surgery, or Complications of Heart Failure; Effective Date of Requirement for Premarket Approval for IABP for Other Specific Intended Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed administrative order to reclassify intra-aortic balloon and