

Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Office of Consumer Protection
124 Halsey Street, 7th Floor, Newark, NJ 07102



MATTHEW J. PLATKIN
Acting Attorney General

SEAN P. NEAFSEY Acting Director

Mailing Address: P.O. Box 45025 Newark, NJ 07101 (973) 504-6200

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March 25, 2022

VIA CERTIFIED AND REGULAR MAIL

Sayreville Pharmacy, Inc. c/o Faresh Patel, Registered Agent 4 Dynasty Drive Monroe, New Jersey 08831

Sayreville Pharmacy, Inc. 89 Main Street Sayreville, New Jersey 08872

Dear Mr. Patel:

Please find the enclosed Notice of Violation, NOV2200038, dated March 25, 2022. Please respond by signing and returning one of the three options within the NOV to Investigator Ediz Laypan, at LaypanE@dca.njoag.gov, by April 18, 2022. Please note, if you fail to respond to this Notice of Violation by the date specified above, a Final Order on Default will be issued.

Please be advised all mitigation conferenced and pre-hearing conferences normally held in the Newark Office located at 124 Halsey Street, 7th Floor, Newark, New Jersey 07102, are being held remotely until further notice.

The call in number for the remote meeting scheduled for April 25, 2022 at 1:00 PM;

• Call in (audio only): 1-(856) 288-3130

Phone Conference ID: 892 443 948#

If you have any questions, you may reach me at LaypanE@dca.njoag.gov

Sincerely

Ediz Laypan

Investigator, Office of Consumer Protection



New Jersey Office of the Attorney General

Division of Consumer Affairs Office of Consumer Protection 124 Halsey Street, 7th Floor, Newark, NJ 07102



SEAN P. NEAFSEY
Acting Director

Mailing Address: P.O. Box 45025 Newark, NJ 07101 (973) 504-6200

SHEILA Y. OLIVER
Lt. Governor

March 25, 2022

VIA CERTIFIED AND REGULAR MAIL

Sayreville Pharmacy, Inc. c/o Faresh Patel, Registered Agent 4 Dynasty Drive Monroe, New Jersey 08831

Sayreville Pharmacy, Inc. 89 Main Street Sayreville, New Jersey 08872

NOTICE OF VIOLATION AND OFFER OF SETTLEMENT

Dear Mr. Patel:

The New Jersey Division of Consumer Affairs, Office of Consumer Protection ("Division") is charged with the enforcement of the New Jersey Consumer Fraud Act, **N.J.S.A.** 56:8-1 to -227 ("CFA"). The Division conducted an investigation of Sayreville Pharmacy, Inc. ("You" or "Your") after receiving information that raises concerns regarding Your sales practices concerning COVID-19 test kits in the midst of the current public health crisis related to the COVID-19 pandemic (hereinafter "Investigation"). Specifically, the Division has determined that You were advertising and selling COVID-19 test kits to the general public that were not permitted for at-home use in violation of the Food and Drug Administration's ("FDA") Emergency Use Authorization ("EUA"), dated September 1, 2021.

The World Health Organization declared COVID-19 a global health emergency on January 30, 2020 and subsequently declared COVID-19 a pandemic on March 11, 2020. On March 9, 2020, Governor Philip D. Murphy issued Executive Order No. 103 (2020), declaring both a Public Health Emergency and a State of Emergency. Shortly thereafter, a national emergency was declared in the United States on March 13, 2020. On February 10, 2022, Governor Murphy issued Executive Order 288 (2022) declaring that a Public Health Emergency continues to exist in the State of New Jersey. The Attorney General of New Jersey and the Division will not tolerate unfair business practices, or any other attempt to prey on or profit from consumers' fears or concerns relating to the COVID-19 pandemic.

The CFA, specifically N.J.S.A. 56:8-2, prohibits:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing[] concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby

As set forth in the attached Certification of Investigator Ediz Laypan ("Investigator Laypan"), You have advertised, offered for sale and sold COVID-19 test kits to the general public that were not permitted for at-home use. As result of the Division's Investigation, You have been found to have violated the CFA by:

1. Advertising, offering for sale and selling COVID-19 tests to the general public that were not permitted for at-home use, in violation of the CFA, **N.J.S.A. 56:8-2**.

Each violation constitutes a separate violation of the CFA, subjecting You to civil penalties pursuant to **N.J.S.A. 56:8-13**.

IF YOU DO NOT CONTEST THE VIOLATIONS ALLEGED and wish to avail Yourself of this opportunity to settle the Investigation, You should sign and return the enclosed Answering Certification within fifteen (15) days from the date of this Notice and agree to:

- 1. Cease and desist from engaging in any practices in violation of the CFA;
- Cease and desist from advertising, offering for sale and/or selling COVID-19 tests to the general public that are not permitted for athome use; and
- 3. Pay a civil penalty in the amount of \$5,000.00.

If the above-referenced payment in the total amount of \$5,000.00 is received by the Division within 15 days of the date of this Notice, along with your signed Answering Certification, You need not do anything further.

IF YOU DO NOT CONTEST THE VIOLATIONS ALLEGED, but want to present information to Division representatives about any mitigating circumstances in Your case that may persuade the Division to reduce the civil penalty, You may request an informal Mitigation Conference. If You request a Mitigation Conference, You will waive Your right to an Administrative Hearing. The Mitigation Conference date is April 25, 2022 at 1:00 p.m., at 124 Halsey Street, 7th Floor, Newark, New Jersey 07102 with Investigator Laypan, a representative of the Division. You may be accompanied by an attorney. Should you have any questions regarding this procedure, or seek an

adjournment of this date, please contact Investigator Laypan at (973) 792-4217 or LaypanE@dca.njoag.gov. Alternatively, You may send written documentation to the Division concerning any mitigating circumstances that You believe may persuade the Division to reduce the civil penalty. In order to elect either of these options, You must return the enclosed Answering Certification within fifteen (15) days from the date of this Notice to Investigator Laypan at the email address indicated above. The Division will then review this material and respond to You.

IF YOU CONTEST THE VIOLATIONS ALLEGED, and do not wish to settle the matter consistent with the terms set forth above, You may request a formal Administrative Hearing by returning the enclosed Answering Certification within fifteen (15) days from the date of this Notice to Investigator Laypan at the email address indicated above. In that event, this Notice will serve as notice of the violations against you. You should be aware that in making his final decision, the Director of the Division may, if violations of the above-referenced statute and regulations have been proven, order civil penalties and remedies other than the settlement offer above. Specifically, You may be ordered to: pay civil penalties in an amount up to \$10,000 for the first violation and up to \$20,000 for the second violation and each subsequent violation pursuant to N.J.S.A. 56:8-13; pay consumer restitution pursuant to N.J.S.A. 56:8-15; pay investigative costs and attorneys' fees to the Division, pursuant to N.J.S.A. 56:8-11 and 56:8-19; and cease and desist from any act or practice in violation of the CFA, pursuant to N.J.S.A. 56:8-18.

Before a determination is made with regard to whether an Administrative Hearing will be conducted before the Director of the Division or referred to the Office of Administrative Law, a Pre-Hearing Conference will be held. If You request an Administrative Hearing, your Pre-Hearing Conference will be scheduled April 25, 2022 at 1:00 p.m., at 124 Halsey Street, 7th Floor, Newark, New Jersey 07102 with Investigator Laypan. You may be accompanied by an attorney. Should You have any questions regarding this procedure, or seek an adjournment of this date, please contact Investigator Laypan, who may be reached at (973)Your attendance at this Pre-Hearing Conference is LavpanE@dca.njoag.gov. mandatory. Any failure to appear without a satisfactory explanation may result in an order barring You from raising certain defenses at the Administrative Hearing, pursuant to N.J.A.C. 1:1-14.4. The purpose of this Pre-Hearing Conference is to discuss the issues in this matter and the defenses which You may wish to raise. You should be prepared to discuss the evidence You will propose to offer at the Administrative Hearing. It may be helpful if You bring to the Pre-Hearing Conference a copy of any documentation that supports Your position. If the Director of the Division determines that there are no material facts in dispute, You will have an opportunity to submit legal arguments and any documentation that may be relevant to the ultimate disposition of this matter. If there are material facts in dispute, an Administrative Hearing will be scheduled. During the Administrative Hearing, You, either personally or with the assistance of an attorney, will have an opportunity to respond to the alleged violations and submit evidence and present testimony as may be necessary for the Director of the Division to make a final determination. Pursuant to N.J.A.C. 1:1-5.1, and except as provided in N.J.A.C. 1:1-5.4, a corporation must be represented by an attorney.

IF YOU FAIL TO RESPOND to this Notice within fifteen (15) days of the date of this Notice, the settlement offer will be withdrawn and You will be deemed in default. The allegations against You will be deemed uncontested. Thereafter, this Notice and the underlying proofs may be reviewed by the Director of the Division, and a Final Decision and Order on Default ("Default Order") will be issued, and You may be ordered to: pay civil penalties in an amount up to \$10,000 for the first violation and up to \$20,000 for the second violation and each subsequent violation pursuant to N.J.S.A. 56:8-13; pay consumer restitution pursuant to N.J.S.A. 56:8-15; pay investigative costs and attorneys' fees to the Division pursuant to N.J.S.A. 56:8-11 and 56:8-19; and cease and desist from any act or practice in violation of the CFA, pursuant to N.J.S.A. 56:8-18. You will receive no further notice from the Division prior to the issuance of a Default Order. Once a Default Order has been entered, Your failure to pay any civil penalties, attorneys' fees, investigative costs and/or restitution within the time allowed will result in the filing of a Certificate of Debt. Any subsequent violation of a Default Order with a cease and desist provision may subject You to a penalty of up to \$25,000 per violation pursuant to N.J.S.A. 56:8-18. Service of a Default Order will be deemed effective if sent by first-class mail and certified mail, return receipt requested, to your last known mailing address.

Should You have any questions, please contact **Investigator Laypan** at (973) 792-4217 or <u>LaypanE@dca.njoag.gov</u>.

New Jersey Division of Consumer Affairs Office of Consumer Protection

Gregory K. Turner

Assistant Deputy of Enforcement

ANSWERING CERTIFICATION

I read an 227.	, d revi	ewed the Notice, regarding alleged	, here violations of t	eby acknowledge that I have he CFA , N.J.S.A. 56:8-1 to -						
PLEASE CHECK ONE OF THE OPTIONS BELOW:										
OPTION 1): Sayreville Pharmacy, Inc.										
I DO NOT CONTEST THE VIOLATIONS ALLEGED and acknowledge the conduct that has been alleged and agree to:										
1	L.	Cease and desist from engaging in CFA;	in any practio	ees in violation of the						
2	2.	Cease and desist from advertising COVID-19 tests to the general pulhome use; and								
3	3.	Pay a civil penalty in the amount	of \$5,000.00							
I understand that if the above-referenced payment in the total amount of \$5,000.00 is received by the Division, along with my signed Answering Certification, I need not do anything further.										
I am also aware that the action taken against Sayreville Pharmacy, Inc. by the Division herein is a matter of public record and that the Division's Notice and this Answering Certification are public documents. I am enclosing herewith a cashier's check or money order in the sum of \$5,000.00 made payable to the "New Jersey Division of Consumer Affairs," which I am mailing or delivering to: New Jersey Department of Law and Public Safety, Division of Consumer Affairs, Office of Consumer Protection, 124 Halsey Street, P.O. Box 45025, Newark, New Jersey 07101, ATTN: Van Mallett.										
Dated:			Ву:	SIGN NAME						
			Name:	PRINT NAME						

(OPTION 2)	Sayreville Pharmacy, Inc.
rights I may Pharmacy,	I DO NOT CONTEST THE VIOLATIONS ALLEGED and hereby waive any have to an Administrative Hearing in this matter to defend Sayreville Inc. against any alleged violations, BUT I ask the Division to consider ircumstances before rendering its final decision.
repre on Aj New	request a Mitigation Conference to present information to Division sentatives; I understand that the Mitigation Conference will be held pril 25, 2022 at 1:00 p.m., at 124 Halsey Street, 7th Floor, Newark, Jersey 07102. I am aware that I may be represented by an ney at the Mitigation Conference.
circu	I am submitting written documentation concerning mitigating mstances; I understand that the Division will consider this material e rendering a final decision.
not persuad	d that, if, after considering the mitigation evidence presented, the Division is led that any reduction in the amounts set forth above and in the Notice is or that any of the other terms or conditions should be modified, the following be ordered and Sayreville Pharmacy, Inc. will be obligated to:
1.	Cease and desist from engaging in any practices in violation of the CFA;
2.	Cease and desist from advertising, offering for sale and/or selling COVID-19 tests to the general public that are not permitted for athome use; and
3.	Pay a civil penalty in the amount of \$5,000.00.
amounts the Pharmacy, I Notice and failure to	nodification in these terms is accepted by the Division, I will be notified of the at I must pay. I am also aware that the action taken against Sayreville nc. by the Division herein is a matter of public record and that the Division's this Answering Certification are public documents. I am further aware that comply may subject Sayreville Pharmacy, Inc. to further enforcement and any failure to make a required payment will result in the filing of a of Debt .
Dated:	By: SIGN NAME
	Name:
	name.

PRINT NAME

(OPTION	31:	Savreville	Pharmacy,	Inc
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I CONTEST THE VIOLATIONS ALLEGED and request a formal Administrative Hearing. I understand that I am required to attend a Pre-Hearing Conference on April 25, 2022 at 1:00 p.m., at 124 Halsey Street, 7th Floor, Newark, New Jersey 07102, at which the issues in this matter will be discussed. I am aware that I may be represented by an attorney at the Pre-Hearing Conference.

If the Division and I agree upon any essential settlement terms at the **Pre-Hearing Conference**, I understand that:

- 1. These terms will be included in a document ("Pre-Hearing Settlement Sheet");
- 2. The Division representative and I will sign the Pre-Hearing Settlement Sheet and Sayreville Pharmacy, Inc. will be bound by it; and
- 3. The Division will send me a **Consent Order**, which will include all settlement terms. I also understand that I must sign and return the **Consent Order and any required payment to the Division within thirty (30) days** of the date that the Division sends it to me.

I further understand that if I fail to do so, the Division will present this matter to the Director of the Division based upon this Notice, and a Final Decision and Order After NOV ("Order") will be issued. I will receive no further notice from the Division prior to issuance of an Order.

Conference, I will thereafter be advised of the time, date and place for the Administrative Hearing if a determination has been made that there are material facts in dispute. I am aware that I may be represented by an attorney at the Administrative Hearing. I am also aware that at the time of the Administrative Hearing, I may offer testimony, documentation and legal argument relevant to the alleged violations. I understand that in making a final decision, the Director of the Division may, if unlawful activity has been proven, assess civil penalties, attorneys' fees and investigative costs and/or issue a cease and desist order exceeding the settlement offer in the Notice, and may order such other remedies as deemed appropriate. I am also aware that this proceeding is a matter of public record and that the Notice and this Answering Certification are public documents.

Dated:	By:	
2404.	SIGN NAME	
6		
	Name:	
	DRINT NAME	

Sayreville Pharmacy, Inc. d/b/a Sayreville Pharmacy 89 Main Street Sayreville, New Jersey 08872

License No: 28RS00629100

INVESTIGATIVE CERTIFICATION

- I, Ediz Laypan, being of full age, do hereby certify as follows:
- 1. I am employed as an Investigator by the Office of the Attorney General, Division of Consumer Affairs, Office of Consumer Protection ("Division"), located at 124 Halsey Street, Newark, New Jersey 07101, and have held that position at all times relevant to this Certification.
- 2. On January 5, 2022, I was instructed to conduct a site inspection of Sayreville Pharmacy, Inc. located at 89 Main Street in Sayreville, NJ 08872 ("Sayreville Pharmacy") based on a consumer complaint alleging that that Sayreville Pharmacy was selling COVID-19 test kits in re-sealable zipper storage bags.
- 3. On the same day, January 5, 2022, I arrived at Sayreville Pharmacy location at approximately 2:13 p.m. Upon entry to the establishment, I observed COVID-19 test kits in a medium-size carton shipping box on the front counter behind a clear plastic partition. The box contained at least twenty (20) "Great Value" brand re-sealable zipper storage bags plastic bags with Celltrion Dia Trust test tubes (**Exhibit 1**). The bags were not priced; neither was the price affixed to the box or anywhere in the vicinity where they were offered for sale. A copy of the Quick Reference Instructions were offered next to the box (**Exhibit 2**).
- 4. I introduced myself and asked one of the employees behind the counter to speak with the manager and/or owner of the establishment. Jayesh Patel, who presented himself as a co-owner of Sayreville Pharmacy, admitted that they were selling Celltrion Dia Trust COVID-19 test kits separately in re-sealable zipper storage bags.
- 5. Mr. Patel handed me one of the bags which a Celltrion Dia Trust test device, test tube with extraction buffer and filter cap, NPS swab, positive control swab and negative control swab (**Exhibit 3**).
- 6. Mr. Patel added that Sayreville Pharmacy made photocopy of the original Celltrion Dia Trust Quick Reference Instruction contained in the original 25-test box and offered it for free with the sale of each individual plastic bag (**Exhibit 4**).
- 7. Mr. Patel proceeded to show me the original Celltrion Dia Trust 25-test box (**Exhibit 5**) one of the thirty six (36) that Sayreville Pharmacy acquired on December 29, 2021 and December 30, 2021 for approximately \$360.00 each (**Exhibit 6**). Mr. Patel stated that Sayreville Pharmacy sold approximately 400-500 COVID-19 test kits in these re-sealable zipper storage bags for \$25.00 each.

- 8. Mr. Patel further stated that Sayreville Pharmacy also stocked Flowflex COVID-19 Antigen Home Test which they intended to sell for \$20.00 each in their original manufacturer's boxes (one test per box). Mr. Patel said that Sayreville Pharmacy has not sold any of those tests since they just started offering it for sale the day before, January 4, 2022 (Exhibit 7).
- 9. I photographed all displayed on the wall behind the counter licenses and registration certificates issued to Sayreville Pharmacy (**Exhibit 8**).
- 10. I left the premises of Sayreville Pharmacy at approximately 2:40 p.m.
- 11. On January 5, 2022, I visited Celltrion Dia Trust COVID-19 dedicated website located at www.celltrion.com and retrieved information related to the test itself. One of the website pages (https://www.celltrion.com/en-us/kit/DiatrustAg) stated that Celltrion Dia Trust COVID-19 Ag Rapid Test is "FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY FOR IN VITRO DIAGNOSTIC USE FOR PRESRCIPTION USE ONLY" (Exhibit 9).
- 12. On January 27, 2022, I obtained New Jersey corporate information for Sayreville Pharmacy (**Exhibit 10**).
- 13. On February 4, 2022, I reviewed the FDA's Emergency Use Authorization (EUA) 210190, dated September 1, 2021, which states that emergency use of the COVID-19 Ag Rapid Test is limited to authorized laboratories. (**Exhibit 11**).
- 14. The documents submitted with this Certification are true copies of the documents in possession of the Division.
- 15. I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

EDIZ LAYPAN

Dated: March 25, 2022 Newark, New Jersey