text should read ''requirements found in (g)(2)(iii)(A)(*1*), (g)(2)(iii)(A)(*2*), and (g)(2)(iii)(A)(*3*).''

This document corrects these various issues contained in the regulatory text.

List of Subjects

14 CFR Part 91

Aircraft, Aviation safety.

14 CFR Part 125

Aircraft, Aviation safety.

14 CFR Part 135

Air taxis, Aircraft, Aviation safety.

Accordingly, 14 CFR part 91, Part 125, and Part 135 are corrected by making the following correcting amendments:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); Pub. L. 118–383; articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.609 by revising paragraphs (i)(2)(i)(B) and (i)(2)(i)(C) to read as follows:

§ 91.609 Flight data recorders and cockpit voice recorders.

* * * * *

(i) * * *

(2) * * *

(i) * * *

(A) * * *

(B) Manufactured on or after February 2, 2027, for airplanes or rotorcraft with a maximum certified takeoff weight (MCTOW) of 59,525 pounds or more and type-certificated with 29 or fewer passenger seats; or

(C) Manufactured on or after February 2, 2029, for airplanes or rotorcraft with a maximum certified takeoff weight (MCTOW) of 59,524 pounds or less.

* * * * *

PART 125—CERTIFICATION AND OPERATIONS: AIRCRAFT HAVING A SEATING CAPACITY OF 20 OR MORE PASSENGERS OR A MAXIMUM PAYLOAD CAPACITY OF 6,000 POUNDS OR MORE; AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 3. The authority citation for part 125 continues to read as follows:

Authority: 49 U.S.C. 106(f), 40113, 44701–44702, 44705, 44710–44711, 44713, 44716–44717, 44722; Pub. L. 118–383.

■ 4. Amend § 125.227 by revising paragraph (h)(2)(i)(B) to read as follows:

§ 125.227 Cockpit voice recorders.

* * * * *

(h) * * *

(2) * * *

(i) * * *

(B) If manufactured on or after February 2, 2027, for airplanes with a maximum certified takeoff weight (MCTOW) of 59,525 pounds or more and type-certificated with 29 or fewer passenger seats;

* * * * *

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 5. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(f), 40113, 41706, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722, 44730, 45101–45105; Pub. L. 112–95, 126 Stat. 58 (49 U.S.C. 44730), Pub. L. 118–383.

■ 6. Amend § 135.151 by revising paragraphs (g)(1)(iii) and (g)(2)(iii) to read as follows:

§ 135.151 Cockpit voice recorders.

* * * * *

(g) * * *

(1) * * *

(iii) Retains at least—

(A) The last 25 hours of recorded information using a recorder that meets the standards of TSO–C123c, or later revision, if:

(*1*) Manufactured on or after May 16, 2025, for a transport category aircraft type-certificated with 30 or more passenger seats; or

(*2*) Manufactured on or after February 2, 2027, for airplanes or rotorcraft with a maximum certified takeoff weight (MCTOW) of 59,525 pounds or more and type-certificated with 29 or fewer passenger seats; or

(*3*) Manufactured on or after February 2, 2029, for airplanes or rotorcraft with a maximum certified takeoff weight (MCTOW) of 59,524 pounds or less.

(B) The last 2 hours of recorded information using a recorder that meets the standards of TSO–C123a, or later revision, unless the airplane or rotorcraft meets the manufacturing date and requirements found in paragraphs (g)(1)(iii)(A)(*1*), (g)(1)(iii)(A)(*2*), or (g)(1)(iii)(A)(*3*) of this section.

* * * * *

(2) * * *

(iii) Retains at least—

(A) The last 25 hours of recorded information using a recorder that meets the standards of TSO–C123c, or later revision, if:

(*1*) Manufactured on or after May 16, 2025, for airplanes or rotorcraft type-certificated with 30 or more passenger seats; or

(*2*) Manufactured on or after February 2, 2027, for airplanes or rotorcraft with a maximum certified takeoff weight (MCTOW) of 59,525 pounds or more and type-certificated with 29 or fewer passenger seats; or

(*3*) Manufactured on or after February 2, 2029, for airplanes or rotorcraft with a maximum certified takeoff weight (MCTOW) of 59,524 pounds or less.

(B) The last 2 hours of recorded information using a recorder that meets the standards of TSO–C123a, or later revision, unless the airplane or rotorcraft meets the manufacturing date and requirements found in paragraphs (g)(2)(iii)(A)(*1*), (g)(2)(iii)(A)(*2*), or (g)(2)(iii)(A)(*3*) of this section.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2026–09143 Filed 5–7–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2026–N–4659]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the External Condom for Anal Intercourse or Vaginal Intercourse

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the external condom for anal intercourse or vaginal intercourse into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the external condom for anal intercourse or vaginal intercourse. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective May 8, 2026. The classification was applicable on February 23, 2022.

FOR FURTHER INFORMATION CONTACT: Sharon Andrews, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2640, Silver Spring, MD 20993–0002, 301–796–6529, *Sharon.Andrews@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the external condom for anal intercourse or vaginal intercourse into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 9, 2021, FDA received Global Protection Corp.'s request for De Novo classification of the ONE Male Condom. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 23, 2022, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 884.5305.[1] We have named the generic type of device ''external condom for anal intercourse or vaginal intercourse,'' and it is identified as a barrier device which covers the penis and is used to prevent the transmission of sexually transmitted infections (when used for anal intercourse or vaginal intercourse) and for contraception (when used for vaginal intercourse). This classification does not include condoms intended for vaginal intercourse only.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final 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.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR EXTERNAL CONDOM FOR ANAL INTERCOURSE OR VAGINAL INTERCOURSE

Identified risks to health	Mitigation measures
Transmission of sexually transmitted infection	Acute failure modes clinical study; Non-clinical performance testing; Shelf life testing; and Labeling.
Pregnancy	Acute failure modes clinical study; Non-clinical performance testing; Shelf life testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation; and Labeling.
Mechanical injury leading to ulceration, laceration, trauma	Acute failure modes clinical study; Non-clinical performance testing; Shelf life testing; and Labeling.
Use error/improper device use leading to the risks above	Acute failure modes clinical study; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for external condoms for anal intercourse or vaginal intercourse. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for part 884 continues to read as follows:

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

■ 2. Add § 884.5305 to subpart F to read as follows:

§ 884.5305 External condom for anal intercourse or vaginal intercourse.

(a) *Identification.* An external condom for anal intercourse or vaginal intercourse is a barrier device which covers the penis and is used to prevent the transmission of sexually transmitted infections (when used for anal intercourse or vaginal intercourse) and for contraception (when used for vaginal intercourse). This classification does not include condoms intended for vaginal intercourse only.

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

(1) Clinical performance data must demonstrate the total rate of clinical failure and rate of individual failure modes of the device based on an acute failure modes study.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The data must include an assessment of mechanical and material integrity, including an evaluation of device failure modes. For devices made of materials other than natural rubber latex, viral penetration testing must be conducted to evaluate barrier effectiveness to sexually transmitted infections.

(3) The device must be demonstrated to be biocompatible.

(4) Performance data must support the shelf life of the device by demonstrating device functionality and package integrity over the identified shelf life.

(5) Labeling must include:

(i) If indicated for vaginal intercourse, a contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;

(ii) Statement regarding compatibility with additional lubricant types;

(iii) Statement regarding the adverse events associated with the device, including transmission of infection, pregnancy, adverse tissue reaction, mechanical injury, or improper device use;

(iv) Expiration date; and

(v) The following information, warnings and precautions:

(A) The sexually transmitted infections (STIs) for which the device is most protective, the degree of protection the device provides against specific types of STIs, and the STIs the device does not protect against;

(B) A statement that the device does not completely eliminate the risks of pregnancy and sexually transmitted infections and that risk can be decreased with correct and consistent use;

(C) A warning regarding the risk of device failure during anal intercourse if adequate lubricant is not used;

(D) A warning stating that the device cannot be used multiple times and is limited to one sex act; and

(E) A precaution stating not to use the device if the user is at risk for material related allergic reactions.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09152 Filed 5–7–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Part 479

[ATF No. 2025R–45F]

RIN 1140–AA83

Changes to National Firearms Act Tax Remittance Provisions

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.

ACTION: Final rule.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms, and Explosives (''ATF'') is amending Department of Justice (''Department'') regulations on the National Firearms Act (''NFA'') to reflect statutory changes made to the NFA by the One Big Beautiful Bill Act (''OBBBA''). Among other things, the OBBBA reduced the tax remittance rate for certain NFA firearms. This rule is necessary to make conforming changes to ensure that ATF's regulations are current and consistent with the statute.

DATES: This rule is effective on June 10, 2026.

FOR FURTHER INFORMATION CONTACT: Office of Regulatory Affairs, by email at *ora@atf.gov,* by mail at Office of Regulatory Affairs; Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms, and Explosives; 99 New York Ave. NE, Washington, DC 20226, or by telephone at (202) 648–7070 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Attorney General is responsible for enforcing the National Firearms Act (''NFA''), as amended, 26 U.S.C. chapter 53.[1] Congress and the Attorney General have delegated the responsibility for administering and enforcing the NFA to the Director of ATF (''Director''), subject to the direction of the Attorney General and the Deputy Attorney General. *See* 28 U.S.C. 599A(b)(1), (c)(1); 28 CFR 0.130(a)(1)–(2); Treas. Order No. 221(2)(a), (d), 37 FR 11696–97 (June 10, 1972).[2] Accordingly, the Department and ATF have promulgated regulations to implement the NFA in 27 CFR part 479.

Firearms subject to NFA provisions include machine guns; shotguns having a barrel or barrels of less than 18 inches in length; weapons made from a shotgun if such weapon as modified has an overall length of less than 26 inches or a barrel or barrels less than 18 inches in length; rifles having a barrel or barrels of less than 16 inches in length; weapons made from a rifle if such weapon as modified has an overall length of less than 26 inches or a barrel or barrels less than 16 inches in length; silencers; destructive devices; and any other weapons (''AOWs'') as defined by the Act. 26 U.S.C. 5845(e). Section 5841 of the NFA requires the Attorney General to maintain a central registry of NFA firearms in the United States that the United States does not possess or are not under its control. The registry is called the National Firearms Registration and Transfer Record (''NFRTR''). All firearms must be registered by their maker, manufacturer, or importer. Section 5821 sets forth the tax that persons making NFA firearms must pay, and section 5822 provides that makers must submit a request to the Attorney General and receive approval before making an NFA firearm. The term ''make'' under the NFA includes ''manufacturing (other than by one qualified to engage in such business under this chapter), putting together, altering, any combination of these, or otherwise producing a firearm.'' 26 U.S.C. 5845(i). Section 5811 sets forth the tax that a person wishing to transfer an NFA firearm must pay, and section 5812 provides that transferors must submit a request to the Attorney General and receive approval before transferring an NFA firearm to a given transferee. The NFA provides that a transfer includes ''selling, assigning, pledging, leasing, loaning, giving away, or otherwise disposing of'' a firearm. 26 U.S.C. 5845(j).

Transfer taxes in the amount of $200 were established in 1934 when the NFA was enacted. Taxes on making NFA firearms in the amount of $200 were established in 1968 when the NFA was revised. Under the NFA, ATF also collects special (occupational) taxes from federally licensed importers, manufacturers, and dealers in NFA firearms. 26 U.S.C. 5801. While tax revenues from sales of non-NFA firearms and ammunition are generally allocated to the Federal Aid to Wildlife Restoration Fund for wildlife restoration and hunter education and safety, 16 U.S.C. 669b(a)(1), taxes collected from NFA-generated tax receipts are deposited into the General Fund of the Treasury. Congress has previously considered, but has not passed, various proposals pertaining to changing the taxing and registering provisions for NFA firearms.

On July 4, 2025, the OBBBA became law. Public Law 119–21. Section 70436 of the OBBBA amended 26 U.S.C. 5811(a) to require that the transfer tax for all firearms regulated under the NFA, other than machine guns and destructive devices, be reduced to $0. Similarly, this section amended 26 U.S.C. 5821(a) to require that the making tax for all NFA firearms, except machine guns and destructive devices, also be reduced to $0. Accordingly, ATF is amending 27 CFR 479.61, 479.62, 479.81, 479.82, and 479.84 to reflect the changes to the statute and to make minor agency procedure and plain writing edits as described below.

II. Final Rule

The OBBBA specified that the tax reduction amendments to the NFA would be effective on January 1, 2026, at which point the NFA making and transfer taxes for NFA firearms other than machine guns and destructive devices would be reduced to $0. As a result, those statutory changes have already occurred. ATF is issuing this final rule to make conforming changes to the tax amounts within ATF's corresponding regulatory provisions under 27 CFR part 479. Although ATF is revising its rule to reflect that OBBBA reduced the tax amount for these NFA firearms to $0, all other regulatory provisions of the NFA application and registration process remain in full force and effect. In addition, the rule makes minor administrative edits to allow the ATF approval stamp on making and transfer applications to be electronic and to make the revised provisions easier to read.

[1] Some NFA provisions still refer to the ''Secretary of the Treasury.'' However, the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, transferred the functions of ATF from the Department of the Treasury to the Department of Justice, under the general authority of the Attorney General. 26 U.S.C. 7801(a)(2); 28 U.S.C. 599A(c)(1). Thus, for ease of reference, this final rule refers to the Attorney General where relevant.

[2] In Attorney General Order Number 6353–2025, the Attorney General delegated authority to the Director to issue regulations pertaining to matters within ATF's jurisdiction, including under the NFA, Gun Control Act, and Title XI of the Organized Crime Control Act. ATF's jurisdiction also includes those portions of sec. 38 of the Arms Export Control Act pertaining to permanently importing defense articles and services and the Contraband Cigarette Trafficking Act.