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People's Custom Rx

September 22, 2015

Melissa C. Williams
Legal Administrative Specialist
U.S. Food & Drug Administration
New Orleans District
404 BNA Drive, Building 200 – Suite 500
Nashville, TN 37217

Dear Ms. Williams:

On behalf of People's Custom Rx and Clinical Care, LLC, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's web site. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331 0), and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Information to be disclosed: People's Custom Rx and Clinical Care, LLC's letter dated August 13, 2015 excluding attachments/exhibits, which responds to FDA's Form 483 dated July 29, 2015.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of People's Custom Rx and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Regards,

William C. Johns, D.Ph.
Owner, People's Custom Rx and Clinical Care, LLC
785 Brookhaven Circle East
Memphis, Tennessee 38117
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People's Custom Rx

August 13, 2015

Department of Health and Human Services
Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, Tennessee 37217-2597

ATTN: Ruth Dixon, District Director
Zada Giles, Investigator
Mary Millner, Investigator

Re: Form FDA 483 Response, People's Custom Rx and Clinical Care, LLC, Memphis, Tennessee

Dear District Director Dixon and Investigators Giles and Millner:

On July 20-29, 2015, the United States Food and Drug Administration (the "FDA") investigators Zada Giles and Mary Millner conducted an inspection of our pharmacy located at 785 Brookhaven Circle East, Memphis, Tennessee 38117-4501. At the conclusion of the inspection, on July 29, 2015, People's Custom Rx and Clinical Care, LLC, (People's Custom Rx) was issued an FDA Form 483 setting forth nine (9) observations. This letter is in response to the FDA Form 483.

I respectfully request that this response, excluding the attachments, be posted on the FDA's website alongside the Form 483 and be included every time the FDA provides a copy of People's Custom Rx's Form 483 to anyone outside the FDA. Authorization is given to the FDA to disclose the above mentioned information. As indicated by my signature below, I am authorized to provide this consent on behalf of People's Custom Rx and my full name, title, and address and telephone number are provided for verification.

The observations noted on FDA Form 483 are largely based on requirements imposed upon drug manufacturers under the Current Good Manufacturing Practices ("cGMPs") for finished pharmaceuticals contained in 21 C.F.R. Part 211, and further clarified in the FDA's document *Industry Guidance on cGMPs for Sterile Drug Products Produced by Aseptic Processing*. People's Custom Rx is a Tennessee Board of Pharmacy licensed pharmacy with controlled substances, and is subject to the oversight and rules and regulations of the Tennessee Board of Pharmacy. People's Custom Rx does not practice drug manufacturing. The Tennessee Board of Pharmacy adopted the United States Pharmacopeia (USP) *Chapter <797> on Sterile Compounding* as its standard for sterile compounding within a pharmacy in the State of Tennessee. People's Custom Rx feels that we are currently in compliance with these standards based on a recent inspection by the Tennessee Board of Pharmacy, our internal quality assurance programs, and Standard Operating Procedures (SOPs). People's Custom Rx is also an accredited Sterile and Non-Sterile Compounding Pharmacy with the Pharmacy Compounding Accreditation Board (PCAB), a service of Accreditation Commission for Health Care (ACHC). Accreditation by ACHC demonstrates our commitment to quality through compliance with national standards and industry best practices.

During the FDA inspection that led to the issuance of Form 483 to People's Custom Rx, it was brought to our attention that the FDA may consider People's Custom Rx to fall under section 503b as a pharmacy outsourcer. People's Custom Rx feels that we were able to show FDA that our pharmacy only compounds sterile preparations upon receipt of patient specific prescriptions. Affidavit Form FDA 463a issued by FDA on July 29, 2015 and signed by People's Custom Rx pharmacist, Christopher S. Gilbert outlines the procedure People's Custom Rx follows, showing this process. People's Custom Rx does prepare and dispense small amounts of non-sterile compounds to physician offices "for office use", only in states where we are licensed by those states and only in those states which have "office use" compounding laws. The number of these non-patient specific, non-sterile compounds "for office use" is approximately 1% of the compounds dispensed by our pharmacy. In August 2014, Peoples Custom Rx requested from the Tennessee Board of Pharmacy clarification on the issue if a pharmacy must be an outsourcer to dispense non-sterile compounds "for office use." We received a response dated August 29, 2014 stating that the Tennessee Board of Pharmacy representative contacted an FDA representative and that the FDA representative was working with her colleagues for a response. Then, on November 26, 2014 we received an email from the Tennessee Board of Pharmacy stating that the FDA is still working on our question. Attached are the emails documenting this correspondence with the Tennessee Board of Pharmacy. No further correspondence has occurred regarding this issue. Also in a letter to the FDA dated June 27, 2014, members of the U.S. Congress clarified its intent as follows:

Pharmacies that produce small amounts of compounded products in advance of receiving a patient-specific prescription and practice within States where office use is authorized and regulated by State Boards of Pharmacy should not be the focus of FDA oversight. Expecting these small pharmacies that practice in accordance with State law to register as outsourcing facilities solely because products are intended for office use is unreasonable. As FDA prioritizes its resources in a way that best protects public health, we believe the focus should be on manufacturers, not small pharmacies providing safely-compounded products for physicians and hospitals in their communities.

For the reasons stated above, People's Custom Rx respectfully submits the following responses to the observations made in FDA Form 483 on the grounds that the cGMPs are not applicable to our pharmacy. People's Custom Rx complies with state and federal laws and adheres to the USP <797> guidelines for compounding sterile products, as required by the Tennessee State Board of Pharmacy and USP <795> for compounding non-sterile products. We are, however, committed to providing our patients with preparations which are safe and effective, thus we have reviewed the FDA's observations and have made changes in our policies and procedures to adopt some of the recommended best practices as well as taken extra measures to re-educate and train our staff. As previously stated, People's Custom Rx does not prepare sterile compounds "for office use;" however, if in the FDA's opinion we are practicing as a 503b outsourcer or manufacturer by providing very small numbers of non-sterile compounds to physicians or hospitals "for office use" we will immediately cease that practice upon notification and will require patient-specific prescriptions for all non-sterile compounds.

Regards,

Wm. C. Johns D.P.S

William C. Johns, D.Ph.
Owner, People's Custom Rx and Clinical Care, LLC

Response to Observations made in FDA Form 483 for People's Custom Rx and Clinical Care, LLC

Observation 1:
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed:

Specifically:

1. ***Per your firm's SOP No. 3.300.302 "Garbing and Gloving Procedures for Sterile Compounding", when leaving the clean room technicians should replace hair covers, face masks, and gloves before re-entering the clean room. On 07/21/2015 we observed a technician leave the clean room to retrieve supplies from the ante room. This technician did not change their hair net, mask, or gloves before re-entering the clean room to perform aseptic processing.***
   Response: On July 29, 2015, all sterile compounding staff, including the technician observed were re-educated on SOP No. 3.300.302, specifically the requirement to change hair net, mask, and gloves prior to re-entering the clean room. See Form 1.400.1 attached documenting the employees' understanding of SOP No. 3.300.302.
2. ***Your firm does not use sterile alcohol to sanitize the technician's gloves or hood surface during aseptic processing. Your firm uses non-sterile 99% Isopropyl Alcohol.***
   Response: Per our policies, SOP No. 3.300.302 and 3.300.304, sterile alcohol is to be used for glove and hood surface sanitation. Non-sterile 99% Isopropyl Alcohol was ordered incorrectly. Sterile 70% Isopropyl Alcohol was ordered on the date this observation was made and placed in use by the pharmacy staff the following day. This has been corrected, SOP No. 3.300.302 was updated to specifically state the use of Sterile 70% Isopropyl Alcohol, and sterile compounding staff was re-educated on both policies. See Form 1.400.1 attached documenting the employees' understanding of SOP No. 3.300.302 and 3.300.304.
3. ***The gowning components your firm uses during aseptic processing are not sterile. The hair covers, face masks, and shoe covers are stored in open containers in the ante room. Per your firm's SOP No. 3.300.302 "Garbing and Gloving Procedure for Sterile Compounding," non-sterile gowning can be reused and is to be left hanging in the ante room when not in use. Your firm allows gowns to be re-used throughout a technician's shift.***
   Response: USP <797> states "*When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only.*" Also, USP <797> does not require hair covers, face masks, and shoe covers to be sterile. Pending FDA's decision on jurisdiction, People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.

Observation 2:
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically:

1. ***Your firm performs weekly air and surface monitoring in the prep room, ante room, and ISO 5 hoods. This is inadequate as environmental conditions are not monitored every day production occurs.***
   Response: USP <797> states "*Air Sampling Frequency and Process—Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-*

certification of facilities and equipment." and *"Surface sampling shall be performed in all ISO classified areas on a periodic basis."* Pending FDA's decision on jurisdiction, People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.

2. ***Your procedure for weekly air and surface monitoring is inadequate as you only take 1 surface sample and 1 air sample from each room. Your clean room contains 2 hoods; therefore, each hood is not being monitored when you do perform air and surface sampling.***

   Response: As previously stated, USP <797> states *"Air Sampling Frequency and Process—Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment."* and *"Surface sampling shall be performed in all ISO classified areas on a periodic basis."* Pending FDA's decision on jurisdiction, People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy..

3. ***Your compounding technicians' fingertips are monitored every 6 months. Per your firm's SOP 3.300.604 "Environmental Monitoring of the Aseptic Compounding Area: Glove Fingertip Testing," your aseptic technicians' fingertips should be monitored biweekly. Neither is adequate as technicians are not monitored each time they perform aseptic processes.***

   Response: USP <797> states *"Gloved Fingertip Sampling: ... After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs..."* On July 30, 2015, SOP 3.300.604 was updated to indicate our actual process of annual for medium/low risk and semi-annual gloved fingertip sampling for high risk re-assessment for all sterile compounding employees. The updated SOP has been attached for review. Pending FDA's decision on jurisdiction, People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.

Observation 3:

The flow of components, drug product containers, closures, in-process materials, and drug products though the building is not designed to prevent contamination.

Specifically:

1. ***Per your firm's SOP 3.300.308 "General Aseptic Compounding Procedures when Working within the Secondary Engineering Controls and Primary Engineering Controls," all supplies should be decontaminated in the ante room and transferred into a clean sanitized cart for introduction into the clean room. On 07/21/2015 we observed a technician carry 3 plastic totes containing components (sterile syringes, sterile needles, compounded stock solution) to be used during aseptic processing into the ante room. After gowning, the technician stacked these totes and entered the clean room without decontaminating the totes or components. The technician was processing Myers vitamin injections with Vitamin C.***

   Response: On 7/30/2015, the sterile compounding staff was re-trained/re-educated on the procedures outlined in SOP 3.300.308. Our ante-room is small, thus technicians and pharmacists also discussed ways to accomplish this practice in an efficient and effective manner. See Form 1.400.1 attached documenting the employees' understanding of SOP No.3.300.308.

2. ***Per your firm's SOP 3.300.308 "General Aseptic Compounding Procedures when Working within the Secondary Engineering Controls and Primary Engineering Controls," decontamination should be performed as supplies are introduced into the***

aseptic work area. On 07/20/2015 and 07/21/2015 we observed a technician place components under the ISO 5 hood to be used for aseptic processing without any decontamination step. On 07/20/2015 the technician was processing HCG/B12 injections and Mitomycin bladder irrigation. On 07/21/2015, the technician was processing Myers vitamin injections with Vitamin C.

Response: On 7/30/2015, the sterile compounding staff was re-trained/re-educated on the procedures outlined in SOP 3.300.308. See Form 1.400.1 attached documenting the employees' understanding of SOP No.3.300.308.

Observation 4:

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically:

1. ***Your Cleanroom Certification Report dated 03/27/2015 indicates smoke studies were performed for the ISO 5 hoods; however, these studies were not video recorded or documented. Also, these studies were not performed in dynamic conditions.***

   Response: USP <797> states *"In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions."* ENV, the company that certifies our hoods was contacted and requested that the smoke test be done "under dynamic" conditions in the future. The company representative stated that "video recording" was not something they usually did, because this was not a requirement for USP <797> or the Tennessee State Board of Pharmacy. The next certification will take place in September 2015. Pending FDA's decision on jurisdiction, People's Custom Rx will continue to certify our rooms and hoods per USP <797> guidelines and the Tennessee State Board of Pharmacy (adding the addition of smoke studies under dynamic conditions.)

2. ***Your firm does not continually monitor pressure in the laminar flow hoods, clean room, or ante room. Air pressure is only checked once per day.***

   Response: USP <797> states *"Pressure Differential Monitoring-A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device".* Pending FDA's decision on jurisdiction, People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.

Observation 5:

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically:

1. ***Your firm produces stock solutions used to fill individual prescriptions. Your stock solution lot sizes supply the firm with enough product to fill approximately 3 weeks of prescriptions. Each stock solution container can be used for multiple fills. You have not conducted the appropriate test to validate this process.***

   Response: We have developed a plan to validate this process. We have first, minimized the use of stock solutions as much as possible, and second we are sending at least 5 samples to our independent lab for sterility testing. We are selecting samples at 1 week, 2 weeks, 3 weeks, and at the last day we would use a stock solution. We will document the solution, the lot number, the date the vial was first opened, the date the sample was taken and sent to the lab, and the results of the

sterility test. We will repeat this validation process on a regular basis as part of our quality assurance plan.

2. ***Your firm has not validated your sterilization process for autoclaving rubber stoppers and finished drug products (suspensions including prednisolone and stanozolol).***
   Response: People's Custom Rx believes it is in compliance with the guidelines within USP <797> regarding sterilization via autoclave. USP <797> states, *"The process of thermal sterilization employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed. To achieve sterility, all materials are to be exposed to steam at 121° under a pressure of about 1 atmosphere or 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for CSPs. An allowance shall be made for the time required for the material to reach 121° before the sterilization exposure duration is timed. Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores. Before their sterilization, plastic, glass, and metal devices are tightly wrapped in low-particle-shedding paper or fabrics or sealed in envelopes that prevent poststerilization microbial penetration. Immediately before filling ampuls and vials that will be steam sterilized, solutions are passed through a filter having a nominal pore size not larger than 1.2 mm for removal of particulate matter. Sealed containers shall be able to generate steam internally; thus, stoppered and crimped empty vials shall contain a small amount of moisture to generate steam. The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of steam sterilization shall be verified using appropriate BIs of Bacillus stearothermophilus and other confirmation methods such as temperature-sensing devices."* However, because we are committed to patient safety and agree with the FDA that this process should be periodically validated, on July 20, 2015 our pharmacist validated the sterilization process for autoclaving. The autoclave was filled with #25 100ml vials filled with product. Two (2) sterilization tests were placed in the autoclave, one in the middle of the vials and one on the outer edge of the tray near the door. Both tests were negative after incubating for 48 hours. Attached is Form 3.300.313 documenting the date, lots of the tests used, and the results. This process will be repeated on a regular basis and documented; however, pending FDA's decision on jurisdiction, People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.

3. ***Your firm has not validated the process of depyrogenating/sterilizing glassware via a dry heat oven. The glassware is used in the mixing and holding of drug products to be aseptically filled or terminally sterilized.***
   Response: People's Custom Rx is in compliance with the guidelines within USP <797> regarding depyrogenation of glassware. USP <797> states, *"Dry heat depyrogenation shall be used to render glassware or containers such as vials free from pyrogens as well as viable microbes. A typical cycle would be 30 minutes at 250°. The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs). The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin."* People's Custom Rx has not needed to depyrogenate/sterilize glassware via the dry heat oven since the time this observation was made; however, because we are committed to patient safety, we agree that it would be beneficial to validate this process; therefore, when the next batch is done, we plan to fill the oven to capacity

with glassware, wrapped per our policy, and place validation tests in several areas within the oven, including the center and outer edges to verify that the depyrogenation/sterilization process is effective. The results will be documented on Form 3.300.314 Validation Convection Oven Log. This process will be repeated on a regular basis and documented; however, pending FDA's decision on jurisdiction, People's Custom Rx belives it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.

4. ***Your firm has not validated the process of terminal sterilization for oil based drug products using a dry heat oven.***

   Response: People's Custom Rx believes it is in compliance with the guidelines with USP <797> regarding terminal sterilization for oil based drug products using a dry heat oven. USP <797> states, *"Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. Heated filtered air shall be evenly distributed throughout the chamber by a blower device. The oven should be equipped with a system for controlling temperature and exposure period. Sterilization by dry heat requires higher temperatures and longer exposure times than does sterilization by steam. Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable. During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air. The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate BIs of Bacillus subtilis and other confirmation methods such as temperature-sensing devices."* People's Custom Rx has not needed to sterilize an oil based drug product via the dry heat oven since the time this observation was made; however, because we are committed to patient safety, we agree that it would be beneficial to validate this process; therefore, when the next batch is done, we plan to place the 200ml of oil alone in the center of the oven and place validation tests in several areas within the oven, including the center and outer edges to verify that the sterilization process is effective. The results will be documented on Form 3.300.314 Validation Convection Oven Log. This process will be repeated on a regular basis and documented; however, pending FDA's decision on jurisdiction, People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.

Observation 6:

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically:

1. ***Your firm uses a Boekel model incubator for sterility samples. The directions for use for the TSB syringes your firm uses states to incubate at 22.5C+/-2.5C. During a review of your firm's temperature logs for this incubator for the last 4 months (April-July 2015), it was found that temperature was out of range for this entire time period. The temperature ranged from 25.2C to 30.8C.***

   Response: This correction was made immediately upon notification. Find attached Form 3.100.2 Daily Temperature Log-Incubator for July 2015. The change was made on July 22, 2015 and the temperature has been in range since that time.

2. ***Your firm uses a Lab-Line model incubator for environmental monitoring. The directions for use for the TSA plates your firm uses state to incubate at 35C +/-2C. During a review of your firm's temperature logs for this incubator for the last 4 months (April-July 2015), it was found that temperature was out of range for 37 days***

(approximately 30% of the time) during this time period. The temperature range was 39C to 44C for the out of range readings.

Response: This correction was made immediately upon notification. Find attached Form 3.100.2 Daily Temperature Log-Incubator for July 2015. The change was made on July 22, 2015 and the temperature has been in range since that time.

Observation 7:

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically:

Your firm uses sterile isopropyl alcohol, Sporicidin, and Accel TB disinfectant for daily cleaning of the ISO 5 hoods and clean room. Per your firm's SOP 3.300.303 "Disinfectant Selection and Use Rotation," these 3 cleansers are rotated on a quarterly cycle with sterile isopropyl alcohol being used twice. This only allows for a sporacide to be used for 1 quarter of the year for cleaning your ISO 5 hoods and clean room.

Response: After review of our policy, we agree that a more frequent rotation of disinfectant solutions for daily cleaning of the ISO 5 hoods and clean room would be beneficial. Please find attached Form 3.300.303 Approved Disinfectant Rotation Form. Rather than quarterly rotations, we will begin monthly rotations and will use sterile IPA once in the rotation allowing for more frequent use of a sporacide.

Observation 8:

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically:

Your firm does not conduct identity and potency testing of each lot of drug tested.

Response: USP <797> does not require compounding pharmacies to conduct identity and potency testing of each lot of drug tested. Attached are the SOPs for People's Custom Rx in regards to potency. Our staff is trained, validated, and re-validated at least semi-annually. People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.

Observation 9:

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically:

Your firm has not performed stability studies for your sterile products that include ID, potency, degradant, impurity, and other stability indicating parameters. Beyond use dates greater than 48 hours are given to sterile injectable drugs that do not contain preservatives.

Response: USP <797> does not require compounding pharmacies to conduct these specific stability studies. Attached are the SOPs for People's Custom Rx in regards to potency and beyond use dating. Our staff is trained, validated, and re-validated at least semi-annually. People's Custom Rx believes it is in compliance with the guidelines indicated in USP <797> as adopted as the standard for a compounding pharmacy by the Tennessee State Board of Pharmacy.