this requirement. As explained above, the adjustments required for years subsequent to 2017 are not subject to the requirements of the Administrative Procedure Act. Moreover, the 2017 adjustments are made according to a statutory formula that does not provide for agency discretion. Accordingly, a delay in effectiveness of the 2017 adjustments is not required.

IV. Regulatory Requirements

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.\(^9\)

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,\(^{10}\) NASA reviewed this interim final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the interim final rule.

List of Subjects in 14 CFR Parts 1264 and 1271

Claims, Lobbying, Penalties.

For the reasons stated in the preamble, the National Aeronautics and Space Administration adopts as final the interim rule amending 14 CFR parts 1264 and 1271 which published on June 26, 2017, at 82 FR 28760, with the following changes:

PART 1264—IMPLEMENTATION OF THE PROGRAM FRAUD CIVIL PENALTIES ACT OF 1986

\(^{1}\) The authority citation for part 1264 continues to read as follows:


§ 1264.102 [Amended]

\(^{2}\) In § 1264.102, paragraphs (a) and (b), remove the number “$10,781” and add in its place the number “$10,957.”

PART 1271—NEW RESTRICTIONS ON LOBBYING

\(^{3}\) The authority citation for part 1271 continues to read as follows:


§ 1271.400 [Amended]

\(^{4}\) In § 1271.400:

\(^{a}\) In paragraphs (a) and (b) remove the words “not less than $18,936 and not more than $189,361” and add in their place the words “not less than $19,246 and not more than $192,459.”

\(^{b}\) In paragraph (e), remove the two occurrences of “$18,936” and add in their place “$19,246” and remove “189,361” and add in its place “192,459.”

Appendix A to Part 1271 [Amended]

\(^{5}\) In appendix A to part 1271, in the paragraph following paragraph (3) and in the last paragraph of the appendix, remove the words “not less than $18,936 and not more than $189,361” and add in their place the words “not less than $19,246 and not more than $192,459.”

Granette J. Smith, NASA Federal Register Liaison Officer.

FR Doc. 2017–22847 Filed 10–19–17; 8:45 am

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2017–N–5371]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Microbial Pathogen Nucleic Acids in Cerebrospinal Fluid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid into class II (special controls). We determine whether a new device is substantially equivalent under section 513(f) of the FD&C Act (21 U.S.C. 360c(f)(1)) 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. 360c(k)) and part 807 (21 CFR part 807). We 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. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144).

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After
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. In order for a device to fail 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 order. This device is 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 individually or cumulatively 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. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0073, and the collections of information in 21 CFR parts 801 and 809, regarding labeling have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.
sequences from patients suspected of meningitis or encephalitis. A device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid is intended to aid in the diagnosis of meningitis or encephalitis when used in conjunction with clinical signs and symptoms and other clinical and laboratory findings.

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

(1) Premarket notification submissions must include detailed device description documentation, including the device components, ancillary reagents required but not provided, and a detailed explanation of the methodology, including primer/probe sequence, design, and rationale for sequence selection.

(2) Premarket notification submissions must include detailed documentation from the following analytical studies: Analytical sensitivity (limit of detection), inclusivity, reproducibility, interference, cross reactivity, and specimen stability.

(3) Premarket notification submissions must include detailed documentation from a clinical study. The study, performed on a study population consistent with the intended use population, must compare the device performance to results obtained from well-accepted comparator methods.

(4) Premarket notification submissions must include detailed documentation for device software, including, but not limited to, software applications and hardware-based devices that incorporate software.

(5) The Intended Use statement in the device labeling must include a statement that the device is intended to be used in conjunction with standard of care culture.

(6) A detailed explanation of the interpretation of results and acceptance criteria must be included in the device’s 21 CFR 809.10(b)(9) compliant labeling.

(7) The device labeling must include a limitation stating that the negative results do not preclude the possibility of central nervous system infection.

(8) The device labeling must include a limitation stating that device results are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions.

(9) The device labeling must include a limitation stating that positive results do not mean that the organism detected is infectious or is the causative agent for clinical symptoms.

(10) As part of the risk management activities performed as part of your 21 CFR 820.30 design controls, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.


Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that certain vessels of the VIRGINIA SSN Class are vessels of the Navy which, due to their special construction and purpose, cannot fully comply with the special provisions of the 72 COLREGS without interfering with their special function as a naval ships. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective October 20, 2017 and is applicable beginning September 30, 2017.


SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706. This amendment provides notice that 72 COLREGS, under authority delegated by the Secretary of the Navy, has certified that certain vessels of the SSN Class are vessels of the Navy which, due to their special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with their special function as a naval ship: Rule 23(a) and Annex I, paragraph 2(a)(i), pertaining to the vertical placement of the masthead, light and Annex I, paragraph 2(f)(i), pertaining to the masthead light being above and clear of all other lights and obstructions; Rule 30 (a), Rule 21(e), and Annex I, paragraph 2(k), pertaining to the vertical separation of the anchor lights, vertical placement of the forward anchor light above the hull, and the arc of visibility of all around lights; Rule 23 (a) and Annex I, paragraph 3(b), pertaining to the location of the sidelights; and Rule 21(c), pertaining to the location and arc of visibility of the sternlight. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on these vessels in a manner differently from that prescribed herein will adversely affect these vessels’ ability to perform their military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

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