deemed manufacturers provide tobacco health document submissions from the specified period, at least 90 days prior to the delivery for introduction into interstate commerce of tobacco products to which the health documents relate. Manufacturers or importers of cigarettes, cigarette tobacco, RYO, or smokeless tobacco products must provide all health documents developed between June 23, 2009, and December 31, 2009, at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce.

After publication of the 60-day notice however, on March 15, 2022, President Biden signed H.R. 2471—the Consolidated Appropriations Act, 2022. As a result, the FD&C Act now includes specific language that makes clear that FDA has the authority to regulate tobacco products containing nicotine from any source, which includes synthetic. On April 14, 2022, firms engaged in the manufacture, preparation, compounding, or processing of tobacco products containing non-tobacco nicotine products (NTN) must therefore provide health documents.

In the **Federal Register** of February 25, 2022 (87 FR 10800), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600
Tobacco Health Document Submissions and Form 3743 for Non-Tobacco Nicotine Products (NTN)	100	1	100	2	200
Total					1,800

The number of documents received each year since the original collection period has fallen to less than 5 percent of what was received in the original collection period. FDA expects this is because documents created within the specified period should have already been submitted. The Agency bases this estimate on the total number of tobacco firms it is aware of and its experience with document production and the number of additional documents that have been reported each year since the original estimate of the reporting burden.

FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers, or agents thereof, would have health documents to submit. We anticipate documents will be submitted on an annual basis for a total of 10 respondents. FDA estimates the annual reporting burden for these respondents to be 1,600 hours.

As mentioned previously in this document, with the new authority provided to FDA, firms engaged in the manufacture, preparation, compounding, or processing of tobacco products containing NTN must provide health documents. Although these firms are unlikely to have health documents created within the specified period, we are estimating for this extension that we will receive 100 new NTN respondents who will be required to provide a declaration to such effect via Form 3743, which is expected to take 2 hours, for a total 200 burden hours.

Based on a review of the information collection of our current OMB approval, we have increased the burden by 200 hours.

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15727 Filed 7–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION**

section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet and can be accessed from *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

III. The Authorizations

Having concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued from January 25, 2022, through June 15, 2022, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. In addition, the EUAs that have been reissued can be accessed from

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

FDA is hereby announcing the following Authorizations for molecular diagnostic and antigen tests for COVID–19, excluding multianalyte tests: [3]

- Fluidigm Corporation's Advanta Dx COVID–19 EASE Assay, issued February 7, 2022;
- Uh-Oh Labs Inc.'s UOL COVID–19 Test, issued February 8, 2022;
- Oceanit Foundry LLC's ASSURE–100 Rapid COVID–19 Test, issued February 28, 2022;
- Siemens Healthcare Diagnostics, Inc.'s ADVIA Centaur SARS–CoV–2 Antigen (CoV2Ag), issued March 11, 2022;
- Siemens Healthcare Diagnostics, Inc.'s Atellica IM SARS–CoV–2 Antigen (CoV2Ag), issued March 11, 2022;
- Minute Molecular Diagnostics, Inc.'s DASH SARS–CoV–2/S Test, issued March 15, 2022;
- PHASE Scientific International, Ltd.'s INDICAID COVID–19 Rapid Antigen At-Home Test, issued March 16, 2022;
- Helix OpCo LLC's (dba Helix) Helix SARS–CoV–2 Test, issued March 17, 2022;
- Quest Diagnostics Nichols Institute's Quest RC COVID–19 PCR DTC, issued March 21, 2022;
- Quest Diagnostics Nichols Institute's Quest PF COVID–19 PCR DTC, issued March 21, 2022;
- Quest Diagnostics Nichols Institute's Quest COVID–19 PCR DTC, issued March 21, 2022;
- DC Department of Health's Test Yourself DC At-Home COVID–19 Collection Kit, issued April 6, 2022;
- OSANG LLC's OHC COVID–19 Antigen Self Test, issued April 6, 2022;
- Xiamen Boson Biotech Co., Ltd.'s Rapid SARS–CoV–2 Antigen Test Card, issued April 6, 2022;
- UCSD BCG EXCITE Lab's UCSD EXCITE COVID–19 EL Test, issued April 7, 2022;
- MicroGEM U.S., Inc.'s MicroGEM Sal6830 SARS–CoV–2 Saliva Test, issued April 14, 2022;
- LGC, Biosearch Technologies's Biosearch Technologies SARS–CoV–2 ultra-high-throughput End-Point RT–PCR Test, issued April 26, 2022;
- Abbott Diagnostics Scarborough, Inc.'s ID NOW COVID–19 2.0, issued May 6, 2022;
- Cepheid's Xpert Xpress CoV–2 *plus,* issued May 10, 2022;
- Nexus Medical Labs, LLC.'s Nexus High Throughput SARS–CoV–2 Assay, issued May 17, 2022;
- DxLab Inc.'s DxLab COVID–19 Test, issued June 1, 2022;
- Roche Molecular Systems, Inc.'s cobas SARS–CoV–2 Duo for use on the cobas 6800/8800 Systems (cobas SARS–CoV–2 Duo), issued June 14, 2022;

FDA is hereby announcing the following Authorizations for serology tests: [4]

- LG Chem, Ltd.'s *AdvanSure* SARS–CoV–2 IgG(S1) ELISA, issued May 19, 2022;
- LG Chem, Ltd.'s *AdvanSure* SARS–CoV–2 IgG(RBD) ELISA, issued May 31, 2022.

FDA is hereby announcing the following Authorizations for multianalyte in vitro diagnostics:

- Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute's SelfCheck cobas SARS–CoV–2 + Flu Assay, issued April 11, 2022; [5]
- OPTI Medical Systems, Inc.'s OPTI SARS–CoV–2/Influenza A/B RT–PCR Test (Version 1 and Version 2), issued April 21, 2022; [6]
- Laboratory Corporation of America's (Labcorp's) Labcorp Seasonal Respiratory Virus RT–PCR DTC Test, issued May 16, 2022; [7]
- Laboratory Corporation of America's (Labcorp's) Labcorp Seasonal Respiratory Virus RT–PCR Test, issued May 17, 2022; [8]

FDA is hereby announcing the following Authorization for a SARS–CoV–2 genotyping test:

- Laboratory Corporation of America's (Labcorp's) Labcorp VirSeq SARS–CoV–2 NGS Test, issued June 10, 2022.[9]

FDA is hereby announcing the following Authorization for a SARS–CoV–2 diagnostic test that analyzes breath samples:

[3] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID–19, and that the known and potential benefits of the products, when used for diagnosing COVID–19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[4] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing recent or prior infection with SARS–CoV–2 by identifying individuals with an adaptive immune response to the virus that causes COVID–19, and that the known and potential benefits of the products when used for such use, outweigh the known and potential risks of the products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[5] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus ribonucleic acid (RNA) and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[6] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus RNA and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[7] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, influenza B virus and/or respiratory syncytial virus (RSV) RNA and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[8] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, influenza B virus and/or RSV RNA and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[9] As set forth in the EUAs for this product, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, through the identification and differentiation of SARS–CoV–2 Phylogenetic Assignment of Named Global Outbreak (PANGO) lineages, and that the known and potential benefits of the product, when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

• InspectIR Systems LLC's InspectIR COVID–19 Breathalyzer, issued April 14, 2022; [10]

FDA is hereby announcing the following Authorizations for other medical devices:

• Quest Diagnostics Nichols Institute's Quest COVID–19 PCR Test Home Collection Kit, issued March 21, 2022; [11]

• Audere's HealthPulse@home Fusion, issue April 26, 2022.[12]

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15699 Filed 7–21–22; 8:45 am]

BILLING CODE 4164–01–P

[10] As set forth in the EUAs for this product, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, and that the known and potential benefits of the product, when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[11] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the home-collected human specimen, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[12] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the collected human specimen, and that the known and potential benefits of the product when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

DEPARTMENT OF HOMELAND SECURITY

[Docket No. USCBP–2022–0027]

Privacy Act of 1974; System of Records

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

ACTION: Notice of new Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP) proposes to establish a new DHS system of records titled, ''DHS/CBP–027 Customs Broker Management (CBM).'' The records in this system are currently covered under the ''DHS/CBP–010 Persons Engaged in International Trade in Customs and Border Protection Licensed/Regulated Activities Systems of Records'' and historically under the ''Treasury/CS.069 Customs Brokers File''. DHS/CBP is creating this new System of Records Notice (SORN) to distinguish the Customs Broker application and exam, license, and vetting records from the other records in ''DHS/CBP–010 Persons Engaged in International Trade in Customs and Border Protection Licensed/Regulated Activities Systems of Records''. This newly established system will be included in DHS's inventory of record systems.

DATES: Submit comments on or before August 22, 2022. This new system will be effective upon publication. New or modified routine uses will be effective August 22, 2022.

ADDRESSES: You may submit comments, identified by docket number USCBP–2022–0027 by one of the following methods:

• *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Fax:* 202–343–4010.

• *Mail:* Lynn Parker Dupree, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number USCBP–2022–0027. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Debra L. Danisek, (202) 344–1610, *privacy.cbp@cbp.dhs.gov,* CBP Privacy Officer, U.S. Customs and Border Protection, Ronald Reagan Building, 1300 Pennsylvania Avenue NW, Washington, DC 20229. For privacy questions, please contact: Lynn Parker Dupree, (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) proposes to establish a new DHS system of records titled, ''DHS/U.S. Customs and Border Protection (CBP)–027 Customs Broker Management.'' The records in this system are currently covered under the ''DHS/CBP–010 Persons Engaged in International Trade in Customs and Border Protection Licensed/Regulated Activities Systems of Records'' (73 FR 77753, December 19, 2008) and historically under the ''Treasury/CS.069 Customs Brokers File'' (66 FR 52984, October 18, 2001). DHS/CBP is creating this new System of Records Notice to distinguish the Customs Broker application, exam, license, and vetting records from the other records in ''DHS/CBP–010 Persons Engaged in International Trade in Customs and Border Protection Licensed/Regulated Activities Systems of Records'' (73 FR 77753, December 19, 2008). In addition, CBP provides notice for a new collection and maintenance of information (*i.e.,* audio and video recordings) from individuals taking the Customs Broker License Exam (CBLE).

Customs Brokers are private individuals, associations, corporations, or partnerships licensed, regulated, and empowered by CBP to assist importers and exporters in meeting federal requirements governing imports and exports. Customs Brokers submit necessary information and appropriate payments to DHS/CBP on behalf of their clients and charge a fee for their service. Customs Brokers must have expertise in the entry procedures, admissibility requirements, classifications, valuation, and applicable rates of duties, taxes, and fees for imported merchandise.

Pursuant to 19 CFR 111.11, an individual is eligible to qualify for a Customs Broker license if he or she (1) is a U.S. citizen on the date of submission of the application referred to in 19 CFR 111.12(a) (OMB Control Number 1651–0034/CBP Form 3124) and is not an officer or employee of the U.S. government, (2) is the age of 21 prior to the date of submission of the application, (3) possesses good moral character, and (4) has passed the Customs Broker License Exam, by attaining a passing grade (75 percent or higher) on the examination taken within the 3-year period before submission of the application.

A partnership is eligible to qualify for a Customs Broker license if they have at