This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Dassault Aviation: Docket No. FAA–2026–13805; Project Identifier MCAI–2026–00064–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 28, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Dassault Aviation Model MYSTERE–FALCON 50, FALCON 2000, and FALCON 2000EX airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Unsafe Condition

This AD was prompted by a reported quality escape and a determination that high-temperature oxidation of main landing gear (MLG) upper and lower torque links may have occurred during manufacturing. The FAA is issuing this AD to address this condition. The unsafe condition, if not addressed, could result in failure of the MLG, possibly resulting in damage to the airplane and injury to occupants.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2026–0012, dated January 19, 2026 (EASA AD 2026–0012).

(h) Exceptions to EASA AD 2026–0012

(1) Where EASA AD 2026–0012 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2026–0012 defines a serviceable MLG as ''Any MLG, eligible for installation in accordance with Dassault instructions, which is not an affected MLG; and any affected MLG, having an affected part installed, provided that the affected part accumulated less than 7,100 flight cycles (FC) since first installation on an aeroplane'', this AD requires replacing that text with ''Any MLG, eligible for installation, which is not an affected MLG; and any affected MLG, having an affected part installed, provided that the affected part accumulated less than 7,100 flight cycles (FC) since first installation on an airplane''.

(3) This AD does not adopt the ''Remarks'' section of EASA AD 2026–0012.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Additional Information

For more information about this AD, contact Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7350; email: *9-AVS-AIR-BACO-COS@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2026–0012, dated January 19, 2026.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA 98198. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on November 3, 2026.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026–23074 Filed 11–10–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2026–N–12508]

Hematology and Pathology Devices; Reclassification of Immunohistochemistry Test Systems for Use With a Corresponding Approved Oncology Therapeutic Product

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify immunohistochemistry (IHC) test systems indicated for use with a corresponding approved oncology therapeutic product (product codes

MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, and SHF), which are postamendments class III devices, from class III (premarket approval) into class II (special controls), subject to premarket notification. FDA is proposing minor revisions to an existing classification regulation and also proposing a new device classification regulation, along with the special controls that FDA believes are necessary to provide a reasonable assurance of safety and effectiveness for these devices.

DATES: Either electronic or written comments on the proposed order must be submitted by January 11, 2027. Please see section X of this document for the proposed effective date when the new requirements would 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 11, 2027. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 (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–2026–N–12508 for ''Hematology and Pathology Devices; Reclassification of Immunohistochemistry Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product.'' 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, 240–402–7500.

- 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.'' FDA 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, the plain language summary of the proposed order of not more than 100 words consistent with the ''Providing Accountability Through Transparency Act,'' 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Soma Ghosh, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3316, Silver Spring, MD 20993, 240–402–5333, *Soma.Ghosh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, 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) establishes three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (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 section 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 the safety and effectiveness of the device; 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 issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions FDA (Agency or we) 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 introduced or delivered for introduction into interstate commerce for commercial distribution before 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 approval of a premarket approval application (PMA), unless and until: (1) FDA reclassifies the device into class I or 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 the procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and our implementing regulations (21 CFR part 807, subpart E).

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 class 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 reasonable assurance of the safety and effectiveness of the device for its intended use.[1]

FDA relies on ''valid scientific evidence'' as stated in section 513(a)(3) of the FD&C Act and defined in 21 CFR 860.7(c)(2) in the classification process to determine the level of regulation for devices.[2] To be considered in the reclassification process, the ''valid scientific evidence'' on which the Agency relies generally must be publicly available. 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). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of the device, but it does not include the descriptions of methods of manufacture and product composition and other trade secrets.

In accordance with section 513(f)(3) of the FD&C Act, FDA is issuing this proposed order to reclassify postamendments class III IHC-based test systems indicated for use with a corresponding approved oncology therapeutic product (product codes MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, and SHF),[3] [4] hereafter collectively referred to as oncology therapeutic IHC-based test systems, into class II (special controls) subject to premarket notification under a new device classification regulation with the name ''Immunohistochemistry Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product.'' [5]

The identification in the proposed classification regulation characterizes oncology therapeutic IHC-based test systems as prescription in vitro diagnostic (IVD) devices that utilize IHC technology to qualitatively or quantitatively detect protein expression in human specimens and are indicated for use with a corresponding approved oncology therapeutic product. These test systems include companion diagnostic (CDx) test systems, which are devices that provide information that is essential for the safe and effective use of a corresponding approved therapeutic product and the use of which is stipulated in the instructions for use in the labeling of both the diagnostic device and the approved corresponding therapeutic product (Ref. 1). These test systems also include those test systems that provide information about known benefits and/or risks of an approved therapeutic product, where the use of the test system is referenced in the product labeling of the corresponding approved oncology therapeutic product, but the test system is not essential for the safe and effective use of the approved therapeutic product.

As discussed further throughout this proposed order, FDA has issued PMAs for various oncology therapeutic IHC-based test systems designated under product codes MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, and SHF. The oncology therapeutic IHC-based test systems within the different product codes have distinct characteristics in certain respects; for example, each product code generally represents devices with specific antibodies utilized, specific biomarker(s) detected by the test system, specimen type(s), and/or specific FDA-approved therapeutic product(s) for

[1] See generally section 513 of the FD&C Act.

[2] See generally *id.*

[3] FDA's Center for Devices and Radiological Health (CDRH) uses product codes to assist in accurate identification and tracking of current medical devices and to allow for tracking of and easy reference to predicate device types. CDRH and a subset of Center for Biologics Evaluation and Research regulated medical device product codes consist of a three-letter combination which associates a device's type with a product classification designated for the application. There is no definitive meaning for the three-digit classification product codes in CDRH's Product Classification Database. See FDA guidance titled, ''Medical Device Classification Product Codes'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff.*

[4] FDA is aware that product codes for certain previously approved oncology therapeutic IHC-based test systems (NKF, NQF, QUL, QNH, QZJ, SBL, and SER) are identified in the PMA and Product Classification Databases as being associated with a preexisting classification regulation for IHC reagents and kits (§ 864.1860 (21 CFR 864.1860)). The association of these devices and product codes with § 864.1860 is an administrative error and does not reflect the Agency's intent to classify these devices under § 864.1860. FDA intends to update the PMA and Product Classification Databases and remove references to the classification regulation, § 864.1860, mistakenly assigned to these devices/product codes. If this proposed order is finalized, previously approved oncology therapeutic IHC-based test systems designated under product codes MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, or SHF will be reclassified from class III into class II (special controls) under § 864.1895 (21 CFR 864.1895). Through this proposed order, FDA is also proposing to amend the identification paragraph under § 864.1860 to clarify that IHCs indicated for use with a corresponding approved oncology therapeutic product will be classified under § 864.1895, when finalized.

[5] FDA notes that the ''ACTION'' caption for this proposed order is styled as ''Proposed amendment; proposed order; request for comments'' rather than ''Proposed order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The 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.

which the device is indicated for use. FDA has considered the distinctions of these test systems across the 12 product codes and has determined that these test systems, including those devices that provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product, as well as test systems that, while not essential to the safe and effective use of the corresponding approved oncology therapeutic product, provide information about known benefits and/or risks related to the use of the approved oncology therapeutic product, have the same or a similar risk profile and sufficiently similar purposes, design considerations, functions, and other features related to safety and effectiveness such that the same or similar regulatory controls are necessary and sufficient to provide reasonable assurance of safety and effectiveness.[6] For these reasons and considering that FDA did not identify any unique risks associated with the distinctions across these devices, FDA is proposing a single classification regulation to classify all oncology therapeutic IHC-based test systems into class II. There would generally not be changes to the product codes (*i.e.,* MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, and SHF) for previously approved oncology therapeutic IHC-based test systems, and future oncology therapeutic IHC-based test systems would either be assigned to one of the currently existing product codes or a new product code, as appropriate. The new classification regulation would apply to both current and new devices that are oncology therapeutic IHC-based test systems.

Based on the extensive PMA data available to FDA in accordance with section 520(h)(4) of the FD&C Act,[7] [8] published peer-reviewed literature studying this longstanding and well-understood technology, and data available to the Agency demonstrating a lack of significant postmarket safety signals with oncology therapeutic IHC-based test systems, FDA believes there is sufficient information to reclassify these devices from class III (premarket approval) into class II (special controls). FDA 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, would provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing to establish a new device classification regulation, ''Immunohistochemistry Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product,'' and classify this device type into class II along with the special controls that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

Under the FD&C Act, premarket notification (510(k)) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt from 510(k) requirements under section 510(m) of the FD&C Act.[9] FDA has not made this determination for oncology therapeutic IHC-based test systems and, therefore, FDA is not proposing that this class II device type be exempt from the 510(k) 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 prior to marketing the device.[10]

II. Regulatory History of the Devices

In accordance with section 513(f)(1) of the FD&C Act, oncology therapeutic IHC-based test systems are automatically classified into class III because they were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, have not been reclassified into class I or II, and have not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently classified or reclassified into class I or class II. Therefore, these devices are subject to the PMA requirements under section 515 of the FD&C Act (21 U.S.C. 360e).

On September 25, 1998, FDA approved an original PMA for the first oncology therapeutic IHC-based test system, a CDx device, Dako HercepTest (P980018, product code MVC) for use in determining human epidermal growth factor receptor 2 (HER2) overexpression in breast cancer tissues routinely processed for histological evaluation as an aid in the assessment of patients for whom trastuzumab treatment is being considered (Ref. 2). In a June 22, 1999, **Federal Register** notice (64 FR 33306), FDA announced the approval order and the availability of the Summary of Safety and Effectiveness Data (SSED) for the device.

[6] For example, a specific device could be indicated for and approved to provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product and to provide information about known benefits and/or risks related to the use of a corresponding approved oncology therapeutic product that is not essential to the safe and effective use of a corresponding approved oncology therapeutic product. The distinction is determined by the data from the clinical development program of the corresponding therapeutic product and how the therapeutic product is labeled (*i.e.,* whether the use of the IVD device is essential for the safe and effective use of the therapeutic product or not essential for the safe and effective use of the therapeutic product but provides information about known benefits and/or risks related to the use of the therapeutic product). The devices have sufficiently similar purposes, design considerations, functions, and other features related to safety and effectiveness such that the same or similar regulatory controls are necessary and sufficient to provide reasonable assurance of safety and effectiveness and the devices can be part of the same device type.

[7] In proposing to reclassify oncology therapeutic IHC-based test systems from class III to class II, FDA, on its own initiative, is relying on data from relevant PMAs (under product codes NKF, NQF, PLS, PKW, and MVC) available to FDA in accordance with the 6-year rule (see section 520(h)(4) of the FD&C Act); see also, FDA, ''Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997—Guidance for Industry and for FDA Reviewers,'' August 9, 2000 (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-section-216-food-and-drug-administration-modernization-act-1997-guidance-industry-and-fda*). This data was from relevant PMAs approved after November 28, 1990, and before October 15, 2020, for devices that would fall under this specific proposed reclassification as noted in section II of this proposed order. See also, FDA's premarket approval database, available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm.*

[8] For the purpose of this proposed order, PMA data considered in accordance with section 520(h)(4) of the FD&C Act includes only that data that was submitted to and, therefore, considered by FDA at the time the PMA was reviewed and approval was issued.

[9] In considering whether to exempt class II devices from premarket notification, FDA considers whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA generally considers the factors initially identified in the January 21, 1998, **Federal Register** notice (63 FR 3142) and further explained in FDA's guidance issued on February 19, 1998, titled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' in determining whether premarket notification is necessary for class II devices. FDA also considers that, even when exempting devices from the 510(k) requirements, these devices would still be subject to certain limitations on exemptions, for example, the general limitations set forth in 21 CFR 864.9.

[10] If this proposed order is finalized, oncology therapeutic IHC-based test systems, including those currently approved devices designated under product codes MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, and SHF will be reclassified from class III into class II (special controls) under the new classification regulation. If this proposed order is finalized, oncology therapeutic IHC-based test systems with prior PMA approval at the time of the final order may continue to be marketed per the previous PMA approval and would not require an additional marketing authorization. For changes or modifications to such devices that could significantly affect the safety or effectiveness of such devices or a major change or modification in the intended use of such devices (see 21 CFR 807.81(a)(3)), FDA would expect that manufacturers would submit a 510(k) for the modified device.

On October 9, 2015, FDA approved an original PMA for the first oncology therapeutic IHC-based test system that, while not essential to the safe and effective use of the corresponding approved therapeutic product, provides information about known benefits and/or risks related to the use of the approved oncology therapeutic product. The approval was for the original PMA for PD–L1 IHC 28–8 pharmDx under the product code PLS (P150025). The PD–L1 IHC 28–8 pharmDx is an oncology therapeutic IHC-based test system using monoclonal rabbit anti-Programmed Cell Death Ligand 1 (PD–L1), Clone 28–8 intended for use in the detection of PD–L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-squamous non-small cell lung cancer (NSCLC) tissue using EnVision FLEX visualization system on Autostainer Link 48. PD–L1 protein expression is defined as the percentage of tumor cells exhibiting positive membrane staining at any intensity. PD–L1 expression as detected by PD–L1 IHC 28–8 pharmDx in non-squamous NSCLC may be associated with enhanced survival from OPDIVO (nivolumab) (Ref. 3). Since the approval of P150025, as of November 3, 2025, FDA has approved four additional PMAs for oncology therapeutic IHC-based test systems that provide information about known benefits and/or risks of an approved oncology therapeutic product, but the test system is not considered to be essential for the safe and effective use of the approved oncology therapeutic product.

Since the first approval order for an oncology therapeutic IHC-based test system, FDA has reviewed and approved an additional 21 original PMAs and approximately 270 PMA supplements for oncology therapeutic IHC-based test systems under product codes MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, and SHF.[11]

In accordance with the ''6-year rule'' described in section 520(h)(4) of the FD&C Act (Ref. 4), FDA considered data contained in the following 14 original PMAs, representing oncology therapeutic IHC-based test systems from 5 of the 12 product codes (*i.e.,* MVC, NKF, NQF, PLS, and PKW) for oncology therapeutic IHC-based test systems: Dako HercepTest (P980018, product code MVC) (Ref. 2), Ventana Medical Systems' PATHWAY Her 2 (P990081, product code MVC) (Ref. 5), DakoCytomation EGFR pharmDx (P030044, product code NQF, Ref. 6), Ventana® Medical Systems' PATHWAY Anti-c-KIT (9.7) Primary Antibody (P020055, product code NKF) (Ref. 7), BioGenex InSite™ Her-2/neu kit (P040030, product code MVC) (Ref. 8), DakoCytomation c-Kit pharmDx™ (P040011, product code NKF) (Ref. 9), Bond™ Oracle™ HER2 IHC System (P090015, product code MVC) (Ref. 10), VENTANA ALK (D5F3) CDx Assay (P140025, product code PKW) (Ref. 11), PD–L1 IHC 22C3 pharmDx (P150013, product code PLS) (Ref. 12), PD–L1 IHC 28–8 pharmDx (P150025, product code PLS) (Ref. 3), PD–L1 IHC 28–8 pharmDx (P150027, product code PLS) (Ref. 13), VENTANA PD–L1(SP142) Assay (P160002, product code PLS) (Ref. 14), VENTANA PD–L1 (SP142) Assay (P160006, product code PLS) (Ref. 15), VENTANA PD–L1 (SP263) ASSAY (P160046, product code PLS) (Ref. 16).[12] No information from PMAs and PMA supplements for which fewer than 6 years have passed since FDA's approval has been used in support of this proposed order to reclassify oncology therapeutic IHC-based test systems into class II (see section 520(h)(4) of the FD&C Act).[13]

A review of data from FDA's Manufacturer and User Facility Device Experience (MAUDE) database, which contains Medical Device Reports (MDRs) of adverse events, indicates that as of July 15, 2026, there have been 48 reported events for oncology therapeutic IHC-based test systems under the product codes PLS (N=35 MDRs), MVC (N=7 MDRs), PKW (N=4 MDRs), QNH (N=1 MDR), and QUL (N=1 MDR) since the approval of the first oncology therapeutic IHC-based test system in 1998. There have been no MDRs reported under the product codes NKF, QQT, NQF,[14] QZJ, SBL, SER, and SHF.

After review of the data, the Agency has determined that false negative results account for the device problem associated with a majority of the MDR reported events, with less frequently reported device problems, including, for example, other incorrect, inadequate, or imprecise results or readings, adverse events without identified device or use problem, incorrect or inadequate test results, and false positive results. Notably, a majority of the MDR reported events (over 70 percent) under these product codes stated in their reports that no clinical signs, symptoms or conditions to the patient, no health consequences or impact, and/or no known impact or consequence to patient.

A search of these product codes in FDA's Medical Device Recalls database indicates that as of July 15, 2026, there has been 1 class III recall, 10 class II recalls,[15] and no class I recalls[16] involving oncology therapeutic IHC-based test systems. Of the 10 class II recalls and 1 class III recall, 10 occurred between 2004 and 2020, have since been terminated, and were due to (1) a

[11] FDA has determined that the test systems assigned to product codes MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, and SHF all utilize IHC-based technology for use with a corresponding approved oncology therapeutic product and have sufficiently similar purposes, design considerations, functions, and other features related to safety and effectiveness such that all oncology therapeutic IHC-based test systems have the same or a similar risk profile. Further, FDA has not identified any unique risks associated with the distinctions across these test systems.

[12] For the reasons discussed in footnote 11, FDA has determined that these 14 original PMAs, representing oncology therapeutic IHC-based test systems from 5 of the 12 product codes that are proposed to be reclassified, provide an adequate basis for identifying the risks to health associated with oncology therapeutic IHC-based test systems assigned to 1 of the 12 product codes and for developing special controls for oncology therapeutic IHC-based test systems assigned to 1 of the 12 product codes that, together with general controls, would provide a reasonable assurance of safety and effectiveness. Although oncology therapeutic IHC-based test systems may differ with respect to characteristics such as the specific antibody utilized, biomarker detected, indicated tumor type, and corresponding approved oncology therapeutic product, and product codes have been used to distinguish these technological differences, FDA has determined that these differences do not alter the principal device-related risks identified in section V (*i.e.,* false test results, failure of the test system to perform as intended or indicated, and failure to correctly interpret test results). Accordingly, FDA believes that the information from these 14 PMAs is relevant to identifying the risks to health and developing special controls for oncology therapeutic IHC-based test systems across all 12 product codes and that such special controls, together with general controls, would provide a reasonable assurance of safety and effectiveness.

[13] In accordance with section 520(h)(4) of the FD&C Act, FDA has not relied on information in PMAs and PMA supplements approved within the last 6 years to develop the proposed special controls or to otherwise inform this proposed reclassification action.

[14] The database searches initially identified one MDR reported under the NQF product code. However, after manual review of the data, it has been determined that this MDR was improperly reported under this product code. The MDR appears to be intended to report an adverse event for a drug product, and not a device. As such, for the purpose of this proposed order, the data related to this MDR is not included in the Agency's postmarket surveillance analysis and discussion.

[15] One Class II recall was reported under product code NQF; however, it has been determined to have been improperly reported. The class II recall is related instead to a device product code that falls outside the scope of this proposed order. As such, for the purpose of this proposed order the data related to this recall has been excluded from the Agency's postmarket surveillance analysis and discussion surrounding recall data.

[16] As defined in 21 CFR 7.3(m), the numerical designation *i.e.,* I, II, or III, assigned by the FDA to a particular product recall indicates the relative degree of health hazard presented by the product being recalled. Class I recalls are those classified as the highest level of risk in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

process control issue related to storage time which may have led to a false negative result, (2) distribution without premarket approval, (3) nonconforming material/component resulting in light staining inconsistencies isolated to a specific lot, or (4) per the manufacturer, granular staining which may have led to a false positive result, increased background staining related to a process change for the purification of the raw material, and a formulation error in the visualization reagent (*i.e.,* violations of production and process controls and purchasing controls). There are 29 MDR reported events associated with the remaining class II recall (these are included in the earlier discussion of MDR reported events), which occurred in 2023 due to manufacturer identified unacceptable light staining which could potentially lead to a false negative result. This class II recall is currently open with the investigation ongoing.

In response to FDA's announcement that the Agency intended to initiate the reclassification process for certain IVD devices, including CDx tests (Ref. 17), FDA received a petition on January 7, 2026, from Ventana Medical Systems, Inc., (Docket No. FDA–2026–P–1301) requesting FDA reclassify all PD–L1 IHC qualitative assays to identify PD–L1 expression in human clinical tissue specimens (under product code PLS) from class III to class II. As discussed in this proposed order, FDA has considered the information available to the Agency and believes that there is sufficient information available to establish special controls, and that the special controls proposed in section VII, together with general controls, would provide a reasonable assurance of the safety and effectiveness of such devices under the PLS product code, as well as other similar devices under product codes MVC, NKF, QQT, NQF, PKW, QUL, QNH, QZJ, SBL, SER, and SHF. As such, FDA is proposing, on its own initiative, that oncology therapeutic IHC-based test systems, including those under product code PLS, be reclassified from class III to class II.

III. Device Description

Oncology therapeutic IHC-based test systems are postamendments devices classified into class III under section 513(f)(1) of the FD&C Act. These oncology therapeutic IHC-based test systems are prescription IVD devices intended for the quantitative, semi-quantitative, or qualitative detection of protein expression in human specimens using IHC technology through manual techniques, automated instrumentation, or a combination of manual techniques and automated instrumentation and are indicated for use with a corresponding approved oncology therapeutic product. These oncology therapeutic IHC-based test systems include IVD CDx devices which are devices that provide information that is essential for the safe and effective use of a corresponding therapeutic product.[17] The use of an IVD CDx device with a therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding approved therapeutic product, including the labeling of any generic equivalents of the therapeutic product.[18] An IVD CDx device could be essential for the safe and effective use of a corresponding approved therapeutic product to:

- Identify patients who are most likely to benefit from the therapeutic product;
- Identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with the therapeutic product;
- Monitor response to treatment with the therapeutic product for the purpose of adjusting treatment (*e.g.,* schedule, dose, discontinuation) to achieve improved safety or effectiveness;
- Identify patients in the population for whom the therapeutic product has been adequately studied and found safe and effective; *i.e.,* there is insufficient information about the safety and effectiveness of the therapeutic product in any other population.

An IVD CDx does not include devices that are not essential to the safe and effective use of a therapeutic product.[19] For more information on CDx devices, see FDA's guidance titled ''In Vitro Companion Diagnostic Devices—Guidance for Industry and Food and Drug Administration Staff'' (Ref. 1).

Additionally, the oncology therapeutic IHC-based test systems in this proposed order include IVD test systems that provide information about known benefits and/or risks to patient populations related to the use of a corresponding approved oncology therapeutic product and are referenced in the labeling for the corresponding approved therapeutic product but are not essential for the safe and effective use of the therapeutic product. For example, such devices can be used to assess a biomarker-defined population of patients and provide information regarding the overall survival rate or objective response rate for those patients compared to the broader population of patients for whom the corresponding therapy is indicated. The use of these devices is not a prerequisite for receiving treatment with the corresponding therapeutic product but can aid in the benefit-risk assessment as to the use of the corresponding therapy for those biomarker-defined patients.

FDA proposes to revise 21 CFR part 864 to create a new device classification regulation with the name ''Immunohistochemistry Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product.'' IHC-based test systems indicated for use with a corresponding approved oncology therapeutic product are identified as prescription IVD devices consisting of polyclonal or monoclonal antibodies intended for the quantitative, semi-quantitative, or qualitative detection of protein expression in human clinical specimens to provide information related to the use of a corresponding approved oncology therapeutic product as described in the corresponding approved oncology therapeutic product labeling. These test systems provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product and/or are test systems that, while not essential to the safe and effective use of the corresponding approved oncology therapeutic product, provide information about known benefits and/or risks related to the use of the corresponding approved oncology therapeutic product.

IV. Proposed Reclassification and Summary of Reasons for Reclassification

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify oncology therapeutic IHC-based test systems from class III into class II, subject to 510(k) requirements. FDA believes that there is sufficient information available to establish special controls and that these special controls, together with general controls, would effectively mitigate the risks to health identified in section V and are necessary to provide a reasonable assurance of the safety and effectiveness of oncology therapeutic IHC-based test systems.

Under this proposed order, if finalized, oncology therapeutic IHC-based test systems will be identified as prescription IVD devices. Such devices are subject to the prescription labeling requirements for IVD products (see 21

[17] FDA, ''In Vitro Companion Diagnostic Devices—Guidance for Industry and Food and Drug Administration Staff,'' August 6, 2014. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/in-vitro-companion-diagnostic-devices.*

[18] *Id.*

[19] *Id.*

CFR 809.10(a)(4) and (b)(5)(ii)). In this proposed order, FDA has identified the special controls under section 513(a)(1)(B) of the FD&C Act that it believes, together with general controls, will provide a reasonable assurance of the safety and effectiveness of these test systems.

Under the FD&C Act, 510(k) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt from 510(k) requirements under section 510(m) of the FD&C Act.[20] FDA has not made this determination for oncology therapeutic IHC-based test systems, and therefore, FDA is not proposing this class II device type be exempt from 510(k) requirements. If this proposed order is finalized, persons who intend to market an oncology therapeutic IHC-based test system will need to submit to FDA a 510(k) 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 this type of device but can instead submit a 510(k) to the Agency for review prior to marketing their device. The 510(k) pathway is less burdensome and generally more cost-effective for industry and FDA than the PMA pathway, the most stringent type of device marketing application required by FDA. A 510(k) typically results in a shorter premarket review timeline compared to a PMA, which ultimately may provide more timely patient access for this type of device. FDA expects that the reclassification of these devices would enable more manufacturers to develop this type of device such that patients would benefit from increased access to appropriately safe and effective test systems.

Additionally, manufacturers may wish to use predetermined change control plans (PCCPs) as a way to implement future modifications to their devices without needing to submit a new 510(k) for each significant change or modification [21] while continuing to provide a reasonable assurance of device safety and effectiveness.[22] FDA reviews a PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification described in the PCCP. When used appropriately, PCCPs authorized by FDA are expected to be least burdensome for manufacturers and FDA.[23]

FDA believes that there is sufficient information available to FDA through the 14 original PMAs for Dako HercepTest (P980018, product code MVC), Ventana Medical Systems' PATHWAY Her 2 (P990081, product code MVC), DakoCytomation EGFR pharmDx (P030044, product code NQF), Ventana® Medical Systems' PATHWAY Anti-c-KIT (9.7) Primary Antibody (P020055, product code NKF), BioGenex In Site ™ Her-2/neu (P040030, product code MVC), DakoCytomation c-Kit pharmDx™ (P040011, product code NKF), Bond ™ Oracle ™ HER2 IHC System (P090015, product code MVC), VENTANA ALK (D5F3) CDx Assay (P140025, product code PKW), PD–L1 IHC 22C3 pharmDx (P150013, product code PLS), PD–L1 IHC 28–8 pharmDx (P150025, product code PLS), PD–L1 IHC 28–8 pharmDx (P150027, product code PLS), VENTANA PD–L1(SP142) Assay (P160002, product code PLS), VENTANA PD–L1 (SP142) Assay (P160006, product code PLS), and VENTANA PD–L1 (SP263) ASSAY (P160046, product code PLS) (Ref. 2 and 3 and 5 through 16), published peer-reviewed literature on IHC technology, and FDA's publicly available MAUDE and Medical Device Recalls databases to establish special controls that effectively mitigate the risks to health identified in section V. More specifically, in evaluating these data sources, FDA has identified the risks to health for inclusion in the overall risk assessment for oncology therapeutic IHC-based test systems. The Agency has considered the risks to health identified by these sources and used certain information from these sources in developing proposed special controls that include mitigation measures for each of the risks to health identified in section V. Accordingly, there would continue to be a reasonable assurance of safety and effectiveness for the devices upon their reclassification from class III to class II when there is conformity with general and special controls. FDA does not believe that the general controls applicable to the devices are sufficient to effectively mitigate the risks to health identified for these devices and, therefore, does not believe that the general controls applicable to the devices are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

V. Risks to Health

FDA is providing a substantive summary of the valid scientific evidence concerning the public health benefits of the use of oncology therapeutic IHC-based test systems and the risks to health of these devices (see further discussion of the special controls being proposed to mitigate these risks in section VII of this proposed order). FDA considered data from 14 PMAs available to FDA under section 520(h)(4) of the FD&C Act, published peer-reviewed literature on IHC technology, and postmarket information regarding oncology therapeutic IHC-based test systems.

Cancer continues to be one of the two leading causes of death in the United States (Ref. 18). Biomarker tests for molecularly targeted cancer therapies aim to provide information for healthcare providers to target and/or tailor cancer treatment based on identifiable molecular differences between patients, with the goal of improving patient outcomes while minimizing risks related to treatment side effects. Oncology therapeutic IHC-based test systems provide a benefit to the public health by aiding in oncology therapeutic product treatment decisions. These test systems may provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product and/or provide information about known benefits and/or risks related to the use of a corresponding approved oncology therapeutic product that is not essential for its safe and effective use. For example, healthcare providers may use a relevant oncology therapeutic IHC-based test system to identify specific

[20] See *supra* note 9.

[21] For the purpose of this proposed order, reference to ''modification'' means a significant change or modification that would generally require a new premarket notification under 21 CFR 807.81(a)(3). For additional details, see FDA guidances titled ''Deciding When To Submit a 510(k) for a Change to an Existing Device,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device* and ''Deciding When To Submit a 510(k) for a Software Change to an Existing Device,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device.*

[22] Section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023 (FDORA) (Pub. L. 117–328), enacted on December 29, 2022, added section 515C ''Predetermined Change Control Plans for Devices'' to the FD&C Act (21 U.S.C. 360e–4). Section 515C has provisions regarding PCCPs for devices requiring premarket approval or premarket notification. Under section 515C, supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP approved or cleared by FDA.

[23] Sections 513 and 515 of the FD&C Act. See also, FDA's guidance titled, ''The Least Burdensome Provisions: Concept and Principles—Guidance for Industry and FDA Staff,'' February 5, 2019, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.*

patients who are eligible for the safe and effective use of a corresponding oncology therapeutic product, including those patients for which the drug is contraindicated, or monitor a particular patient's response to an approved oncology therapeutic product for the purpose of optimizing a dosing regimen. These devices can be used to enable personalization of oncology care by identifying patients who are most likely to benefit from a specific therapy and yield improved clinical outcomes, or who are at varying degrees of risk for a particular side effect related to the use of a specific therapy. Ultimately, the use of these devices informs treatment decisions and has a significant public health impact for cancer patients.

The Agency has identified the following risks to health associated with the use of oncology therapeutic IHC-based test systems:

- *False negative test results or false positive test results.* False negative test results or false positive test results may negatively influence oncology therapeutic product treatment decisions for patients. For those test systems intended to provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product, the risk of false test results may, for example, result in the withholding of appropriate oncology therapeutic treatment, delayed treatment from an available appropriate alternative therapy, or receiving inappropriate therapy with varying degrees of consequence (*e.g.,* failing to adjust therapy to achieve optimal clinical outcome or exposing a patient to otherwise avoidable serious adverse health risks caused by the therapeutic product). For those test systems that provide information about known benefits and/or risks related to the use of a corresponding approved oncology therapeutic product but are not essential for the safe and effective use of the corresponding approved oncology therapeutic product, this risk may negatively influence patient management based on a misinformed benefit-risk assessment related to the use of a corresponding approved oncology therapeutic product and could lead to many of the same negative patient outcomes associated with test systems intended to provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product as previously described.
- *Failure of the test system to perform as intended or indicated.* For test systems intended to provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product, failure of the test system to perform as intended or indicated may result in inappropriate clinical management, due to, among other things, the potential need to rerun the test, leading to a delay in effective treatment or inappropriate treatment for a patient based on delayed results that are essential for the safe and effective use of a corresponding approved oncology therapeutic product. Similarly, for those test systems that provide information about known benefits and/or risks related to the use of a corresponding approved oncology therapeutic product but are not essential for the safe and effective use of the corresponding approved oncology therapeutic product, this risk may result in the potential need to rerun the test, leading to a delay in treatment or inappropriate treatment for a patient based on delayed results that would provide important benefit-risk information for a healthcare provider to aid in the clinical decision making related to the use of a corresponding approved oncology therapeutic product.
- *Failure to correctly interpret test results.* Failure to correctly interpret test results, such as incorrect interpretation/reading of the stained slides, may result in the same negative outcomes associated with false negative or false positive test results as previously discussed. For example, for test systems intended to provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product, incorrectly interpreting the test results as positive (*i.e.,* false positive test results) may lead to a patient receiving ineffective or unnecessary treatment that may unnecessarily expose them to treatment toxicities. Similarly, for those test systems that provide information about known benefits and/or risks related to the use of a corresponding approved oncology therapeutic product but are not essential for the safe and effective use of the corresponding approved oncology therapeutic product this risk may, for example, lead to inappropriate patient management decisions made by a healthcare provider, such as, selecting a suboptimal treatment for a patient, and failure for the patient to realize benefit from a different therapy based on inaccurate benefit-risk information related to the use of a corresponding approved oncology therapeutic product.

VI. Summary of Data Upon Which the Reclassification Is Based

The safety and effectiveness of this device type has become well established since the initial approval of the first oncology therapeutic IHC-based test system in 1998. FDA believes that oncology therapeutic IHC-based test systems should be reclassified from class III (premarket approval) into class II (special controls) on the basis that special controls can be established to mitigate the risks to health identified in section V and there is sufficient information to establish special controls which, in addition to general controls, would provide a reasonable assurance of the safety and effectiveness of these devices. The proposed special controls are identified by FDA in section VII of this proposed order.

Taking into account the available evidence, including the health benefits of the use of these devices and the nature and known incidence of the risks to health 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, oncology therapeutic IHC-based test systems can provide significant benefits to healthcare providers and patients.

In proposing to reclassify and establish special controls for oncology therapeutic IHC-based test systems, FDA has considered and analyzed the following information: (1) data from 14 PMAs for oncology therapeutic IHC-based test systems available to FDA in accordance with section 520(h)(4) of the FD&C Act, (2) published peer-reviewed literature on IHC technology, and (3) MDR and recall data from the Agency's publicly available MAUDE and Medical Device Recalls databases. The available evidence demonstrates that there are public health benefits derived from the use of oncology therapeutic IHC-based test systems which provide information related to the use of a corresponding approved oncology therapeutic product. In addition, the nature of the associated risks to health are known, and special controls can be established to sufficiently mitigate these risks.

FDA considered the safety and effectiveness of oncology therapeutic IHC-based test systems through review of PMA data going back to the initial approval of the first oncology therapeutic IHC-based test system in 1998, under product code MVC (P980018) (Ref. 2). Subsequently, between 2000 and 2025, FDA approved 21 additional original PMAs for oncology therapeutic IHC-based test systems under the product codes MVC, NKF, QQT, NQF, PLS, PKW, QUL, QNH, QZJ, SBL, SER, and SHF. For the purpose of this reclassification, FDA was able to consider data from the following 14 original PMAs in accordance with section 520(h)(4) of the FD&C Act: Dako HercepTest (P980018,

product code MVC), Ventana Medical Systems' PATHWAY Her 2 (P990081, product code MVC), DakoCytomation EGFR pharmDx (P030044, product code NQF), Ventana® Medical Systems' PATHWAY Anti-c-KIT (9.7) Primary Antibody (P020055, product code NKF), BioGenex In Site™ Her-2/neu (P040030, product code MVC), DakoCytomation c-Kit pharmDx™ (P040011, product code NKF), Bond™ Oracle™ HER2 IHC System (P090015, product code MVC), VENTANA ALK (D5F3) CDx Assay (P140025, product code PKW), PD–L1 IHC 22C3 pharmDx (P150013, product code PLS), PD–L1 IHC 28–8 pharmDx (P150025, product code PLS), PD–L1 IHC 28–8 pharmDx (P150027, product code PLS), VENTANA PD–L1(SP142) Assay (P160002, product code PLS), VENTANA PD–L1 (SP142) Assay (P160006, product code PLS), and VENTANA PD–L1 (SP263) ASSAY (P160046, product code PLS) (Refs. 2 and 3 and 5 through 16).[24]

As part of the Agency's analysis for the proposed reclassification of oncology therapeutic IHC-based test systems, FDA reviewed and considered information provided within each of these applications, including information available in the SSEDs and device labeling for each application, which helped to demonstrate a reasonable assurance of safety and effectiveness for the devices. The Agency considered the analytical and clinical studies performed and device performance data, demonstrating appropriate performance of the device, which supported each approval, when developing the proposed special controls which FDA believes can effectively mitigate the risks to health identified in section V and, along with general controls, can provide a reasonable assurance of the safety and effectiveness for oncology therapeutic IHC-based test systems. Additionally, FDA identified the probable adverse effects or risks to health of the tests consistent with information provided within the applications. As diagnostic tests, oncology therapeutic IHC-based test systems generally do not pose additional safety hazards or direct adverse effects to the patients being tested beyond those associated with routine procedures typical for a diagnostic workup of the disease. The risks to health identified within the applications were false test results (*i.e.,* false positive and false negative test results), failure of the test system to perform as intended or indicated, and failure to correctly interpret test results. Consistent with data collected in the corresponding clinical studies submitted in support of the approvals, the adverse event profile for these devices was generally deemed acceptable.

While the oncology therapeutic IHC-based test systems that are the subject of the 14 PMAs have unique test attributes in certain respects (*e.g.,* specific antibodies utilized, specific biomarker(s) detected by the test system, specimen type(s), and/or specific FDA-approved therapeutic product(s) for which the device is indicated for use), FDA has determined that these tests have sufficiently similar purposes, design considerations, functions, and other features related to safety and effectiveness such that the information and data reviewed and analysis conducted by FDA was analogous across all 14 applications available to the Agency in accordance with section 520(h)(4) of the FD&C Act. As such, to avoid redundancy, the following 2 summaries are intended to provide examples that are representative of the PMA information and data that was reviewed and considered by FDA across the 14 applications in proposing to reclassify oncology therapeutic IHC-based test systems from class III (premarket approval) into class II (special controls).

For example, FDA reviewed the original PMA data for the first FDA-approved oncology therapeutic IHC-based test system, which was approved on September 25, 1998, through an original PMA, for a CDx test, Dako HercepTest with an intended use to determine HER2 overexpression in breast cancer tissues and for use as an aid in the assessment of patients for whom Herceptin (Trastuzumab) treatment is being considered (product code MVC) (P980018) (Ref. 2). The Agency considered the submitted analytical and clinical studies and data provided in the approved submission, which demonstrated that the Dako HercepTest has acceptable performance, including accuracy and reproducibility demonstrating a reasonable assurance of the safety and effectiveness of the device for its intended use. For example, such studies include a clinical study demonstrating that the concordance of the Dako HercepTest to the clinical trial assay (CTA) used to screen potential patients for the Herceptin clinical trials was 79 percent with a two-sided 95 percent confidence interval (CI) of 76–82 percent. Additionally, a second clinical study was performed to determine the agreement between the DAKO HercepTest and the HER2 status of ''well-characterized'' tissues. Results from this clinical study indicated an 85 percent concordance (95 percent CI: 78–89 percent) between the degree of positivity (2+ and 3+) and negativity (0 and 1+ DAKO IHC score) determined using the DAKO kit and some degree of overexpression by five different methods for determination of HER2 overexpression. This level of concordance indicated that the Dako HercepTest performed in a similar manner to the CTA and would identify a patient population eligible for Herceptin therapy. Probable adverse effects of the device include the identified risks of false positive or false negative results. Beyond the risk to patients of false positive or false negative test results, there is one hazardous material (the 3,3′-diaminobenzidine (DAB) chromogen) included in the test system, which also identifies instructions for the safe handling of the hazardous material to be included in the device labeling. This safety precaution is considered and the risks to technicians are mitigated by labeling requirements stipulated under general controls.

Additionally, FDA considered the original PMA studies and data from the VENTANA PD–L1 (SP263) Assay, which FDA approved on May 1, 2017, (P160046, product code PLS) (Ref. 16). The VENTANA PD–L1 (SP263) Assay is a qualitative IHC test using rabbit monoclonal anti-PD–L1 clone SP263 intended for use in the assessment of the PD–L1 protein in FFPE urothelial carcinoma tissue stained with OptiView DAB IHC Detection Kit on a VENTANA BenchMark ULTRA instrument. Further, the VENTANA PD–L1 (SP263) Assay provides information about known benefits related to the use of an approved therapeutic product. PD–L1 High status as determined by the VENTANA PD–L1 (SP263) Assay was associated with increased objective response rate (ORR) in a single arm study of IMFINZI (durvalumab). Analytical and clinical data provided in this PMA supported that there is reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The clinical performance of VENTANA PD–L1 (SP263) Assay investigated in the single arm study, was evaluated in a non-randomized, multi-center, open label study of IMFINZI (durvalumab) on patients with locally advanced or metastatic urothelial carcinoma. High PD–L1

[24] In accordance with section 520(h)(4) of the FD&C Act. FDA has not relied on information in PMAs and PMA supplements approved within the last 6 years to develop proposed special controls or to otherwise inform this proposed reclassification.

status, as determined by VENTANA PD–L1(SP263) Assay, is associated with increased ORR according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by Blinded Independent Central Review (BICR) for patients with locally advanced or metastatic urothelial carcinoma that have progressed while on or after a platinum-based therapy who are treated with IMFINZI (durvalumab). The clinical performance data demonstrated that results of this device provide known benefits related to the use of the therapeutic product and may help physicians determine the best treatment regimen and tailor therapies accordingly. The performance of the VENTANA PD–L1 (SP263) Assay was also supported by the analytical validation studies demonstrating acceptable analytical performance supporting a reasonable assurance of the safety and effectiveness of the device for its intended use. Clinical and analytical performance data ultimately supported the approval of this PMA. Probable adverse effects of the VENTANA PD–L1 (SP263) Assay include failure of the device to perform as intended or indicated, failure to correctly interpret test results, and/or false positive test results or false negative test results which have the potential to adversely affect patient management. Further, the risks of the device are also based on data collected in the clinical study conducted to support the PMA approval. As an IVD device, the VENTANA PD–L1 (SP263) Assay tests tumor FFPE specimens collected from patients with urothelial carcinoma, which are routinely removed for diagnosis and, therefore, does not present additional significant safety concerns.

In addition to PMA data from the 14 available PMAs, FDA further considered that IHC is a well-established technology and it has been commonly used in both research and clinical settings for decades, and at this time, its general principles are well understood and widely published in the literature. Over the past 8 decades, there have been significant scientific developments aimed at addressing certain IHC limitations and expanding the applications of the technology, such as the monoclonal antibody discovery and the emergence of the heat-induced antigen (epitope) retrieval technique. These developments further demonstrate the maturity of this technology (Refs. 19 and 20). FDA considered the breadth of knowledge available regarding IHC as an established technology in proposing to reclassify oncology therapeutic IHC-based test systems from class III into class II. This includes, for example, the establishment of special controls that FDA believes can effectively mitigate those identified risks to health (discussed in section V) and, along with general controls, are necessary to provide a reasonable assurance of the safety and effectiveness for these devices.

Finally, a search of FDA's publicly available MAUDE database revealed 48 reported events for oncology therapeutic IHC-based test systems under the product codes PLS, MVC, PKW, QNH, and QUL. There have been no MDRs reported under product codes NKF, QQT, NQF,[25] QZJ, SBL, SER, and SHF. A search of FDA's publicly available recall database revealed no entries for devices under the QQT, PKW, QUL, QNH, QZJ, SBL, SER, and SHF product codes. There have been 1 class III recall, 10 class II recalls,[26] and no class I recalls involving oncology therapeutic IHC-based test systems. The lack of class I recalls, and relatively low number of class II and class III recalls, coupled with the relatively low number of reported events that caused patient harm, indicate a generally good safety record for this device type (see further discussion of the MDR and recall data in section II of this proposed order).

Based on the Agency's review of the information described in this proposed order, FDA has determined that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for these devices, and that sufficient information exists to establish such special controls. Therefore, FDA, on its own initiative, is proposing to reclassify these postamendment devices from class III (premarket approval) into class II (special controls) subject to 510(k) requirements.

VII. Proposed Special Controls

FDA believes that oncology therapeutic IHC-based test systems can be reclassified into class II with the establishment of special controls. FDA believes that the following proposed special controls would mitigate each of the risks to health described in section V and that these special controls, in addition to general controls, would provide a reasonable assurance of safety and effectiveness for oncology therapeutic IHC-based test systems. Table 1 demonstrates how FDA believes each risk to health described in section V would be mitigated by the proposed special controls, including certain design verification and validation activities as well as certain labeling requirements.

Risks of false negative test results or false positive test results, failure of the test system to perform as intended or indicated, and failure to correctly interpret test results (caused by, for example, failure of the antibodies, instruments, or software to perform as expected or failure of the intended user to correctly perform the test) can be mitigated by special controls, including certain design verification and validation activities. For example, documentation of clinical performance testing must include clinical data demonstrating acceptable performance of the device for its intended use based on data generated using a dataset representative of the intended use population. This may include, for example, data from use of the device as the clinical trial enrollment assay in the therapeutic product clinical trial or data from a method comparison study to an appropriate FDA-authorized device. The analytical performance testing must include data demonstrating appropriate analytical performance of the device, such as the precision, analytical sensitivity, analytical specificity, and sample stability of the test system (*e.g.,* unstained cut-tissue section stability). In addition, device design verification and validation information must include the specifications for risk mitigation elements intended to mitigate risks associated with testing and results interpretation, including controls, procedures, and user training requirements.

The risks of false test results (*i.e.,* false negative test results and false positive test results) and failure to correctly interpret test results can be further mitigated by special controls that require specific information in the labeling for these test systems. For example, specific required limiting statement(s) explaining that test results are intended to be interpreted by a qualified or appropriately trained reader in conjunction with other diagnostic laboratory test results and/or pathology

[25] The database searches initially identified one MDR reported under the NQF product code. However, after manual review of the data, it has been determined that this MDR was improperly reported under this product code. The MDR appears to be intended to report an adverse event for a drug product, and not a device. As such, for the purpose of this proposed order, the data related to this MDR is not included in the Agency's postmarket surveillance analysis and discussion.

[26] One Class II recall was reported under product code NQF; however, it has been determined to have been improperly reported. The class II recall is instead related to a device product code that falls outside the scope of this proposed order. As such, for the purpose of this proposed order, the data related to this recall has been excluded from the Agency's postmarket surveillance analysis and discussion surrounding recall data.

test results, relevant clinical information, and proper controls can aid in mitigating these risks.

The risk of failure of the test system to perform as intended or indicated can be mitigated by special controls that require an appropriate, as determined by FDA, summary of the performance studies performed and for the results of those studies to be included in labeling, thus informing the user of the expected performance of the device. Table 1 shows how FDA believes such risks to health described in section V would be mitigated by the proposed special controls.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR ONCOLOGY THERAPEUTIC IHC-BASED TEST SYSTEMS

Identified risks to health	Mitigation measures
False negative test results or false positive test results	Certain design verification and validation activities, including certain analytical validation and clinical validation data. Certain labeling information, including certain limiting statement(s) and certain performance information.
Failure of the test system to perform as intended or indicated	Certain design verification and validation activities, including certain analytical validation and clinical validation data. Certain labeling information, including certain limiting statement(s), and certain performance information.
Failure to correctly interpret test results	Certain design verification and validation activities, including certain analytical validation and clinical validation data. Certain labeling information, including certain limiting statement(s), and certain performance information.

If this proposed order is finalized, oncology therapeutic IHC-based test systems will be identified as prescription IVD devices. Therefore, these devices would be subject to the prescription labeling requirements for IVD products (see 21 CFR 809.10(a)(4) and (b)(5)(ii)).

If this proposed order is finalized, oncology therapeutic IHC-based test systems will be reclassified into class II (special controls) and will be subject to premarket notification requirements under section 510(k) of the FD&C Act. As discussed in this proposed order, the intent is for the reclassification to be codified in the new classification regulation § 864.1895 (21 CFR 864.1895). If finalized, firms submitting a premarket notification under section 510(k) of the FD&C Act for oncology therapeutic IHC-based test systems 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 oncology therapeutic IHC-based test systems.

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 normally 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

While this proposed order contains no new collections of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 820 (Quality Management System Regulation) have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E (Premarket Notification Procedures), have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR parts 801 and 809 (Device Labeling) have been approved under OMB control number 0910–0485.

X. Proposed Effective Date

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

XI. 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) of the FD&C Act, in the proposed order, we are proposing to codify Immunohistochemistry Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product in the new § 864.1895, under which these oncology therapeutic IHC-based test systems would be reclassified from class III into class II.

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. Although FDA verified the website addresses as of the date this document publishes in the **Federal Register**, websites are subject to change over time.

* 1. FDA, In Vitro Companion Diagnostic Devices—Guidance for Industry and Food and Drug Administration Staff, August 6, 2014. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/in-vitro-companion-diagnostic-devices.*

* 2. PMA P980018 Summary of Safety and Effectiveness. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf/P980018.pdf.*

* 3. PMA P150025 Summary of Safety and Effectiveness. Available at: *https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150025B.pdf.*

* 4. FDA, ''Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997,'' August 9, 2000. Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-section-*

216-food-and-drug-administration-modernization-act-1997-guidance-industry-and-fda.
* 5. PMA P990081 Summary of Safety and Effectiveness. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf/P990081B.pdf.*
* 6. PMA P030044 Summary of Safety and Effectiveness. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030044B.pdf.*
* 7. PMA P020055 Summary of Safety and Effectiveness. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020055B.pdf.*
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* 9. PMA P040011 Summary of Safety and Effectiveness. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040011B.pdf.*
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* 16. PMA P160046 Summary of Safety and Effectiveness. Available at *https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160046B.pdf.*
* 17. FDA, ''CDRH Announces Intent to Initiate the Reclassification Process for Most High Risk IVDs,'' January 31, 2024. Available at *https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-intent-initiate-reclassification-process-most-high-risk-ivds.*
18. Curtin, S.C., B. Tejada-Vera, and B.A. Bastian, ''Deaths: Leading Causes for 2021,'' National Center for Health Statistics, *National Vital Statistics Reports,* 73(4), April 2024. Available at *https://stacks.cdc.gov/view/cdc/147882.*
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List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 864 be amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for part 864 continues to read as follows:

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

■ 2. In § 864.1860, revise paragraph (a) to read as follows:

§ 864.1860 Immunohistochemistry reagents and kits.

(a) *Identification.* Immunohistochemistry test systems (IHC's) are in vitro diagnostic devices consisting of polyclonal or monoclonal antibodies labeled with directions for use and performance claims, which may be packaged with ancillary reagents in kits. Their intended use is to identify, by immunological techniques, antigens in tissues or cytologic specimens. Similar devices intended for use with flow cytometry devices are not considered IHC's. IHC's indicated for use with a corresponding approved oncology therapeutic product are classified under § 864.1895.

* * * * *

■ 3. Add § 864.1895 to subpart B to read as follows:

§ 864.1895 Immunohistochemistry Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product.

(a) *Identification.* Immunohistochemistry (IHC) test systems indicated for use with a corresponding approved oncology therapeutic product are identified as prescription in vitro diagnostic devices consisting of polyclonal or monoclonal antibodies intended for the quantitative, semi-quantitative, or qualitative detection of protein expression in human clinical specimens to provide information related to the use of a corresponding approved oncology therapeutic product as described in the corresponding approved oncology therapeutic product labeling. These test systems include devices that provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product and devices that, while not essential to the safe and effective use of the corresponding oncology therapeutic product, provide information about known benefits and/or risks related to the use of the corresponding oncology therapeutic product.

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

(1) Design verification and validation must include:

(i) Specification for risk mitigation elements intended to mitigate risks associated with testing and results interpretation, including controls, procedures, and user training requirements, as appropriate.

(ii) Specification of the criteria for test result interpretation and reporting, including device cut-off(s) (*i.e.,* clinical threshold(s) or the medical decision point(s) between positive and negative results), scoring method or other relevant criteria that distinguishes positive and negative results, or ordinal classes of biomarker expression. This information must include the rationale for the chosen cut-off(s) or other relevant criteria and results supporting validation of the cut-off(s) evaluating borderline samples around the clinical threshold(s).

(iii) Device performance data demonstrating appropriate analytical specificity of the device for the intended use specimen type(s), as determined to be appropriate by FDA. These studies must include antigen/antibody characterization and characterization with a panel of well-characterized tissue samples, including as applicable, but not limited to, western blots, peptide inhibition, testing in a variety of normal tissues and neoplastic tissues (*i.e.,* tour of body and tour of tumor testing), interference by endogenous and exogenous substances, and cross-reactivity and cross-contamination testing.

(iv) Device performance data demonstrating appropriate precision and reproducibility of the device using clinical specimens representing the intended use specimen type(s) and intended use biomarker(s) from the intended use population and investigating major sources of variability (*e.g.,* multiple reagent lots, multiple operators, instruments over multiple days, and inter- and intra-reader precision). Surrogate samples that adequately represent the intended use specimen type(s) and intended use biomarker(s) may be appropriate, as determined by FDA, to supplement clinical specimens. If the device will be used at more than one site, data must

demonstrate adequate reproducibility across multiple intended use sites. Additionally, precision and reproducibility of the device must be evaluated with specimens near the clinical decision threshold(s) and near the limits of reportable range. Precision studies must include evaluation of the controls. Precision of the device must be evaluated per specimen, in aggregate, and for repeat testing/invalid rate, as appropriate.

(v) Device performance data demonstrating appropriate device robustness, as determined to be appropriate by FDA. The study must assess the tolerance ranges for critical test and specimen parameters, as applicable.

(vi) Device performance data demonstrating linearity of quantitative results using samples covering the device measuring range, as applicable.

(vii) Device performance data demonstrating appropriate specimen stability for the intended specimen type(s) (*e.g.,* unstained cut-tissue section stability).

(viii) Clinical data generated using well-characterized clinical specimens representative of the intended use population demonstrating appropriate clinical performance of the device for its intended use, as determined to be appropriate by FDA.

(2) Labeling must include:

(i) An appropriate summary, as determined by FDA, of the performance studies performed and the results of those studies, including those that relate to all design verification and validation special controls.

(ii) A limiting statement, as appropriate, that explains that the test results are intended to be interpreted by a qualified or appropriately trained reader in conjunction with other diagnostic laboratory test results and/or pathology test results, relevant clinical information, and proper controls.

(iii) For those test systems intended to provide information that is essential for the safe and effective use of a corresponding approved oncology therapeutic product, language indicating that the test system is indicated for use with a corresponding FDA-approved oncology therapeutic product. Device labeling must be consistent with the information set forth in the corresponding FDA-approved oncology therapeutic product labeling.

(iv) For those test systems intended to provide information about known benefits and/or risks related to the use of a corresponding FDA-approved oncology therapeutic product but are not essential for the safe and effective use of the corresponding approved oncology therapeutic product, language summarizing the benefits and/or risks related to the use of a corresponding FDA-approved oncology therapeutic product that must be consistent with the information set forth in the corresponding FDA-approved oncology therapeutic product labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–23005 Filed 11–10–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–117199–25]

RIN 1545–BR97

Federal Scholarship Tax Credit; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notification of change to telephonic-only public hearing on a proposed rulemaking.

SUMMARY: This document announces that the public hearing scheduled for December 15, 2026, at 10 a.m. ET, for the notice of proposed rulemaking and notice of public hearing (REG–117199–25) published in the **Federal Register** on October 2, 2026, has been changed to a telephonic-only hearing. These proposed regulations would provide guidance regarding the non-refundable Federal tax credit for qualified contributions to scholarship granting organizations to fund qualified elementary and secondary school education scholarships.

DATES: The public hearing scheduled to be held on December 15, 2026, at 10 a.m. ET, has been changed to a telephonic-only hearing.

ADDRESSES: Public comments that have been submitted on the proposed regulations (REG–117199–25) are available on the Federal eRulemaking Portal at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Constance Chien, (202) 317–7002, or Andrew Fahmy, (202) 317–3840; concerning submissions of comments and the public hearing, the Publications and Regulations Section at (202) 317–6901 (not toll-free numbers) or by email at *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed rulemaking and notice of public hearing (REG–117199–25) published in the **Federal Register** on October 2, 2026 (91 FR 62818). This hearing will now be held in a telephonic-only format.

The rules of 26 CFR 601.601(a)(3) apply to the public hearing. Individuals who wish to present oral comments at the public hearing are required to submit an outline of the topics to be discussed as well as the time to be devoted to each topic by December 1, 2026. Individuals who made requests to testify either in-person or by telephone prior to this Notification of change, and individuals who subsequently make timely requests to testify by telephone will receive the telephone number and access codes for the public hearing. A period of 10 minutes will be allotted to each person testifying.

Individuals who have already sent an email to *publichearings@irs.gov* to request to attend the hearing by telephone or in person do not need to make a second request to attend the hearing now being held by telephone only. The IRS will provide those individuals with a telephone number and access code for the rescheduled hearing by email.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available via the Federal eRulemaking Portal (*https://www.regulations.gov*) under the title of Supporting & Related Material.

Individuals who want to attend the public hearing by telephone without testifying must also send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number (REG–117199–25) and the language ''ATTEND Hearing Telephonically.'' For example, the subject line may say: Request to ATTEND Hearing Telephonically for REG–117199–25. Requests to attend the hearing must be received by 5 p.m. ET on Thursday, December 10, 2026.

Public hearings will be made accessible to people with disabilities. To request special assistance during a public hearing, please contact the Publications and Regulations Section of the Office of Associate Chief Counsel (Procedure and Administration) by sending an email to *publichearings@irs.gov* (preferred) or by telephone at (202) 317–6901 (not a toll-free number) no later than Wednesday, December 9, 2026.

Any additional questions regarding speaking at or attending the hearing may