d.1.b.1. Capable of being sterilized or disinfected in-situ; *or*

d.1.b.2. Using disposable or single-use filtration ''parts'' or ''components''.

N.B.: 2B352.d.1 does not control reverse osmosis and hemodialysis equipment, as specified by the manufacturer.

d.2. Cross (tangential) flow filtration ''parts'' or ''components'' (*e.g.,* modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square meters (0.2 m^2) for each ''part'' or ''component'' and designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

Technical Note: *In this ECCN, ''sterilized'' denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g., steam) or chemical agents. ''Disinfected'' denotes a process to reduce the number of microorganisms, but not usually of bacterial spores, through the use of chemical agents, without necessarily killing or removing all organisms.*

e. Steam, gas or vapor sterilizable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours (10 liters of water or greater in 24 hours) and less than 1000 kg of ice in 24 hours (less than 1,000 liters of water in 24 hours).

f. Spray-drying equipment capable of drying toxins or pathogenic microorganisms having all of the following characteristics:

f.1. A water evaporation capacity of ≥0.4 kg/h and ≤400 kg/h;

f.2. The ability to generate a typical mean product particle size of ≤10 micrometers with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size; *and*

f.3. Capable of being sterilized or disinfected in situ.

g. Protective and containment equipment, as follows:

g.1. Protective full or half suits, or hoods dependent upon a tethered external air supply and operating under positive pressure.

Technical Note to 2B352.g.1: 2B352.g.1 does not control suits designed to be worn with self-contained breathing apparatus.

g.2. Biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:

g.2.a. Fully enclosed workspace where the operator is separated from the work by a physical barrier;

g.2.b. Able to operate at negative pressure;

g.2.c. Means to safely manipulate items in the workspace; *and*

g.2.d. Supply and exhaust air to and from the workspace is high-efficiency particulate air (HEPA) filtered.

Note 1 to 2B352.g.2: 2B352.g.2 controls class III biosafety cabinets, as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) or constructed in accordance with national standards, regulations or guidance.

Note 2 to 2B352.g.2: 2B352.g.2 controls any isolator having all of the characteristics described in 2B352.g.2.a through g.2.d, regardless of its intended use and its designation, except for medical isolators ''specially designed'' for barrier nursing or transportation of infected patients.

h. Aerosol inhalation equipment designed for aerosol challenge testing with microorganisms, viruses or toxins, as follows:

h.1. Whole-body exposure chambers having a capacity of 1 cubic meter or greater;

h.2. Nose-only exposure apparatus utilizing directed aerosol flow and having a capacity for the exposure of 12 or more rodents, or two or more animals other than rodents, and closed animal restraint tubes designed for use with such apparatus.

i. Spraying or fogging systems and ''parts'' and ''components'' therefor, as follows:

i.1. Complete spraying or fogging systems, ''specially designed'' or modified for fitting to aircraft, ''lighter than air vehicles,'' or ''UAVs,'' capable of delivering, from a liquid suspension, an initial droplet ''VMD'' of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.2. Spray booms or arrays of aerosol generating units, ''specially designed'' or modified for fitting to aircraft, ''lighter than air vehicles,'' or ''UAVs,'' capable of delivering, from a liquid suspension, an initial droplet ''VMD'' of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.3. Aerosol generating units ''specially designed'' for fitting to the systems as specified in paragraphs i.1 and i.2 of this ECCN.

Technical Notes to 2B352.i:

1. Aerosol generating units are devices ''specially designed'' or modified for fitting to aircraft and include nozzles, rotary drum atomizers and similar devices.

2. This ECCN does not control spraying or fogging systems, ''parts'' and ''components,'' as specified in 2B352.i, that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.

3. Droplet size for spray equipment or nozzles ''specially designed'' for use on aircraft or ''UAVs'' should be measured using either of the following methods (pending the adoption of internationally accepted standards):

a. Doppler laser method,

b. Forward laser diffraction method.

j. Nucleic acid assemblers and synthesizers that are both:

j.1 Partly or entirely automated; *and*

j.2. Designed to generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run.

* * * * *

Thea D. Rozman Kendler,

Assistant Secretary, for Export Administration.

[FR Doc. 2023–00397 Filed 1–13–23; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

19 CFR Chapter I

Termination of Arrival Restrictions Applicable to Flights Carrying Persons Who Have Recently Traveled From or Were Otherwise Present Within Uganda

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Announcement of termination of arrival restrictions.

SUMMARY: This document announces the decision of the Secretary of Homeland Security to terminate arrival restrictions applicable to flights to the United States carrying persons who have recently traveled from, or were otherwise present within, Uganda due to an outbreak of Ebola disease in Uganda. These restrictions directed such flights to only land at one of the United States airports where the United States Government had focused public health resources to implement enhanced public health measures.

DATES: The arrival restrictions applicable to flights to the United States carrying persons who have recently traveled from, or were otherwise present within, Uganda are terminated as of 11:59 p.m. Eastern Standard Time on January 11, 2023.

FOR FURTHER INFORMATION CONTACT: Stephanie Watson, Office of Field Operations, U.S. Customs and Border Protection at 202–255–7018.

SUPPLEMENTARY INFORMATION:

Background

On October 12, 2022, the Secretary of Homeland Security announced arrival restrictions applicable to flights carrying persons who have recently traveled from, or were otherwise present within, Uganda, consistent with 6 U.S.C. 112(a), 19 U.S.C. 1433(c), and 19 CFR 122.32, in a **Federal Register** document titled ''Arrival Restrictions Applicable to Flights Carrying Persons Who Have Recently Traveled From or Were Otherwise Present Within Uganda'' (87 FR 61488). For purposes of the October 2022 arrival restrictions, a person recently traveled from Uganda if that person departed from, or was otherwise present within, Uganda within 21 days of the date of the person's entry or attempted entry into the United States.

For the reasons set forth below, the Secretary has decided to terminate the arrival restrictions applicable to flights

carrying persons who have recently traveled from, or were otherwise present within, Uganda. These restrictions funnel relevant arriving air passengers to one of five designated airports of entry where the U.S. is implementing enhanced public health measures. Since November 27, 2022, there have been no new confirmed Ebola disease cases reported in Uganda and two 21-day incubation periods have passed. With no new hospitalized patients with Ebola disease, and no contacts of confirmed Ebola disease cases still requiring monitoring, the potential risk for Ebolavirus exposure in Uganda has greatly diminished. Therefore, flight arrival restrictions are no longer required for flights to the United States carrying persons who have recently traveled from, or were otherwise present within, Uganda.

Notice of Termination of Arrival Restrictions Applicable to All Flights Carrying Persons Who Have Recently Traveled From or Were Otherwise Present Within Uganda

Pursuant to 6 U.S.C. 112(a), 19 U.S.C. 1433(c), and 19 CFR 122.32, and effective as of 11:59 p.m. Eastern Standard Time on January 11, 2023, for all affected flights arriving at a United States airport, I hereby terminate the arrival restrictions applicable to flights to the United States carrying persons who have recently traveled from, or were otherwise present within, Uganda announced in the Arrival Restrictions document published at 87 FR 61488 (October 12, 2022).

Alejandro Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2023–00793 Filed 1–11–23; 4:45 pm]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2022–N–3335]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Prognostic Test for Assessment of Liver Related Disease Progression

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the prognostic test for assessment of liver related disease progression 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 prognostic test for assessment of liver related disease progression'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.

DATES: This order is effective January 17, 2023. The classification was applicable on August 20, 2021.

FOR FURTHER INFORMATION CONTACT: Irene Tebbs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3526, Silver Spring, MD 20993–0002, 340–402–0283, *Irene.Tebbs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the prognostic test for assessment of liver related disease progression 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 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, 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 (see 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. 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 application 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 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.

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 November 4, 2020, FDA received Siemens Healthcare Diagnostics Inc.'s request for De Novo classification of the ADVIA Centaur Enhanced Liver Fibrosis. FDA reviewed the request in order to classify the device under the