2020, DHS will further expand the list of authorized airports to include DFW and DTW. Arrival restrictions continue until cancelled or modified by the Secretary of DHS and notification is published in the **Federal Register** of such cancellation or modification.

FOR FURTHER INFORMATION CONTACT: Alyce Modesto, Office of Field Operations, 202–344–3788.

SUPPLEMENTARY INFORMATION:

Background

The Centers for Disease Control and Prevention (CDC) is closely monitoring an outbreak of respiratory illness caused by a novel (new) coronavirus first identified in Wuhan City, Hubei Province, China. Coronaviruses are a large family of viruses that are common in many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).

The potential for widespread transmission of this virus by infected individuals seeking to enter the United States threatens the security of our transportation system and infrastructure, and the national security. In an abundance of caution and to assist in preventing the introduction and spread of this communicable disease in the United States, DHS, in coordination with the CDC and other Federal, state and local agencies charged with protecting the American public, is implementing enhanced arrival protocols to ensure that all travelers with recent travel from the People's Republic of China are provided public health services. Entry screening is part of a layered approach used with other public health measures already in place to detect arriving travelers who are exhibiting overt signs of illness, reporting of ill travelers by air carriers during travel, and referral of ill travelers arriving at a U.S. port of entry by U.S. Customs and Border Protection (CBP) to appropriate public health officials to slow and prevent the spread of communicable disease into the United States.

To ensure that travelers with recent travel from the People's Republic of China are screened, DHS directs that all flights to the United States carrying persons who have recently traveled from, or were otherwise present within, the People's Republic of China arrive at airports where enhanced public health services and protocols are being implemented. While DHS anticipates working with air carriers to identify potential persons from the affected area prior to boarding, air carriers shall comply with the requirements of this document.

On Friday, January 31, 2020, DHS posted a document on the **Federal Register** public inspection page, announcing the DHS Secretary's decision that arrival restrictions would go into effect at 5 p.m. EST on Sunday, February 2, 2020 at seven airports. This document adds four additional airports to the list of airports where flights can land and describes when the arrival restrictions will include those airports.

DHS notes that implementation of the arrival restrictions in this document and in the January 31, 2020 document may entail technical and logistical difficulties for airlines. We are confident that all airlines will make every effort to comply. DHS is appreciative of good faith attempts at compliance by airlines.

Notification of Arrival Restrictions Applicable to All Flights Carrying Persons Who Have Recently Traveled From or Were Otherwise Present Within the People's Republic of China

Pursuant to 19 U.S.C. 1433(c), 19 CFR 122.32, 49 U.S.C. 114, and 49 CFR 1544.305 and 1546.105, DHS has the authority to limit the location where all flights entering the U.S. from abroad may land. Under this authority and effective for flights departing after 5 p.m. EST on Sunday, February 2, 2020, I hereby direct all operators of aircraft to ensure that all flights carrying persons who have recently traveled from, or were otherwise present within, the People's Republic of China only land at one of the following airports:

- John F. Kennedy International Airport (JFK), New York;
- Chicago O'Hare International Airport (ORD), Illinois;
- San Francisco International Airport (SFO), California;
- Seattle-Tacoma International Airport (SEA), Washington;
- Daniel K. Inouye International Airport (HNL), Hawaii;
- Los Angeles International Airport, (LAX), California;
- Hartsfield-Jackson Atlanta International Airport (ATL), Georgia;
- Washington-Dulles International Airport (IAD), Virginia;

Effective at 6:30 a.m. EST on Monday February 3, this list of airports is expanded to include:

- Newark Liberty International Airport (EWR), New Jersey.

Effective at 7:30 a.m. EST on Monday February 3, this list of airports is expanded to include:

- Dallas/Fort Worth International Airport (DFW), Texas; and
- Detroit Metropolitan Airport (DTW), Michigan.

This direction considers a person to have recently traveled from the People's Republic of China if that person departed from, or was otherwise present within, the People's Republic of China (excluding the special autonomous regions of Hong Kong and Macau) within 14 days of the date of the person's entry or attempted entry into the United States. Also, for purposes of this document, crew, and flights carrying only cargo (*i.e.,* no passengers or non-crew), are excluded from the measures herein. This direction is subject to any changes to the airport landing destination that may be required for aircraft and/or airspace safety as directed by the Federal Aviation Administration.

This list of affected airports may be modified by the Secretary of Homeland Security in consultation with the Secretary of Health and Human Services and the Secretary of Transportation. This list of affected airports may be modified by an updated publication in the **Federal Register** or by posting an advisory to follow at *www.cbp.gov.* The restrictions will remain in effect until superseded, modified, or revoked by publication in the **Federal Register**.

For purposes of this **Federal Register** document, ''United States'' means the States of the United States, the District of Columbia, and territories and possessions of the United States (including Puerto Rico, the Virgin Islands, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and Guam).

Chad F. Wolf,

Acting Secretary, U.S. Department of Homeland Security.

[FR Doc. 2020–02413 Filed 2–6–20; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2019–N–5325]

Medical Devices; Immunology and Microbiology Devices; Classification of Human Immunodeficiency Virus Drug Resistance Genotyping Assay Using Next Generation Sequencing Technology

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the human immunodeficiency virus (HIV) drug resistance genotyping assay using next generation sequencing (NGS) technology 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 the HIV drug resistance genotyping assay using NGS technology's classification. We are taking this action because we have determined that classifying the device into class II (special controls) 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 on February 7, 2020. The classification was applicable on November 5, 2019.

FOR FURTHER INFORMATION CONTACT: Sana F. Hussain, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the HIV drug resistance genotyping assay using NGS technology as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. 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 as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 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 (Pub. L. 94–295), 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 [1] finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate 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. 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). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 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 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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 19, 2019, Vela Diagnostics USA Inc. submitted a request for De Novo classification of the SENTOSA SQ HIV Genotyping Assay. 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, 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 21 U.S.C. 360c(a)(1)(B)). 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 November 5, 2019, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 866.3955. We have named the generic type of device ''Human immunodeficiency virus drug resistance genotyping assay using next generation sequencing technology,'' and it is identified as a prescription in vitro diagnostic device intended for use in detecting HIV genomic mutations that confer resistance to specific antiretroviral drugs. The device is intended to be used as an aid in monitoring and treating HIV infection.

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

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

TABLE 1—IN VITRO HIV DRUG RESISTANCE GENOTYPE ASSAY USING NGS TECHNOLOGY RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Inaccurate detection of resistance mutation(s).	Device description information, including performance characteristics, and performance studies in labeling.
	Device description validation procedures and performance studies meeting acceptance criteria.
	Device limitations in labeling for genetic mutation detection.
Incorrect interpretation of test results.	Device description information, performance characteristics, and performance studies in 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. 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 order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, HIV drug resistance genotyping assays using NGS technology are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine by order that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. We are not announcing intent to exempt at this time.

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 FDA collections of information. 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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, 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 866

Biologics, Laboratories, Medical devices.

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

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

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

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

■ 2. Add § 866.3955 to subpart D to read as follows:

§ 866.3955 Human immunodeficiency virus (HIV) drug resistance genotyping assay using next generation sequencing technology.

(a) *Identification.* The HIV drug resistance genotyping assay using next generation sequencing (NGS) technology is a prescription in vitro diagnostic device intended for use in detecting HIV genomic mutations that confer resistance to specific antiretroviral drugs. The device is intended to be used as an aid in monitoring and treating HIV infection.

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

(1) The intended use of the device must:

(i) Specify the analyte (RNA or DNA), the genes in which mutations are detected, the clinical indications appropriate for test use, the sample type, and the specific population(s) for which the device in intended.

(ii) State that the device in not intended for use as an aid in the diagnosis of infection with HIV or to confirm the presence of HIV infection, or for screening donors of blood, plasma, or human cells, tissues, and cellular and tissue-based products.

(2) The labeling must include:

(i) A detailed device description, including but not limited to, all procedures from collection of the patient sample to reporting the final result, all device components, the control elements incorporated into the test procedure, instrument requirements, and reagents required for use but not provided as part of the device.

(ii) Performance characteristics from analytical studies and all intended specimen types.

(iii) A list of specific mutations detected.

(iv) The name and version of the standardized database used for sequence comparison and results derivation.

(v) A detailed explanation of the interpretation of test results, including acceptance criteria for evaluating the validity of a test run.

(vi) A limitation statement that the device is intended to be used in conjunction with clinical history and other laboratory findings. Results of this test are intended to be interpreted by a physician or equivalent.

(vii) A limitation statement that lack of detection of drug resistance mutations does not preclude the possibility of genetic mutation.

(viii) A limitation statement indicating the relevant genetic mutations that are included in the standardized database of HIV genomic sequences used for comparison and results derivation but that are not detected by the test.

(ix) A limitation statement that detection of a genomic drug resistance mutation may not correlate with phenotypic gene expression.

(x) A limitation statement that the test does not detect all genetic mutations associated with antiviral drugs.

(xi) A limitation statement listing the HIV types for which the test is not intended, if any.

(3) Device verification and validation must include:

(i) Design of primer sequences and rationale for sequence selection.

(ii) Computational path from collected raw data to reported result.

(iii) Detailed documentation of analytical studies including, but not limited to, characterization of the cutoff, analytical sensitivity, inclusivity, reproducibility, interference, cross reactivity, instrument and method carryover/cross contamination, sample stability, and handling for all genomic mutations claimed in the intended use.

(iv) Precision studies that include all genomic mutations claimed in the intended use.

(v) Detailed documentation of a multisite clinical study evaluating the sensitivity and specificity of the device. Clinical study subjects must represent the intended use population and device results for all targets claimed in the intended use must be compared to Sanger sequencing or other methods found acceptable by FDA. Drug resistance-associated mutations at or above the 20 percent frequency level must detect the mutations in greater than 90 percent of at least 10 replicates, for each of drug class evaluated.

(vi) Documentation that variant calling is performed at a level of coverage that supports positive detection of all genomic mutations claimed in the intended use.

(vii) Detailed documentation of limit of detection (LoD) studies in which device performance is evaluated by testing a minimum of 100 HIV-positive clinical samples including samples with analyte concentrations near the clinical decision points and near the LoD.

(A) The LoD for the device must be determined using a minimum of 10 HIV–1 group M genotypes if applicable. A detection rate at 1 × LoD greater than or equal to 95 percent must be demonstrated for mutations with a frequency greater than 20 percent.

(B) The LoD of genetic mutations at frequency levels less than 20 percent must be established.

(viii) A predefined HIV genotyping bioinformatics analysis pipeline (BAP). The BAP must adequately describe the bioinformatic analysis of the sequencing data, including but not limited to read alignment, variant calling, assembly, genotyping, quality control, and final result reporting.

(ix) A clear description of the selection and use of the standardized database that is used for sequence comparison and results derivation.

(4) Premarket notification submissions must include the information in paragraphs (b)(3)(i) through (ix) of this section.

Dated: January 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01725 Filed 2–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

30 CFR Parts 550 and 553

[Docket ID: BOEM–2019–0079]

RIN 1010–AE05

2020 Civil Penalties Inflation Adjustments for Oil, Gas, and Sulfur Operations in the Outer Continental Shelf

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Final rule.

SUMMARY: This final rule implements the 2020 inflation adjustments to the maximum daily civil monetary penalties contained in the Bureau of Ocean Energy Management (BOEM) regulations for violations of the Outer Continental Shelf Lands Act (OCSLA) and the Oil Pollution Act of 1990 (OPA), pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (FCPIA Improvements Act) and relevant Office of Management and Budget (OMB) guidance. The 2020 adjustment multiplier of 1.01764 accounts for one year of inflation from October 2018 through October 2019.

DATES: This rule is effective on February 7, 2020.

FOR FURTHER INFORMATION CONTACT: Deanna Meyer-Pietruszka, Chief, Office of Policy, Regulation, and Analysis, Bureau of Ocean Energy Management, at (202) 208–6352 or by email at *deanna.meyer-pietruszka@boem.gov*.

SUPPLEMENTARY INFORMATION:

I. Legal Authority
II. Background
III. Calculation of 2020 Adjustments
IV. Procedural Requirements
A. Statutes
1. National Environmental Policy Act
2. Regulatory Flexibility Act
3. Paperwork Reduction Act
4. Unfunded Mandates Reform Act
5. Small Business Regulatory Enforcement Fairness Act
6. Congressional Review Act
B. Executive Orders (E.O.)
1. Governmental Actions and Interference With Constitutionally Protected Property Rights (E.O. 12630)
2. Regulatory Planning and Review (E.O. 12866); Improving Regulation and Regulatory Review (E.O. 13563); and Reducing Regulation and Controlling Regulatory Costs (E.O. 13771)
3. Civil Justice Reform (E.O. 12988)
4. Federalism (E.O. 13132)
5. Consultation and Coordination With Indian Tribal Governments (E.O. 13175)
6. Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)

I. Legal Authority

OCSLA authorizes the Secretary of the Interior to impose a daily civil monetary penalty for a violation of OCSLA or its regulations, leases, permits, or orders and directs the Secretary to adjust the maximum penalty at least every three years to reflect any inflation increase in the Consumer Price Index. 43 U.S.C. 1350(b)(1). Similarly, OPA authorizes civil monetary penalties for failure to comply with OPA's financial responsibility provisions or its implementing regulations. 33 U.S.C. 2716a(a). OPA does not include a maximum daily civil penalty inflation adjustment provision. Id.

The FCPIA Improvements Act [1] requires that Federal agencies publish inflation adjustments to their civil monetary penalties in the **Federal Register** not later than January 15 annually.[2] Public Law 114–74, sec. 701(b)(1). The purposes behind these inflation adjustments are to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes. Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, sec. 2 (codified at 28 U.S.C. 2461 note).

II. Background

BOEM implemented the 2019 inflation adjustment for its civil monetary penalties through a final rule published in the **Federal Register** on March 26, 2019, which accounted for

[1] The FCPIA Improvements Act amended the Federal Civil Penalties Inflation Adjustment Act of 1990. Public Law 101–410 (codified at 28 U.S.C. 2461 note).

[2] Under the FCPIA Improvements Act, Federal agencies were required to adjust their civil monetary penalties for inflation with an initial ''catch-up'' adjustment through an interim final rulemaking in 2016 and are required to make subsequent inflation adjustments not later than January 15 annually, beginning in 2017. Public Law 114–74, sec. 701(b)(1).