performance with all HCV genotypes detected by the device.

(B) Detailed documentation of clinical performance testing from either:

(*1*) A multisite clinical study with an appropriate number of clinical samples from chronically HCV infected patients in which the results are compared to an FDA-cleared or approved quantitative HCV RNA test, or a comparator that FDA has determined is appropriate. This study must include a sufficient number of HCV positive samples containing an analyte concentration near the LLoQ to describe performance at this level. Clinical samples must cover the full range of the device output and must be consistent with the distribution of these genotypes in the U.S. population. Clinical samples may be supplemented with diluted clinical samples for those viral load concentrations that are not sufficiently covered by natural clinical specimens, or

(*2*) A clinical study with prospectively collected samples demonstrating clinical validity of the device.

(C) Detailed documentation of a qualitative analysis near the lower end of the measuring range demonstrating acceptable performance when used as an aid in diagnosis.

(5) For devices intended for HCV RNA genotyping, in addition to the special controls listed in paragraphs (b)(1) and (2) of this section, design verification and validation must include the following:

(i) Detailed documentation of an analytical performance study demonstrating the LoD for all HCV genotypes detected by the device.

(ii) Detailed documentation, including results, of a multisite clinical study that assesses genotyping accuracy (*i.e.,* the proportion of interpretable results that match with the reference method result) and the genotyping rate (*i.e.,* the proportion of results that were interpretable).

(6) For any nucleic acid-based HCV RNA test intended for Point of Care (PoC) use, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, apply:

(i) Clinical studies must be conducted at PoC sites.

(ii) Additional labeling must include a brief summary of the instructions for use that are appropriate for use in a PoC environment.

Dated: March 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06820 Filed 4–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2020–N–1082]

Microbiology Devices; Reclassification of Certain Hepatitis C Virus Antibody Assays Devices, To Be Renamed Hepatitis C Virus Antibody Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed amendment; proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to reclassify certain hepatitis C virus (HCV) antibody assay devices intended for the qualitative detection of HCV, postamendments class III devices (product code MZO) into class II (general controls and special controls), subject to premarket notification. FDA is also proposing a new device classification regulation with the name ''hepatitis C virus (HCV) antibody tests'' along with the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness for these devices. FDA is proposing this reclassification on its own initiative. If finalized, this order will reclassify these types of devices from class III (general controls and premarket approval) to class II (general controls and special controls) and reduce the regulatory burdens associated with these devices, as these types of devices will no longer be required to submit a premarket approval application (PMA), but can instead submit a premarket notification under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and obtain clearance before marketing their device.

DATES: Submit either electronic or written comments on the proposed order by June 1, 2020. Please see section XI of this document for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 1, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 1, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 below (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2020–N–1082 for ''Reclassification of Certain Hepatitis C Virus Antibody Assay Devices, To Be Renamed Hepatitis C Virus Antibody Tests.'' Received comments, those filed in a timely manner (see **ADDRESSES**) will be placed in the docket and, except for

those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Maria Ines Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3104, Silver Spring, MD 20993–0002, 301–796–7017, *Maria.Garcia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The FD&C Act, as amended by the Medical Device Amendments of 1976 (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), 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), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), among other amendments, establishes 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 (general controls and special controls), and class III (general controls and premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, (1) FDA reclassifies the device into class I or class II, or (2) FDA issues 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. FDA 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 (21 CFR part 807), subpart E, of the regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

FDA relies upon ''valid scientific evidence,'' as defined in section 513(a)(3) and 21 CFR 860.7(c)(2), in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available (see section 520(c) of the FD&C Act). Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA (see section 520(c) of the FD&C Act).

In accordance with section 513(f)(3) of the FD&C Act, the Agency is issuing this proposed order to reclassify hepatitis C virus (HCV) antibody tests intended for the qualitative detection of HCV, postamendment class III devices, into class II (general controls and special

controls), subject to premarket notification because the Agency believes the standard in section 513(a)(1)(B) of the FD&C Act is met as there is sufficient information to establish special controls, which, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.[1]

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to reasonably assure the safety and effectiveness of HCV antibody tests intended for the qualitative detection of HCV. Therefore, the Agency does not intend to exempt these proposed class II devices from premarket notification requirements. If this proposed order is finalized, persons who intend to market this type of device must submit to FDA a premarket notification under section 510(k) of the FD&C Act.

II. Regulatory History of the Devices

This proposed order applies to HCV antibody assay device for use as a prescription device as an aid in the diagnosis of HCV infection. These are prescription devices that are assigned product code MZO. On August 30, 2001, FDA approved its first HCV antibody test (Ortho-Clinical Diagnostics, Inc.'s VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI–HCV REAGENT PACK AND CALIBRATOR) intended for use as a prescription device as an aid in the diagnosis of HCV infection by a qualified licensed healthcare professional in conjunction with other relevant clinical and laboratory findings through its PMA process under section 515 of the FD&C Act (21 U.S.C. 360e). In a May 22, 2002, **Federal Register** notice (67 FR 36009), FDA announced the PMA approval order and the availability of the Summary of Safety and Effectiveness Data (SSED) for this device.

Since the first approval order, FDA has approved nine additional original PMAs for HCV antibody tests that are prescription devices intended for use as an aid in the diagnosis of HCV infection by a qualified licensed healthcare professional in conjunction with other relevant clinical and laboratory findings (hereafter referred to as ''HCV antibody test'').

A review of the medical device reporting databases indicates that there is a low number of reported events for HCV antibody tests relative to the number of tests conducted using these devices. Events reported included false positive results, low test results, false negative results, unspecified incorrect or inadequate results, mechanical problems, and leak/splash. As of the date of this proposed order, FDA is aware of two class III recalls,[2] two class II recalls, [3] and no class I recalls for these devices.[4] The class II recalls occurred in 2007 and 2014, and were related to: (1) Sporadic lower than expected anti-HCV test results, and (2) failure of the instrument to open (actuate) some reagent packs from certain lots. All recalls have been resolved and no patient harm has been identified. These facts, coupled with the low number of reported events, indicate a good safety record for this device class. These recall events reflect the risks to health identified in section V below, and FDA believes the special controls proposed herein, in addition to general controls, can effectively mitigate the risks identified in these recalls.

III. Device Description

HCV antibody tests are postamendments prescription devices for the qualitative detection of HCV and are classified into class III under section 513(f)(1) of the FD&C Act. HCV antibody tests are described in FDA's SSEDs and product code database (assigned product code MZO) as devices for the qualitative detection of antibodies to HCV in human serum and plasma. HCV antibodies, when present in samples, bind to HCV antigens to form a complex that is bound to a solid phase (*e.g.* microparticles, microtiter plate or else). Detection of the complexes can be performed using different methods that measure the presence/absence of HCV antibodies in the sample. HCV antibody tests are intended for use as aids in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk of acquiring HCV infection. These devices are not intended for screening blood, plasma, cell or tissue donors. This proposed order does not apply to HCV antibody tests that are intended for home use or over-the-counter use.

FDA is proposing to reclassify HCV antibody tests from class III (general controls and premarket approval) to class II (general controls and special controls) and to establish a new name for the device type that will be within the classification regulation; *i.e.,* hepatitis C virus (HCV) antibody tests. FDA believes that this name and proposed identification language most accurately describes these devices. An HCV antibody test is tentatively identified as a device intended for use with human serum, plasma, or other matrices as a prescription device that aids in the diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test is intended as an aid in the diagnosis of HCV infection in specified populations, and/or as an aid in the management of HCV-infected patients including guiding the selection of genotype-specific treatment in individuals with chronic HCV infection. The test is not intended for screening blood, plasma, cell, or tissue donors.

Based upon our review experience and consistent with the FD&C Act and FDA's regulations in 21 CFR 860.134, FDA believes that these devices should be reclassified from class III into class II with special controls because there is sufficient information to establish special controls that, along with general controls, can provide reasonable assurance of the devices' safety and effectiveness.

IV. Proposed Reclassification

FDA is proposing to reclassify HCV antibody tests. On March 22, 2018, FDA held a public meeting of the Microbiology Devices Panel (Panel) of the Medical Devices Advisory Committee convened to discuss and make recommendations regarding the reclassification of HCV antibody tests from class III (general controls and premarket approval) into class II (general controls and special controls) (Ref. 1). Panel members unanimously agreed that special controls, in addition to general controls, are necessary and sufficient to mitigate the risks to health of patients presented by these devices and to provide reasonable assurance of the safety and effectiveness of these devices (Ref. 2). In addition, Panel members generally agreed with the development of special controls as presented by FDA.

FDA agrees and believes that at this time, sufficient data and information exist such that the risks identified in section V below can be mitigated by

[1] In December 2019, FDA began adding the term ''Proposed amendment'' to the ''ACTION'' caption for these documents, typically styled ''Proposed order'', to indicate that they ''propose to amend'' the Code of Federal Regulations. This editorial change was made in accordance with the Office of **Federal Register**'s (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

[2] Class III recalls are defined in 21 CFR 7.3(m)(3).

[3] Class II recalls are defined in 21 CFR 7.3(m)(2).

[4] Class I recalls are defined in 21 CFR 7.3(m)(1).

establishing special controls that, together with general controls, can provide a reasonable assurance of the safety and effectiveness of these devices and therefore proposes these devices to be reclassified from class III (general controls and premarket approval) to class II (general controls and special controls).

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify postamendments HCV antibody tests to be renamed ''hepatitis C virus (HCV) antibody tests,'' from class III into class II. FDA believes that, at this time, there are sufficient data and information available to FDA through FDA's accumulated experience with these devices from review submissions and from published peer-reviewed literature, as well as the recommendations provided by the Panel, to demonstrate that the proposed special controls, along with general controls, would effectively mitigate the risks to health identified in section V below and provide a reasonable assurance of the safety and effectiveness of these devices. Absent the special controls identified in this proposed order, general controls applicable to the device type are insufficient to provide reasonable assurance of the safety and effectiveness of these devices. FDA expects that the reclassification of these devices would enable more manufacturers to develop HCV antibody tests such that patients would benefit from increased access to safe and effective tests.

FDA is proposing to create a classification regulation for HCV antibody tests that will be reclassified from class III to class II. Under this proposed order, if finalized, HCV antibody tests will be identified as prescription devices. As such, the prescription device must satisfy prescription labeling requirements for in vitro diagnostic products (See 21 CFR 809.10(a)(4) and (b)(5)(ii)). In this proposed order, if finalized, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, will provide a reasonable assurance of the safety and effectiveness for HCV antibody tests.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For HCV antibody tests, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA does not intend to exempt this proposed class II devices from the 510(k) requirements. If this proposed order is finalized, persons who intend to market this type of device must submit a 510(k) to FDA and receive clearance prior to marketing the device.

This proposed order, if finalized, will decrease regulatory burden on industry, as manufacturers will no longer have to submit a PMA for these types of devices but can instead submit a 510(k) to the Agency for review prior to marketing their device. A 510(k) typically results in a shorter premarket review timeline compared to a PMA, which ultimately provides more timely access of these types of devices to patients.

In addition, the Agency believes that certain changes could be made to HCV antibody tests that could significantly affect the safety and effectiveness of those devices and for which a new 510(k) is likely required.[5] Based on FDA's accumulated experience with these devices, changes that likely could significantly affect the safety and effectiveness of these devices include, but are not limited to, changes to critical reagents, changes to final release specifications, and changes in shelf-life of the device. For more information about when to submit a new 510(k), manufacturers should refer to FDA's guidance entitled ''Deciding When to Submit at 510(k) for a Change to an Existing Device'' (Ref. 3).

V. Risks to Health

It is estimated by the Centers for Disease Control and Prevention that chronic HCV infection in the United States affects at least between 2.7 and 3.9 million people (Ref. 4). HCV infection can be asymptomatic, and accordingly, many HCV-infected individuals are unaware of their HCV infection. Between 20 percent and 30 percent of patients with acute infection, defined as the first 6 months after infection, clear the virus spontaneously while the other 70 percent to 80 percent of individuals become chronically infected with HCV (Ref. 5). Later diagnosis can lead to a more severe disease outcome and premature death among those who are chronically infected (Ref. 6). Patients who are tested and become aware that they are HCV infected may modify risk behaviors to prevent transmission to others and can be referred for treatment.

If left untreated, patients with chronic HCV infection have a significant risk of developing severe liver disease and/or hepatocellular cancer. Treatment of chronic HCV is highly effective, resulting in a sustained virological response (SVR) considered synonymous with cure. SVR is associated with improved clinical outcome, and a decrease in HCV-associated mortality (Ref. 7). Therefore, diagnosis of patients with chronic HCV infection through devices such as hepatitis C virus antibody tests is essential to ensure that patients are linked to the appropriate care (Ref. 6).

After consideration of FDA's accumulated experience with these devices from FDA review submissions, recommendations of the Panel for the classification of these devices (Ref. 2), and published literature, FDA has identified the following probable risks to health associated with HCV Antibody Tests:

- *Inaccurate interpretation of test results.* Inaccurate interpretation of test results by clinicians may negatively influence patient management decisions. A reactive test result misinterpreted as non-reactive may delay or prevent a patient with HCV infection from being identified and linked to care. Missed identification of patients with chronic HCV infection could lead to adverse effects on patient health such as progressive liver disease, cirrhosis and/or hepatocellular cancer, all of which are known to contribute to patient morbidity and mortality (Ref. 6). A reactive test incorrectly interpreted as non-reactive also may contribute to public health risk by leading to inadvertent transmission of virus by an infected person. A non-reactive test result incorrectly identified as reactive may contribute to unnecessary additional patient testing to exclude active HCV infection or potentially delay diagnosis of alternative causes of liver disease when present.
- *Failure of the device to perform as indicated (e.g., false negative results or false positive results).* A false negative test result due to failure of the device to perform may delay or prevent a patient with HCV infection from being identified and linked to care. Missed identification of patients with chronic HCV infection could lead to adverse effects on patient health such as progressive liver disease, cirrhosis and/or hepatocellular cancer, all of which are known to contribute to patient morbidity and mortality (Ref. 6). A false negative/false non-reactive test result also may contribute to public health risk by leading to inadvertent transmission of virus by an infected person. Factors that may cause decreased test sensitivity and/or an increased rate of false

[5] See 21 CFR 807.81(a)(3)(i).

negative results include, but are not limited to, the presence of interfering substances in the sample, acute infection at a stage that is too early for a device to detect the infection, and antibody concentrations that are too low to be detected by the device. They also can be caused by misinterpretation of invalid results as negative. A false positive test result may contribute to unnecessary additional patient testing to exclude active HCV infection or potentially delay diagnosis of alternative causes of liver disease when present. Factors that may lead to false positive results include device contamination from positive samples, cross-reactivity with other antibodies, or misinterpretation of invalid results as positive.

VI. Summary of the Reasons for Reclassification

FDA believes that HCV antibody tests should be reclassified from class III (general controls and premarket approval) into class II (general controls and special controls) because special controls, in addition to general controls, can be established to mitigate the risks to health identified in section V and provide a reasonable assurance of the safety and effectiveness of these devices. The proposed special controls are identified by FDA in section VII.

Taking into account the probable health benefits of the use of theses device and the nature and known incidence of the risks of the devices, FDA, on its own initiative, is proposing to reclassify these postamendments class III devices into class II. FDA believes that, when used as indicated, HCV antibody tests can provide significant benefits to clinicians and patients.

FDA's reasons for reclassification are based on the substantial scientific and medical information available regarding the nature, complexity, and risks associated with HCV antibody tests in the identified intended use populations (Ref. 1). The safety and effectiveness of this device type has become well-established since the initial approval of the first HCV antibody test for the qualitative detection of HCV in 2001.

VII. Proposed Special Controls

FDA believes that these devices can be classified into class II with the establishment of special controls. FDA believes that the following special controls, together with general controls, will provide a reasonable assurance of the safety and effectiveness of HCV antibody tests. Table 1 demonstrates how these proposed special controls will mitigate each of the identified risks to health in section V.

The risk of inaccurate interpretation of test results can be mitigated by special controls requiring certain labeling, including providing clearly stated warnings and limitations and information on principles of operation and procedures in performing the test.

Risks associated with the failure of the device to perform as indicated (*e.g.,* false negative and false positive test results) can be mitigated through a combination of special controls including certain labeling requirements, certain design verification and validation information, and performance studies. Examples of verification and validation information to be included in the design of the device includes documentation of performance specifications including analytical and clinical performance criteria. In addition, design verification and validation activities must include documentation of a complete device description, critical reagents, risk analysis strategies, lot release criteria, stability studies and protocols. Required statements in labeling can aid in mitigating the failure of the device to perform as indicated, for example including a statement that use of the test with specimen types other than those specifically identified for use with this device may cause inaccurate test results.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR HCV ANTIBODY TESTS

Identified risks to health	Mitigation measures
Inaccurate interpretation of test results	Certain labeling warnings, limitations, and explanation of procedures.
Failure of the device to perform as indicated	Certain labeling warnings, limitations, and explanation of procedures. Performance specifications including analytical and clinical performance criteria. Certain design verification and validation information including documentation of device description, critical reagents, risk analysis strategies, lot release criteria, stability studies and protocols.

If this proposed order is finalized, HCV antibody tests will be reclassified into class II (general controls and special controls) and would be subject to premarket notification requirements under section 510(k) of the FD&C Act. As discussed below, the intent is for the reclassification to be codified in 21 CFR 866.3169. Firms submitting a premarket notification under section 510(k) of the FD&C Act for HCV antibody tests will be required to comply with the particular mitigation measures set forth in the special controls. Adherence to the special controls, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this 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.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. This proposed order refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR parts 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

X. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. Therefore,

under section 513(f)(3), in the proposed order, we are proposing to codify HCV antibody tests in the new 21 CFR 866.3169, under which certain HCV antibody tests would be reclassified from class III to class II.

XI. Proposed Effective Date

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

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. Executive Summary of the FDA Microbiology Devices Panel Meeting, March 22, 2018 (available at *https://www.fda.gov/media/111502/download*).
* 2. Transcript of the FDA Microbiology Devices Panel Meeting, March 22, 2018 (available at *https://www.fda.gov/media/119966/download*).
* 3. ''Deciding When to Submit a 510(k) for a Change to an Existing Device—Guidance for Industry and Food and Drug Administration Staff,'' issued October 25, 2017 (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device*).
* 4. Department of Health and Human Services—Viral Hepatitis Action Plan for 2017–2020 (available at *https://www.hhs.gov/sites/default/files/National%20Viral%20Hepatitis%20Action%20Plan%202017-2020.pdf*).
5. Aisyah, D.N., L. Shallcross, A.J. Hully, et al., ''Assessing Hepatitis C Spontaneous Clearance and Understanding Associated Factors—A Systematic Review and Meta-Analysis.'' *Journal of Viral Hepatitis,* 25(6): 680–698, 2018.
6. Moorman, A.C., J. Xing, S. Ko, et al., ''Late Diagnosis of Hepatitis C Virus Infection in the Chronic Hepatitis Cohort Study (CHeCS): Missed Opportunities for Intervention.'' *Hepatology,* 61(5): 1479–1484, 2015.
7. Ioannou, G.N., P.K. Green, and K. Berry, ''HCV Eradication Induced by Direct-Acting Antiviral Agents Reduces the Risk of Hepatocellular Carcinoma.'' *Journal of Hepatology,* 68(1): 25–33, 2018.

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 be 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, 360*l,* 371.

■ 2. Add § 866.3169 to subpart D to read as follows:

§ 866.3169 Hepatitis C Virus Antibody Tests.

(a) *Identification.* A hepatitis C virus (HCV) antibody test is identified as an in vitro diagnostic device intended for use with human serum, plasma, or other matrices as a prescription device that aids in the diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test is not intended for screening blood, plasma, cell, or tissue donors.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The labeling required under 21 CFR 809.10(b) must include:

(i) A prominent statement that the test is not intended for the screening of blood, plasma, and cell or tissue donors.

(ii) Limitations, which must be updated to reflect current clinical practice and disease presentation and management. The limitations must include, but are not limited to, statements that indicate:

(A) When appropriate, the performance characteristics of the test have not been established in populations of immunocompromised or immunosuppressed patients or, other special populations where test performance may be affected.

(B) The detection of HCV antibodies indicates a present or past infection with hepatitis C virus, but does not differentiate between acute, chronic, or resolved infection.

(C) The specimen types for which the device has been cleared, and that use of the test with specimen types other than those specifically cleared for this device may result in inaccurate test results.

(D) Test results are to be interpreted by qualified licensed healthcare professionals in conjunction with the individual's clinical presentation, history, and other laboratory results.

(E) A non-reactive test result may occur early during acute infection, prior to development of a host antibody response to infection, or when analyte levels are below the limit of detection of the test.

(iii) A detailed explanation of the principles of operation and procedures for performing the test.

(2) Design verification and validation must include the following:

(i) A detailed device description, including all parts that make up the device, ancillary reagents required but not provided, an explanation of the device methodology, and design of the antigen(s) and capture antibody(ies) sequences, rationale for the selected epitope(s), degree of amino acid sequence conservation of the target, and the design and nature of all primary, secondary, and subsequent standards used for calibration.

(ii) Documentation and characterization (*e.g.,* supplier, determination of identity, and stability) of all critical reagents (including description of the antigen(s) and capture antibody(ies)), and protocols for maintaining product integrity throughout its labeled shelf life.

(iii) Risk analysis and management strategies, such as Failure Modes Effects Analysis and/or Hazard Analysis and Critical Control Points summaries and their impact on test performance.

(iv) Final release criteria to be used for manufactured test lots with appropriate evidence that lots released at the extremes of the specifications will meet the claimed analytical and clinical performance characteristics as well as the stability claims.

(v) Stability studies for reagents must include documentation of an assessment of real-time stability for multiple reagent lots using the indicated specimen types and must use acceptance criteria that ensure that analytical and clinical performance characteristics are met when stability is assigned based on the extremes of the acceptance range.

(vi) All stability protocols, including acceptance criteria.

(vii) Final release test results for each lot used in clinical studies.

(viii) Multisite reproducibility study that includes the testing of three independent production lots.

(ix) Analytical performance studies and results for determining the limit of blank (LoB), limit of detection (LoD), cutoff, precision (reproducibility) including lot-to-lot and/or instrument-to-instrument precision, interference, cross reactivity, carry-over, hook effect,

seroconversion panel testing, matrix equivalency, specimen stability, reagent stability, and cross-genotype antibody detection sensitivity, when appropriate.

(x) Analytical sensitivity of the test is the same or better than that of other cleared or approved tests.

(xi) Detailed documentation of clinical performance testing from a multisite clinical study. Performance must be analyzed relative to an FDA cleared or approved HCV antibody test, or a comparator that FDA has determined is appropriate. This study must be conducted using appropriate patient samples, with an acceptable number of HCV positive and negative samples in applicable risk categories. Additional relevant patient groups must be validated as appropriate. The samples may be a combination of fresh and repository samples, sourced from geographically diverse areas. The study designs, including number of samples tested, must be sufficient to meet the following criteria:

(A) Clinical sensitivity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 95 percent.

(B) Clinical specificity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 96 percent.

(3) For any HCV antibody test intended for Point of Care (PoC) use, the following special controls, in addition to those listed in paragraphs (b)(1) and (2) of this section, apply:

(i) Clinical studies must be conducted at PoC sites.

(ii) Additional labeling must include a brief summary of the instructions for use that are appropriate for use in a PoC environment.

Dated: March 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06821 Filed 4–1–20; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–132529–17]

RIN 1545–BO13

Computation and Reporting of Reserves for Life Insurance Companies

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance on the computation of life insurance reserves and the change in basis of computing certain reserves of insurance companies. These proposed regulations implement recent legislative changes to the Internal Revenue Code. This document invites comments on these proposed regulations. This document affects entities taxable as insurance companies.

DATES: Written or electronic comments and requests for a public hearing must be received by June 1, 2020.

ADDRESSES: Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–132529–17) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment received to its public docket, whether submitted electronically or in hard copy. Send hard copy submissions to: CC:PA:LPD:PR (REG–132529–17), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Dan Phillips, (202) 317–6995; concerning submissions of comments and requests for a public hearing, Regina Johnson, (202) 317–5177 or *fdms.database@irscounsel.treas.gov* (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to 26 CFR part 1 under sections 807 and 816 of the Internal Revenue Code (Code). Sections 807 and 816 were added to the Code by section 211(a) of the Deficit Reduction Act of 1984, Public Law 98–369, 98 Stat. 494. Section 807 was amended by sections 13513 and 13517 of the Tax Cuts and Jobs Act, Public Law 115–97, 131 Stat. 2054, 2143, 2144 (2017) (TCJA). These amendments by the TCJA apply to taxable years beginning after December 31, 2017.

This document also proposes to amend or remove the following regulations in 26 CFR: §§ 1.338–11, 1.381(c)(22)–1, 1.801–2, 1.801–5, 1.801–7, 1.801–8, 1.806–4, 1.807–1, 1.809–2, 1.809–5, 1.810–3, 1.817A–0, 1.817A–1, 1.818–2, 1.818–4, 1.848–1, 1.6012–2, and 301.9100–6T. These proposed changes are conforming changes to regulations that (i) relate to repealed or amended law, (ii) reference regulations that are proposed to be removed, (iii) have no future application, or (iv) relate to other regulations proposed by this document.

A. Reserves Taken Into Account in Determining Life Insurance Company Taxable Income

Section 801(a) imposes a tax on the life insurance company taxable income of every life insurance company. Section 801(b) defines life insurance company taxable income to mean life insurance gross income, reduced by life insurance deductions. Under section 803(a)(2), life insurance gross income includes a net decrease in items described in section 807(c) as required by section 807(a). Under sections 804 and 805(a)(2), life insurance deductions include a deduction for a net increase in items as required by section 807(b).

The items described in section 807(c) are: (i) Life insurance reserves (as defined in section 816(b)); (ii) unearned premiums and unpaid losses included in total reserves; (iii) amounts that are discounted at the appropriate rate of interest to satisfy obligations under insurance and annuity contracts that do not involve life, accident, or health contingencies when the computation is made; (iv) dividend accumulations and other amounts held at interest in connection with insurance and annuity contracts; (v) premiums received in advance and liabilities for premium deposit funds; and (vi) reasonable special contingency reserves under contracts of group term life insurance or group accident and health insurance that are held for retired lives, premium stabilization, or a combination of both.

B. Life Insurance Reserves Taken Into Account in Determining Premiums Earned for a Nonlife Insurance Company

Section 831(a) generally imposes a tax on the taxable income of every insurance company other than a life insurance company (a nonlife insurance company). Section 832 defines taxable income for this purpose to be gross income (as defined in section 832(b)(1)) less allowed deductions. Section 832(b)(1) provides that gross income includes underwriting income, and section 832(b)(3) provides that underwriting income means premiums earned on insurance contracts during the taxable year less losses incurred and expenses incurred.

Under sections 832(b)(4) and 832(b)(7)(A), premiums earned on insurance contracts during the taxable year are reduced by life insurance