EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE WREN LABORATORIES COVID-19 SALIVA TEST COLLECTION KIT DTC

For *In vitro* Diagnostic Use
For Use Under Emergency Use Authorization (EUA) Only

Direct to consumer (DTC) home collected saliva specimens collected by individuals 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 5 years and older (collected with adult assistance) with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC will be sent to high complexity laboratories that have been designated by WREN Laboratories LLC. All laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests and that run specimens collected using the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC on an in vitro diagnostic (IVD) molecular test that is indicated for use with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC for collection of saliva specimens.

INTENDED USE

The WREN Laboratories COVID-19 Saliva Test Collection Kit DTC is a direct to consumer (DTC) product for collecting saliva specimens at home (which includes in a community-based setting) from individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 5 years and older (collected with adult assistance), that are sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC for collection of saliva specimens, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

Testing is limited to laboratories designated by WREN Laboratories LLC that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

All test results are delivered to the user via an encrypted email service. Individuals with positive, presumptive positive, or invalid results will be contacted by a healthcare provider. The direct to consumer home collection system is intended to enable users to access information about their COVID-19 infection status that could aid with determining if self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The WREN Laboratories COVID-19 Saliva Test Collection Kit DTC is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

The WREN Laboratories COVID-19 Saliva Test Collection Kit DTC is only for use under the Food and Drug Administration's Emergency Use Authorization.

SPECIAL CONDITIONS FOR USE STATEMENTS

For *In vitro* Diagnostic Use
For Use Under Emergency Use Authorization (EUA) Only
For Use by Individuals 5 Years of Age and Older

The WREN Laboratories COVID-19 Saliva Test Collection Kit DTC collection device is only authorized for use in conjunction with an *in vitro* diagnostic (IVD) test for the detection of SARS-CoV-2 indicated for use with this collection device for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The WREN Laboratories COVID-19 Saliva Test Collection Kit DTC is available direct to consumer (DTC) without a prescription for any individual age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 5 years and older (collected with adult assistance). When ordering a kit via the WREN Laboratories website or when purchasing a kit through partnering pharmacies, and online retailers, individuals must verify they are 18 years of age or older to receive the kit; however, the collection procedure can be completed by children as young as 5 years old with adult assistance and 14 years or older with adult supervision. Once the individual receives the collection kit, the user must register their kit by using one of the following methods:

- Scanning the QR code located on the collection tube with a smartphone
- Visiting www.wrencovidtesting.com/start

As part of the online registration process, the individual is prompted to enter personally identifiable information as well as the reason for use of the collection kit and COVID-19 vaccination status. During kit activation, it is recommended that the user complete a screening questionnaire as a means for data collection. The medical information collected will not impact the ability to process the individual's saliva sample. Individuals are notified by email of their test results. Additionally, individuals with positive, presumptive positive, or invalid results are contacted by a healthcare provider (HCP) via phone. All HCPs that perform the follow-up calls are employed by WREN Laboratories and have prescribing privileges in the state of residency of the tested individual. For purposes of this EUA, a healthcare provider includes any healthcare professional with prescribing abilities including, but not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists.

The WREN Laboratories COVID-19 Saliva Test Collection Kit is composed of a cardboard shipping box with UN3373 label, two sealing strips, pre-paid/pre-addressed return FedEx label, a biohazard bag with absorbent material, saliva collection tube with QR code, saliva funnel/mouthpiece, instructions for use, and a fact sheet for individuals. Instructions included in the kit guide users on how to collect the saliva specimen appropriately. After collection, the specimen is placed into the biohazard bag containing the absorbent material, followed by placement into the cardboard box containing a UN3373 label which is then sealed with the provided sealing strips. The individual must affix the pre-paid/pre-addressed FedEx return address label to the front of the box for transport to WREN Laboratories or a designated testing laboratory. The completed WREN Laboratories COVID-19 Saliva Test Collection Kit DTC must

be dropped off at a FedEx location or a FedEx drop box on the same day the specimen is collected to ensure timely receipt of the specimen at the testing location. Each WREN Laboratories COVID-19 Saliva Test Collection Kit DTC is intended to be returned via 48-hour shipping at ambient conditions and tested within 96 hours of collection.

Specimens received for testing at WREN Laboratories and designated high complexity certified laboratories (Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a) will undergo a thorough review and accessioning prior to acceptance for testing with an FDA authorized IVD molecular SARS-CoV-2 assay indicated to process saliva specimens per the Instructions for Use.

REAGENTS AND MATERIALS

The WREN Laboratories COVID-19 Saliva Test Collection Kit DTC consists of the following components:

Component
Cardboard shipping box with UN3373 Biological Substance Category B label
Two sealing strips for the cardboard box
Pre-paid/pre-addressed return FedEx label
Biohazard bag with absorbent material for collected specimen
Saliva collection tube with QR code
Saliva funnel/mouthpiece
Instructions for kit registration, sample collection, and shipping
Fact sheet for individuals

INSPECTION OF SALIVA SPECIMENS

Applies to specimens received from individuals using the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC

Specimens collected with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC must be checked for the following criteria upon receipt at WREN Laboratories or at designated testing laboratories prior to processing as outlined in the "Specimen Receipt and Handling for the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC" accessioning SOP:

- Saliva must be collected using the collection device provided with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC.
- Sample collection tube must be intact and not visibly damaged or leaking.
- Sample volume meets the minimum required for testing.
- Sample collection tube contains all required information (individual's initials, date of birth, date/time of saliva collection).
- Specimen must arrive within the established stability window for testing (i.e., within 96 hours from the recorded collection time).
- Specimen is associated with a completed requisition form (electronic copy completed during kit registration).
- Specimen was collected using an unexpired collection kit.

CONTROLS TO BE USED WITH THE AUTHORIZED SARS-COV-2 MOLECULAR ASSAY

The following controls (at a minimum) must be included in the in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with saliva specimens collected with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC:

1) **No Template Control (NTC)**
   A negative (no template) control must be used to monitor for sample contamination during nucleic acid extraction and RT-PCR assay set-up. Molecular grade, nuclease-free water can be processed as a clinical sample beginning with extraction (optional) or can exclude the extraction step and be added during RT-PCR set-up.

2) **SARS-CoV-2 Positive Control**
   A positive SARS-CoV-2 control is needed to verify that the assay is performing as intended. A positive control prepared at ≤5X LoD must be used on every assay plate starting at master mix addition.

3) **Endogenous Internal Control**
   An internal control targeting RNase P or another endogenous human control gene is needed to verify that nucleic acid is present in every sample and is used for every sample that is processed with the assay. This also serves as a positive extraction control to ensure that samples resulting as negative contain nucleic acid for testing. Detection of the RNase P gene/other applicable endogenous human control in individual test samples verifies successful extraction of the sample, proper assay setup, and collection of human biological material.

4) **A Negative Extraction Control (optional)**
   Typically, a negative extraction control is a previously characterized negative patient sample. It serves both as a negative extraction control to monitor for any cross-contamination that could occur during the nucleic acid extraction process, as well as an extraction control to validate extraction reagents and successful RNA extraction.

INTERPRETATION OF RESULTS

All test controls must be examined prior to interpretation of individual results. If the controls are not valid, the individual results cannot be interpreted.

SARS-CoV-2 test results are divided into SARS-CoV-2 positive/detected, SARS-CoV-2 negative/not detected, and presumptive positive.

- Individuals will receive an encrypted email containing their test results.
- Individuals with positive, presumptive positive, or invalid results are contacted by a healthcare provider (HCP) via phone. The HCP will inform individuals of their results, provide education, and a recommended course of care or appropriate follow-up action.
- Results are reported by WREN Laboratories to public health agencies as required.

PERFORMANCE EVALUATION

1) **WREN Laboratories COVID-19 Saliva Test Collection Kit DTC Sample Stability Studies:**

a. Summer and Winter Thermal Excursions:

A simulated shipping study was performed to evaluate the effect of temperature variation on the stability of SARS-CoV-2 RNA during transport of saliva specimens from the patient's home or healthcare setting to WREN Laboratories or a designated laboratory for processing. The shipping study was designed to simulate shipping at ambient temperature as well as extreme temperature conditions that could be experienced during the summer and winter months. See Tables 1 and 2 for summer and winter thermal profiles, respectively, that were evaluated in this study.

Simulated sample stability and shipping studies were performed using a total of 38 contrived positive saliva specimens including 23 samples at 1-2X LoD (based on the LoD determined using synthetic SARS-CoV-2 RNA from Twist Bioscience), 5 samples at 2-5X LoD , and 10 samples at 5-10X LoD. Ten negative saliva samples collected from asymptomatic individuals and screened negative using the WREN Laboratories COVID-19 PCR Test were also included in the simulated shipping studies. After the contrived positive and negative samples underwent the thermal excursions, they were equilibrated to room temperature, extracted with the Qiagen QIAamp Viral RNA Mini Kit, and tested with the WREN Laboratories COVID-19 PCR Test using the liquid primers/probes protocol.

Table 1. Summer Temperature Excursion

Temperature	Cycle Period	Cycle Period Hours	Total Hours[1]
40°C	1	8	8
22°C	2	4	12
40°C	3	2	14
30°C	4	36	50
40°C	5	6	56

[1] Sum of cycle periods

Table 2. Winter Temperature Excursion

Temperature	Cycle Period	Cycle Period Hours	Total Hours[1]
-10°C	1	8	8
18°C	2	4	12
-10°C	3	2	14
10°C	4	36	50
-10°C	5	6	56

[1] Sum of cycle periods

Table 3. Summary of Results from the Simulated Shipping Studies Using Contrived Specimens

Sample Group	Test Point	N	Mean Ct			SARS-CoV-2 Positive (%)
			N1	N3	RNase P	
Negative	Day 0 (RT)[1]	10	Und	Und	29.47	0 (0)

	Summer[2]	10	N/A	N/A	29.27	0 (0)
	Winter[3]	10	N/A	N/A	29.02	0 (0)
Low Positive 1-2X LoD	Day 0 (RT)	23	36.27	35.68	30.08	23/23 (100)
	Summer	23	36.51	35.81	30.04	22/23 (95.7)
	Winter	23	34.88	33.17	27.41	23/23 (100)
Moderate Positive 2-5X LoD	Day 0 (RT)	5	35.36	35.04	29.83	5/5 (100)
	Summer	5	36.64	35.93	29.86	5/5 (100)
	Winter	5	35.72	36.25	29.19	5/5 (100)
High Positive 5-10X LoD	Day 0 (RT)	10	33.61	33.09	29.22	10/10 (100)
	Summer	10	34.54	34.28	28.86	10/10 (100)
	Winter	10	34.62	34.10	28.62	10/10 (100)

[1] UND; Undetermined. Day 0 - room temperature
[2] Testing performed at the conclusion of the thermal excursions described in Table 1
[3] Testing performed at the conclusion of the thermal excursions described in Table 2

The results in Table 3 demonstrate that when tested with the WREN Laboratories COVID-19 PCR Test, SARS-CoV-2 RNA contrived positive saliva specimens are stable in the collection tube buffer when exposed to a broad range of temperature conditions. These data support the use of the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC for transport and storage of specimens following self-collection of saliva in the home setting.

b. Room Temperature Stability Studies:
Twelve different donors collected 0.5 mL of saliva that was stabilized with 1 mL of stabilization buffer, as per the instructions provided with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC. Each saliva/stabilization buffer sample was spiked with Twist Bioscience SARS-CoV-2 RNA material (Cat # MT007544.1, 1,000,000 copies/µL) at 1-2X LoD. Samples were evaluated at Day 0, Day 1 (24 hours), Day 2 (48 hours), Day 3 (72 hours), Day 4, (96 hours) and Day 5 (120 hours) following room temperature (~22°C) incubation. Viral RNA was isolated using the QIAamp Viral RNA Mini Kit (Cat # 52906), and reactions were prepared for RT-PCR using liquid primers/probes followed by testing with the WREN Laboratories COVID-19 PCR Test. The impact of extended saliva storage at room temperature conditions on assay performance for each of the 5 days is summarized in Table 4. The claimed duration of saliva specimen stability is 96 hours prior to testing.

Table 4. Room Temperature Stability Studies Up to 120 Hours (5 Days)

Sample Group	Test Point	N	Mean Ct			SARS-CoV-2 Positive (%)
			N1	N3	RNase P	
Low Positive 1-2X LoD	Day 0	12	35.63	36.14	29.44	12/12 100%)
	Day 1	12	35.76	36.26	29.58	12/12 100%)
	Day 2	12	35.70	36.37	29.76	12/12 100%)
	Day 3	12	35.92	36.48	29.09	12/12 100%)
	Day 4	12	36.10	36.21	29.31	12/12 100%)
	Day 5	12	36.00	36.21	29.31	12/12 100%)

c. Pressure and Travel Stability Testing of Collection Tube:
i. Simulated Testing:

To assess the watertight seal status of the buffer cap (stabilization buffer is contained within an aluminum seal) along with the combined cap/collection tube system as a single unit (i.e., the cap applied to the tube), vacuum testing on the cap and unit was performed based on D6653/D6653M protocols (Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method). Three sealed buffer caps and three cap/tube combinations were evaluated at 0, 25, 50, 75, and 95kPa of pressure for 0.5, 1, 2, 4, 8, 16, 24, and 48 hours.

Aluminum seals within the cap withstood pressures of 95kPa for up to 24 hours (3/3 met acceptance criteria at each test point). One of the three caps at 95kPa for 48 hours failed due to a bond land failure (i.e., where the aluminum foil seals to the plastic; the sealing site) and not to rupture of the PCR foil itself. This seal failure occurred under extreme conditions beyond those that the sealed cap should experience during normal air and ground transportation. All cap/tube combinations (3/3 at each test point) withstood pressure of up to 95kPa for 48 hours.

ii. Real World Pressure and Travel Stability Testing:
Since saliva collection tubes within the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC will be collected from across the United States and sent for testing to WREN Laboratories or a laboratory designated by WREN, pressure testing was evaluated by physically shipping the caps and the combined cap/collection tube units via FedEx. Common pressure conditions that could be experienced during transport include 75kPa (<8 hours) within a cargo air jet and 64.5kPa during ground transportation. Two different transportation studies were completed.

- Study I (n=50): Pre-filled buffer caps were transported by FedEx cross-country (from the manufacture site in Phoenix, AZ) to WREN Laboratories in Branford, CT. Samples were sent from AZ on a Friday at a temperature of 73°F with delivery to WREN Laboratories on Monday afternoon following 72 hours in transit via Indianapolis, IN and East Grandby, CT. No evidence of seal leakage or any alteration of the aluminum sealing was identified (n=50) following long distance road/air transportation.

- Study II (n=40x2): In a separate study, 40 kits were shipped on two separate occasions via FedEx overnight shipping. Tubes were intentionally routed from Connecticut via Memphis, TN to New York City (48 hours transport total). No leaks were noted in the sealed buffer caps after arrival in New York City (80/80). Following saliva collection, samples (i.e., capped, sealed tubes with saliva) were returned to WREN Laboratories in Branford, CT via overnight FedEx shipping (24 hours). No leakage of clinical sample content was identified in the 80 capped saliva tubes. Overall, no leakage of contents was identified on kit send-out or on the return of clinical samples. These data demonstrated the integrity of both the foil seal on the cap and the capped tube under real-world conditions.

2) Home Collection Kit Stability:
The expiration date of the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC is based on the least stable component which is the stabilization buffer. Therefore, the

expiration date for the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC is 12 months from the date of manufacture when stored at room temperature and this is displayed on the back of the kit's outer box. A specific accessioning criterion is to ensure that the kit's expiration date has not been exceeded.

3) **Self-Collection Validation:**

Two usability studies were conducted to assess user comprehension of the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC instructions, including both collection and packaging the saliva specimen for shipment to WREN Laboratories or a designated laboratory for processing. One usability study included 122 participants from an industrial setting and the second study was completed in a school setting with 55 individuals ranging from 5-65 years old. For children aged 5-13 years old, the parent/adult assisted with the collection process including kit activation via the QR code or manual online entry, holding the funnel up to the child's mouth and instructing them to spit to the fill line (i.e., adult assistance), as well as packaging the specimen for shipment. Adolescents/teenagers aged 14-17 years old performed the kit activation, collection, and packaging steps under adult supervision in case they had questions on the procedure. Those individuals 18 years or older performed the entire process of saliva collection and specimen packing unsupervised.

Participants in both studies were recruited to reflect a variety of ages and education levels, including participants currently in elementary and high school, those that received a high school diploma or equivalent, and those currently enrolled in college or have received higher education (i.e., BA, BS, MA, MEd, Ph.D). Other demographics were also documented (See Tables 6 and 7). Each participant was provided with a kit (including instructions for collection, packaging and shipping) and a questionnaire. Note that individuals were given the option to use either the longer version of the collection/shipping instructions or the streamlined instructions. Based on the results of the post-collection questionnaire, all 177 individuals chose to use the streamlined collection instructions which combined the collection and shipping procedures into one document. Subjects were evaluated in-person by staff from WREN Laboratories to monitor the collection procedure and to document potential errors or difficulties with the tasks.

At the conclusion of the two usability studies, each study site shipped the individual samples that were packaged in their own kit boxes via FedEx, as per the instructions, to WREN Laboratories for processing. All samples were processed within the claimed stability window (96 hours when shipped at ambient conditions). A total of 121 adults (and 1 individual 17 years old) completed usability study #1 (Table 6). For usability study #2 performed in a school setting, a total of 40 minors between 5 and 17 years of age along with 15 adults participated (Table 7).

Table 6. Participant Demographics from Usability Study #1 (Industry)

Characteristic	**N / N122 (%)**
Gender	
Male	115/122 (94.3%)
Female	7/122 (5.7%)
Age	

17-25	11/122 (9.0%)
26-35	20/122 (16.4%)
36-45	28/122 (23.0%)
46-55	26/122 (21.3%)
56 and older	37/122 (30.3%)
Race	
White	91/122 (74.6%)
Black/African American	10/122 (8.2%)
Asian	20/122 (16.4%)
American Indian/Asian Native	1/122 (0.8%)
Ethnicity	
Hispanic/Latino	13/122 (10.7%)
Non-Hispanic/Latino	109/122 (89.3%)
Marital Status	
Divorced	20/122 (16.4%)
Married	82/122 (67.2%)
Single	20/122 (16.4%)
Education Level	
In School (elementary – high school)	1/122 (13.9%)
High School Diploma	94/122 (27.8%)
Undergraduate Degree	22/122 (33.3%)
Post-graduate Degree	5/122 (25.0%)

Table 7. Participant Demographics from Usability Study #2 (School)

Characteristic	**N / N55 (%)**
Gender	
Male	30/55 (54.5%)
Female	25/55 (45.5%)
Age	
5-13	20/55 (36.4%)
14-17	20/55 (36.4%)
18-35	8/55 (14.5%)
36-55	3/55 (5.4%)
56 and older	4/55 (7.3%)
Race	
White	32/55 (58.2%)
Black/African American	17/55 (30.9%)
Asian	5/55 (9.1%)
American Indian/Asian Native	1/55 (1.8%)
Ethnicity	
Hispanic/Latino	9/55 (16.4%)
Non-Hispanic/Latino	46/55 (83.6%)
Marital Status	
Divorced	1/55 (1.8%)
Married	6/55 (10.9%)
Single	48/55 (87.3%)
Education Level	
In School (elementary – high school)	42/55 (76.4%)

High School Diploma	8/55 (14.5%)
Undergraduate Degree	4/55 (7.3%)
Post-graduate Degree	1/55 (1.8%)

Children 13 and younger had a parent/adult assist with the collection and shipping procedure
Children 14-17 performed the collection and shipping procedure under the supervision of a parent/adult

Of the 177 kits that were used for self-collection and shipped to WREN Laboratories for downstream testing, all were received and processed using the WREN Laboratories COVID-19 PCR Test DTC within 48 hours of collection. No damage or leaks from the collection tubes were observed upon accessioning. Of those collection kits received at WREN Laboratories, RNase P was detected in 176/177 (99.4%) samples, indicating successful collection of human biological material that was extracted and amplified. During the post-study questionnaire, the participant who provided a sample that was negative for RNase P indicated that they had difficulty generating saliva (i.e., dry mouth) and drank water prior to providing their sample.

The results of the usability testing were analyzed qualitatively to determine if the design of the kit and/or kit instructions needs to be modified to reduce the use-related risks to acceptable levels. Cognitive debriefing interviews were conducted following the actual-use testing to gather users' perspectives on each critical task or use scenario. As discussed previously, one participant had difficulty producing saliva. Noted within the instructions is a helpful hint to rub the outside of the cheeks, just behind the back teeth while performing chewing motions to prevent dry mouth. No other difficulties were noted during the collection process which indicated the user's understanding of the collection and shipping instructions. Answers to the user 15-item questionnaire were also collected for each of the 177 sample kits. Based on the feedback received, the collection instructions were understandable, and the kit was easy to use. No changes or modifications to the new streamlined instructions needed to be made based on discussions with the participants.

The results from the usability studies performed by WREN Laboratories indicate that individuals 5-13 years of age could provide a saliva specimen with adult assistance, individuals 14-17 years of age were able to collect saliva under adult supervision, and those 18 years and older could collect saliva safely and appropriately without supervision, with sufficient human biological material for downstream molecular testing.

4) **Additional Requirement:**
WREN Laboratories and designated laboratories will submit a report to the FDA (within 30 days of authorization) summarizing any testing performed with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC including how many kits were ordered via the WREN Laboratories website or purchased from an authorized distributor, and registered via the online portal. Designated laboratories will also document the number of kits that were processed, how many specimens were rejected during accessioning and the reasons for rejection, and the positivity rate of samples collected with the WREN Laboratories COVID-19 Saliva Test Collection Kit DTC.

WARNINGS

- For *In vitro* Diagnostic Use
- For Use Under and Emergency Use Authorization (EUA) Only
- For Use by Individuals 5 Years of Age or Older
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA);
- This product has been authorized only for the home collection and maintenance of saliva specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.