DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Industry Information: www.fda.gov/oc/industry	11/9, 12, 14-16, 19, 27/2012; 01/04, 07, 08, 10-11, 14, 16, 17/2013; 02/11/2013
	FEI NUMBER 3001779702

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Anthony Grzib, R.Ph., Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Wedgewood Village Pharmacy, Inc.	405 Heron Drive, Suite 200
CITY, STATE AND ZIP CODE Swedesboro, NJ 08085	TYPE OF ESTABLISHMENT INSPECTED Compounding Pharmacy

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

During the inspection, personnel practices, gowning, and environmental conditions were observed that have the potential for compromising the sterility of sterile (b) (4) aseptically filled human and/or veterinary compounded drugs. For example:

A) On 01/04/2013, we observed a roll of IVA seals for multi-dose vials and an IV bag used in compounding suspended from hooks hanging directly on the back surface of the ISO-5 horizontal laminar flow (HLF) hood within aseptic compounding Room (b) (4) Sodium Chloride Injection 0.9%, Preservative Free, in glass vial, lot 20130104@136 (Exp: 07/03/2013, human), was being aseptically filled at that time. The roll of seals was observed at the same location on 01/08/2013 and 01/17/2013. There is no assurance that the placement of these items does not block unidirectional airflow and compromise aseptic conditions.

B) On 11/16/2012, the technician compounding Cyclosporine 1% Ophthalmic Solution in MCT Oil, lot 20121115@237 (Exp: 05/14/2013, veterinary) was observed leaning his/her upper torso inside the ISO-5 HLF hood directly above open containers being filled and stoppered. We observed the technician exiting the ISO-6 room to the ISO-7 Gowning Ante-room to retrieve packaging components three times once the operation had begun. The compounding batch log sheet (paper) and pen were also observed being manipulated with gloved hands by the technician between operations inside the ISO-5 HLF hood; however, the technician was not observed sanitizing his/her hands every time before returning to the hood.

C) The gowning worn by technicians while compounding sterile drugs in all (b) (4) of the ISO-6 rooms (Rooms (b) (4) leaves areas at the neck and top of feet/shoes exposed. Gowning consists of shoe covers, sterile coveralls, bouffant cap, surgical mask, safety glasses, and sterile gloves.

D) Improper gowning practices were observed, such as: hair not completely covered by the bouffant cap (01/11/2013, 01/17/2013), jewelry such as large hoop earrings worn (01/16/2013), holes in gowning of a

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technician prior to beginning an operation in Room (b) (4) (ISO-6, containing ISO-5 Biosafety Cabinet) (01/11/2013), and in-ear headphones hanging outside of a technician's gown to the waist level during the cleaning of the ISO-5 Biosafety Cabinet (BSC) in Room (b) (4) (01/10/2013). Notably, the cord and earpieces of the headphones were observed touching the edges of the ISO-5 BSC near the working surface. While cleaning the drug transfer device, which is intended for use inside the ISO-5 BSC, the technician removed the equipment and held it against his/her body and the headphones as they were cleaning, then replaced the equipment back inside the cleaned BSC.

E) There is no mirror in Room (b) (4), the ISO-7 gowning room, to ensure proper donning of the bouffant cap; nor in Room (b) (4) the ISO-7 Ante-room outside ISO-6 rooms ((b) (4) where sterile coveralls, surgical mask, safety glasses, and sterile gloves are donned. Additionally, SOP COM-AC-518.2, Working Within the Clean Room Complex and Hood(s), does not describe whether any part of the sterile coveralls may touch the ground while donning. On 01/08/2013 and 01/16/2013, technicians demonstrated donning of sterile coveralls, during which parts of the coverall touched the ground.

F) On 01/04/2013, during the sterile (b) (4) of Sodium Chloride Injection 0.9%, Preservative Free, in glass vial, lot 20130104@136 (Exp: 07/03/2013, human) in the ISO-5 HLF hood, a product leak was observed at the sterile tubing set where it attached to the sterilizing (b) (4) outlet. The technician completed the filling operation and wiped up the product, but did not document the leak in the compounding batch log sheet or elsewhere.

G) It does not appear that all materials are routinely sanitized immediately before entering either: one of the ISO-6 aseptic compounding rooms (Rooms (b) (4)), ISO-5 HLF aseptic compounding hoods, or ISO-5 biosafety cabinets. SOP COM-AC-518.2, Working Within the Clean Room Complex and Hood(s), does not have any provisions for this.

• On 01/04/2013, pouches of sterilized closures; aluminum crimp caps; a manual cap crimper; a red/black screwdriver; and the spray bottle of (b) (4) (b) (4) were observed being used and placed inside the ISO-5 HLF hood in Room (b) (4) during the compounding of Sodium Chloride Injection 0.9%, Preservative Free, in glass vial, lot 20130104@136 (Exp: 07/03/2013, human). We did not observe any of these items being sanitized immediately before entry into the hood.

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• On 11/16/2012, pouches of sterilized containers and closures, and a screwdriver were observed being used and placed inside the ISO-5 HLF hood in Room (b) (4) during the compounding of Cyclosporine 1% Ophthalmic Solution in MCT Oil, lot 20121115@237 (Exp: 05/14/2013, veterinary). We did not observe any of these items being sanitized immediately before entry into the hood.

• The pouches of sterilized containers, closures, and tubing are not routinely sanitized before being transferred into one of the ISO-6 aseptic compounding rooms from the stock of open storage shelves in the ISO-7 Ante-room. The storage shelves are located adjacent to the handwashing sink and gowning donning/removal area. This is also not done for the compounding batch log sheets (paper) that are brought into the ISO-6 rooms from the uncontrolled corridor. On 11/16/2012 and 01/04/2013, pouches of components and compounding batch log sheets were observed in use in ISO-6 Room (b) (4) during the compounding of Cyclosporine 1% Ophthalmic Solution in MCT Oil, lot 20121115@237 (Exp: 05/14/2013, veterinary), and Sodium Chloride Injection 0.9%, Preservative Free, in glass vial, lot 20130104@136 (Exp: 07/03/2013, human), respectively.

H) On 01/04/2013, difficult-to-sanitize items were observed in the ISO-6 aseptic compounding Room (b) (4) such as an open laptop computer and RF scanner, compounding batch log sheet (paper), adhesive paper notes, standard push-button calculator, vacuum pump intended for sterile filter integrity test, and two plastic/rubber handled screwdrivers. Within the ISO-5 HLF hood, a roll of IVA seals for multi-dose vials was hanging at the back of the hood. Sodium Chloride Injection 0.9%, Preservative Free, in glass vial, lot 20130104@136 (Exp: 07/03/2013, human) was being compounded. Some of these items, such as the vacuum pump, screwdrivers, and roll of IVA seals, were observed within the room again on 01/08/2013 and 01/17/2013, in addition to a plastic handled box cutter, manual stapler, cardboard containers holding glass vials, and a metal binder clip attached to cart 4.

I) On 01/04/2013, while a single technician was aseptically filling Sodium Chloride Injection 0.9%, Preservative Free, in glass vial, lot 20130104@136 (Exp: 07/03/2013, human) in the ISO-5 HLF hood in ISO-6 Room (b) (4) we observed a second technician open the door to the ISO-6 room and walk across the room to use the laptop computer and RF scanner located on the table in front of the observation window. The second technician walked back to the door and held it open, leaving an open path between the ISO-6 and ISO-7 classified areas, in order to continue a conversation with the first technician that was performing the aseptic fill.

J) According to SOP COM-AC-518.2, Working Within the Clean Room Complex and Hood(s), Section 2.3,

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	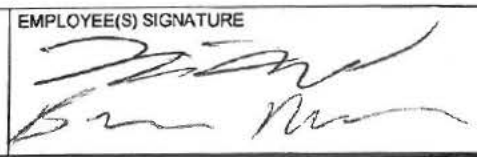	Nicholas Violand, Investigator Barbara Wilimczyk-Macri, Investigator Thomas Friel, Investigator Juanita Versace, Microbiologist	02/11/2013

gowns may be removed in the ante-room and hung up inside-out, so that they may be re-worn again. Although the re-use of gowns was verbally described as limited to one shift, the procedure does not limit how many times this may be done or a timeframe for re-use. There has been no evaluation of this practice to ensure re-worn gowns do not contribute to potential contamination of sterile preparations.

Observation 2
Sterile veterinary compounds are not routinely tested for sterility and endotoxin limit, regardless of quantity produced or method of preparation. Veterinary compounds represent over (b) (4)% of orders dispensed between 10/1/2012 and 1/7/2013. Specifically:

A) Approximately (b) (4) units (2ml vials) of Amikacin Preservative Free Injection, 250 mg/ml, lot 20121112@270 (Exp: 05/11/2013), were aseptically filled on or about 11/29/2012. No sterility or endotoxin limit testing was performed.

B) Approximately (b) (4) units (1000ml IV bags) of Guaifenesin 5% (in Dextrose 5%) Solution for IV Infusion, lot 20130104@363 (Exp: 04/04/2013), were aseptically filled on or about 01/07/2013. No sterility or endotoxin limit testing was performed.

C) Approximately (b) (4) units (30ml vials) of Medroxyprogesterone Acetate 200mg/ml Suspension for Injection, lot 20120917@310 (Exp: 03/16/2013), were (b) (4) sterilized by (b) (4) on or about 09/18/2012. No sterility or endotoxin limit testing was performed.

D) Approximately (b) (4) units (5 gram tubes) of Edetate Disodium 1% Ophthalmic Ointment, lot 20130107@122 (Exp: 07/06/2013), were (b) (4) sterilized by (b) (4) on or about 01/07/2013. No sterility or endotoxin limit testing was performed.

Observation 3
Sterile human compounds are not always tested for sterility, even when made from non-sterile ingredients. Section 2.4 of SOP COM-AC-570.1, Sterility Testing of Human Preparations, requires sterility testing for all high-

risk level compounded sterile products intended for use in humans that are produced (b) (4) (b) (4) (b) (4) before being sterilized. For example:

A) Naltrexone 1.4gm Pellet (implantable) is (b) (4) and sterilized by (b) (4) Since 01/2011, this preparation has been made in batches of up to approximately (b) (4) units, but no sterility or endotoxin testing has ever been performed for this product. Lots 20120822@128 ((b) (4) units) and 20120425@150 ((b) (4) units) were produced in 2012 and remain within their expiry (08/17/2013 and 4/20/2013, respectively).

B) Sodium Bicarbonate 8.4% Preservative Free Injection, lot 20121211@133 (Exp: 06/09/2013), was sterile (b) (4) and aseptically filled on or about 12/11/2012 as (b) (4) units (50ml single-use vial). Sterility or endotoxin limit testing was not performed.

Observation 4

There is a lack of assurance of sterility for compounded sterile human and veterinary drugs, including injectable, implantable and ophthalmic products. Not all methods of sterilization for these products have been fully evaluated for effectiveness and/or consistency. Specifically:

A) (b) (4) Sterilization: There is no assurance the sterilization process of the (b) (4) is reaching the set point of (b) (4) (b) (4) for the duration of (b) (4) The (b) (4) is not calibrated for (b)(4) or time on any routine basis. The sterilization process has not been supported by actual sterility tests on product sterilized at worst case conditions (e.g., varied loading patterns and quantity of units being (b) (4). Examples of products prepared by (b) (4) sterilization include: Medroxyprogesterone Acetate 200mg/ml Suspension for Injection (veterinary), Estrone 5mg/ml Suspension for IM Injection (veterinary) and Cyclosporine 1% Aqueous Ophthalmic Suspension (human).

B) Sterile (b) (4) and Aseptic Fill: The (b) (4) for assurance of (b) (4) integrity after aseptic fill is not always fully documented. The technician is to circle "pass" or "fail" and record a pressure reading at which the (b) (4) was tested; however, instances were seen in which this information was not recorded at all. Examples

include: Pentosan Injection Solution 250mg/ml, lot 20121224@202, exp: 06/22/2013 ((b) (4) units, veterinary); FHS Ferric Hydroxide/Sucrose 20mg/ml Injection, lot 20121203@269, exp: 06/01/2013 ((b) (4) units, veterinary); and Papaverine 30mg/ml Injection, lot 20121115@249, exp: 03/15/2013 ((b) (4) units, human). These examples include the technician's initials in the (b) (4) box, but no indication of integrity test results.

C) (b) (4) Sterilization: The (b) (4) is calibrated for (b)(4) but there is no assurance the process is reaching the (b)(4) and that it is maintained within a tolerance for the specified exposure time. For example, Edetate Disodium 1% Ophthalmic Ointment, lot 20130107@122, was (b)(4) treated on 01/07/2013 from approximately (b) (4) The rack location in the (b) (4) is recorded, but no verification of the actual (b)(4) is recorded, nor is there assurance this (b)(4) was maintained for the specified time of (b) (4) (b)(4) In addition, there is no procedure for (b) (4) sterilization to describe capacity, loading patterns and operation of the (b) (4).

D) (b) (4) The firm provided a theoretical spore log reduction calculation for a particular organism for the minimum dose used by the contract (b) (4), (b) (4) however, actual product sterility is not routinely demonstrated through sterility testing. Certificates of processing received from the contract (b) (4) show the dose used; however, worst case conditions (e.g., lowest possible dose, loading pattern) have not been supported by actual sterility tests on (b) (4) product. Naltrexone 1.4gm Pellet (Implantable, human) is sterilized by (b) (4)

Observation 5

Steps to control routine bioburden in raw materials and/or components to be used in (b) (4) sterilized products are not always taken. For example:

A) Raw materials that will be used in a sterile product are not always stored in a manner to reduce potential contamination. For example: unfilled (bulk) preservative free ophthalmic ointment, lot 20120928@230, exp. 09/23/2013, was observed in aisle (b) (4) (sterile preparations aisle) of the raw material warehouse on 01/04/2013 and 01/17/2013 in a plastic bucket with metal handle. According to management, the bucket is unlined, is not received as sterile, and is not treated prior to use. In addition, Carbomer Gel for Cyclosporin Gel, lot 20120806@156, exp: 02/02/2013, was also observed in aisle (b) (4) on 01/17/2013, in a clear plastic tub. The lid of the tub appeared to have

liquid condensation on the inner surface and the tub did not appear to be lined.

B) Preparation of vial stoppers for products that will be terminally sterilized is performed by rinsing with purchased sterile water for injection (WFI), drying with a lint-free cloth, and transporting to the multi-purpose general compounding room (Room (b) (4) in a plastic weigh boat. This cleaning process is performed inside the washroom, which has many activities occurring, such as (b) (4) glassware washing/ (b) (4) and incubation of bacterial growth media and bio-indicators. The rinsing/preparation of the stoppers should be performed in an environment that is less likely to contribute to bioburden on the container-closure system, which has direct contact with product. This process was verbally described, and is not in a written procedure.

Observation 6

Raw materials such as bulk active ingredients are not routinely tested for identity, and raw materials being used in sterile compounded drugs are not evaluated for routine bioburden. Although quality agreements are maintained with suppliers of active ingredients, sampling and testing has never been performed for any active or inactive ingredients. There are no identity tests performed for any materials. For example:

A) Lot (b) (4) of raw material Medroxyprogesterone Acetate was received with a certificate of analysis and checked into inventory on or about 08/08/2012. No sampling or testing was performed for the material, which was used to compound Medroxyprogesterone Acetate Suspension for Injection 200mg/ml, lot 20121219@273 (Exp: 06/17/2013), which was (b) (4) sterilized by (b) (4) This raw material has not been assessed for routine bioburden.

B) Lot (b) (4) of raw material Sodium Bicarbonate Powder, USP was received with a certificate of analysis and checked into inventory on or about 06/18/2012. No sampling or testing was performed for the material, which was used to compound Sodium Bicarbonate 8.4% Preservative Free Injection, lot 20121211@133 (Exp: 06/09/2013), which was sterile (b) (4) and aseptically filled. This raw material has not been assessed for routine bioburden.

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Observation 7

Reports of adverse events and complaints relating to potential quality or labeling defects are not trended and evaluated for possible systemic issues that could affect more than one product. Quality Event Investigations (QEIs) are generated for customer complaints and adverse events. These typically describe trending for the same product (item code) or specific lot number; however, review for similar adverse events/complaints among different item codes is not typically included in the QEI or in any other document. (Between 11/01/2011 and 10/31/2012, approximately (b) (4) unique human and veterinary item codes were produced.) For example:

A) Between 01/01/2012 and 12/31/2012, approximately 30 reports were received, across multiple sterile injectable or implantable human or veterinary compounds, describing reactions which include but are not limited to: injection/implant site reaction; infection, abscess, redness, or swelling at injection site; inflammation; death; or other non-specific reactions. General trends for adverse events such as injection site reaction or other types of reactions following administration of any injectable or implantable compounded sterile preparation are not noted in the QEIs or elsewhere. Examples include:

i. QEI case 00019139, opened 10/29/2012, describes that a horse administered Medroxyprogesterone compound (item code: MEDROX-INJ005VC, veterinary) was found dead approximately 30 minutes after receiving the injection; and an autopsy found the cause of death to be anaphylaxis. The investigation notes that two possible product lots may have been administered to the horse (20120807@286 , 20120917@310); and no other issues were reported for those lots, and no other complaints of that nature had been received for that item code in the last year. The QEI was closed on 11/01/2012, without any chemical or microbiological testing being performed.

ii. QEI case 00015436, opened 04/20/2012, describes that three patients that had received the Naltrexone implants (item code: NALTRE-PEL003HC, lot 20111208@020, human) were experiencing infection, with swelling and redness at the incision site. Case 00015129 had been opened on 04/02/2012, in which the same reporter described three of five patients complained of white chalky fluid leaking from the site of implant, for the same lot (20111208@020). These were presumed but not confirmed to be the same patients. The investigations did not include any testing or possible root cause determination, and concluded that a lack of other complaints indicated the lot was acceptable. QEI 00015129 was closed on 04/02/2012; and no closure date is included for QEI 00015436, which was cancelled.

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iii. QEI case 00013604, opened 01/05/2012, describes that numerous horses experienced abscesses at the injection site after administration of glucosamine sulfate 250mg/ml (item code: GLUSUL-INJ001VC, lot 20111116@043, veterinary). The investigation concluded that a lack of other complaints for this lot and item code indicated the product was acceptable. The QEI was closed on 01/06/2012, without a possible root cause or any testing being performed.

B) Between 01/01/2012 and 12/31/2012, approximately 18 reports were received across multiple sterile ophthalmic veterinary compounds, describing reactions that include but are not limited to: redness; irritation; swelling; discharge; bacterial conjunctivitis; soreness; ulcer, or other non-specific reactions. General trends for adverse events following administration of any sterile ophthalmic product are not noted in the QEIs or elsewhere. Examples include:

i. QEI case 00017680, opened 08/17/2012, describes "the eye gets 'excessively' irritated and 'lost a lot of skin' and now appears to have an ulcer" following administration of edetate disodium ophthalmic ointment (item code: EDEDIS-OPH027VC, lot 20120706@278, veterinary). The investigation concludes that the product is acceptable, as no other complaints of this nature had been received for the lot and item code. The QEI was closed on 08/21/2012, without any possible root cause being proposed or testing being performed.

ii. QEI case 00017910, opened 08/29/2012, describes that the patient's eyes became sore and watery following the administration of Idoxuridine ophthalmic solution (item code: IDOXUR-OPH001VC, lot 20120618@364, veterinary). The complainant notes the patient had used the same product previously with no issues, and "wanted to know if this was a 'bad batch'." The investigation concludes that the product is acceptable, as no other complaints of this nature had been received for this lot and item code. The QEI was closed on 08/30/2012, without any possible root cause being proposed or testing being performed.

iii. QEI case 00014790, opened 03/10/2012, describes that the patient's eye swelled and turned red following one application of Diclofenac ophthalmic ointment 0.1% (item code: DICLOF-OPH002VC, lot 20120229@106, veterinary). The investigation concludes that the product is acceptable, as no other complaints of this nature had been received for this lot and item code. The QEI was closed on 03/12/2012, without any possible root cause being proposed or testing being performed.

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C) From the log of QEIs initiated between 01/01/2012 and 12/31/2012 for human and veterinary compounds, approximately 28 examples of case files were reviewed that categorize the issue as "NO BIOLOGICAL RESPONSE". Additional entries in the log describe issues such as the subject product(s) did not work or did not produce the expected response. Reports categorized as "NO BIOLOGICAL RESPONSE" and/or reports of lack of effect are not trended in the QEIs or elsewhere, for any potential associations with a specific dosage form, process/procedure, technician(s), equipment, or raw material. Examples include:

i. QEI case 00018405, opened 09/20/2012, is categorized as "NO BIOLOGICAL RESPONSE" for Methimazole Suspension (item code: METHIM-SUS510VC, veterinary). It states the patient's thyroid level "is now above 23 after 2 months of therapy and [the complainant] feels that this methimazole was not compounded correctly." The patient was noted to have been on the same compounded product with no issues. The QEI concludes the product is acceptable, as only 2 other complaints of this nature have been received for this item code in the last year. The QEI was closed on 09/21/2012, without any testing or root cause analysis being performed.

ii. QEI case 00016374, opened 06/13/2012, is categorized as "NO BIOLOGICAL RESPONSE" for Tri-mix Injection (item code: TRIMIX-INJ005HC, lot 20120507@071, human). The patient reported lack of effect. The QEI concludes the product is acceptable as only 2 complaints for this lot and 19 for this item code of this nature had been received. The QEI was closed on 06/14/2012, without any testing or root cause analysis being performed.

iii. QEI case 00016395, opened 06/14/2012, is categorized as "NO BIOLOGICAL RESPONSE" for Corticotrophin Injection (item code: CORTIC-INJ002VC, lot 20120503@055, veterinary). The reporter notes the patient's ACTH test results "were erratic." As per the reporter, the patient was not on any other medication that could interfere or interact. The QEI concludes that the product is acceptable, as only 6 complaints of this nature have been received for this item code. The QEI was closed on 06/15/2012, without any testing or root cause analysis being performed.

D) Between 01/01/2012 and 12/31/2012, approximately 31 complaints across multiple human and veterinary compounds were received, describing either incorrect labeling or receipt of incorrect order. General trends for labeling and shipment errors are not noted in the QEIs or any other report, for any potential associations with a specific process/procedure or technician(s)/pharmacist(s). Specific complaints include:

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i. QEI case 00019218, opened 11/03/2012, describes that the complainant was "confused about the bottles and labels. [He/She] said there was a bottle labeled DES tiny tabs, but there were capsules in the bottle. [He/She] peeled back the label and the label underneath said Prenisolone/Tetracycline caps."

ii. QEI case 00013579, opened 01/04/2012, describes that the complainant received all the items in their order, with an additional item labeled for a different patient.

iii. QEI case 00016859, opened 07/09/2012, describes the receipt of an incorrect item. It states "The request from the doctor was for slow release caps (once daily) but, the technical notes were taken incorrectly and the capsules were formulated as the immediate release."

Observation 8

Efforts to prevent cross contamination of allergens such as cephalosporins and potent materials such as hormones have not been evaluated for effectiveness. Cephalosporin and hormone containing compounds may be produced from powders in the general compounding room (Room (b) (4) under non-dedicated containment hoods, using non-dedicated compounding equipment. Routine cleaning of the hoods and other equipment has not been demonstrated to be effective at removing traces of such materials, nor are there any specific instructions or written procedures for cleaning following the compounding of such materials. For example:

A) Cephalexin 100mg Chew Treat, lot 20130108@231 (veterinary), was compounded on or about 01/08/2013 under an unspecified hood, using a beaker, glass stir rod, and animal treat mold. There are no specific instructions or documentation in the compounding batch log sheet for cleaning following compounding of this cephalosporin containing product.

B) Cefadroxil 100mg Capsules, lot 20130109@247 (veterinary), was compounded on or about 01/09/2013 under an unspecified hood, using a mortar and pestle and unspecified encapsulation equipment. There are no specific instructions or documentation in the compounding batch log sheet for cleaning following compounding of this cephalosporin containing product.

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C) Medroxyprogesterone Acetate Suspension for Injection, 200mg/ml, lot 20121219@273 (veterinary), was compounded on or about 12/20/2012 under an unspecified hood, using a glass mortar and pestle, beaker, and unspecified stirring and (b) (4) equipment. There are no specific instructions or documentation in the compounding batch log sheet for cleaning following compounding of this hormone containing product.

D) Hydroxyprogesterone Caproate 250mg/ml in Castor Oil Solution for Injection, lot 20121214@199 (human), was compounded approximately on 12/17/2012 under an unspecified hood, using an unspecified container and stirring equipment before being sterile (b) (4) and aseptically filled. There are no specific instructions or documentation in the compounding batch log sheet for cleaning following compounding of this hormone containing product.

Additionally, SOP COM-GEN-089.1, Quality Assessment of Equipment, Section 2.2, states "All equipment is to be constructed so that surfaces that contact pharmaceutical components, in-process materials, or finished medications are not reactive, additive, or absorptive in order to prevent adversely affecting the safety, identity, strength, quality, or purity of the preparations." It is unclear how assurance of this procedural requirement is accomplished.

Observation 9

There is no assurance that testing performed by contract laboratories on finished compounded drugs is adequately and appropriately performed. No documented efforts are made to evaluate the services provided by these organizations. There are at least three different contract laboratories used for finished product tests, which include potency, sterility and endotoxin limit testing for sterile human compounds. Products tested by these laboratories include: Hydroxyprogesterone Caproate 250mg/ml Injection in Castor Oil, Sodium Chloride 0.9% in plastic vials (human), and Tri-mix Standard Injection (Prostaglandin E, Papaverine, Phentolamine) (human).

Observation 10

The following deficiencies were observed during review of compounding batch log sheets (batch records):

A) There is no traceability of sterile components used throughout the compounding process, such as sterile tubing

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Industry Information: www.fda.gov/oc/industry	11/9, 12, 14-16, 19, 27/2012; 01/04, 07, 08, 10-11, 14, 16, 17/2013; 02/11/2013
	FEI NUMBER 3001779702

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Anthony Grzib, R.Ph., Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Wedgewood Village Pharmacy, Inc.	405 Heron Drive, Suite 200
CITY, STATE AND ZIP CODE Swedesboro, NJ 08085	TYPE OF ESTABLISHMENT INSPECTED Compounding Pharmacy

and sterilizing (b) (4) as the lot and expiry dates of actual components used are not recorded. In some instances, component lots are listed in log sheets from 2012, with expiry dates from as early as 2009. For example:

i. Hydroxyprogesterone Caproate Injection 250mg/ml in Castor Oil, Preservative Free, lot 20121015@348 (Exp: 04/13/2013, human), was compounded on or about 10/16/2012. The compounding log sheet lists approximately eleven different components with expiry dates prior to 10/16/2012, which include "BAG, STERILE CONTAINER 4000ML ((b) (4) DEVICE" lot (b) (4) expiry 09/30/2009; "(b) (4) (b) (4) W/ (b) (4) (b) (4) DEVICE" lot (b) (4), expiry 04/30/2010; and "TUBE SET, STERILE ((b) (4) DEVICE" lot (b) (4) expiry 10/31/2011.

ii. These same three lots of expired device components are also listed in the compounding log sheet for Medetomidine HCl 1mg/ml Injection Solution, lot 20121218@393 (Exp: 06/16/13, veterinary), compounded on or about 12/19/2012.

B) Compounding batch log sheets do not contain adequate details of the actual compounding process as performed, to ensure proper execution and lot-to-lot consistency. Compounding log sheets for human and veterinary solutions and suspensions do not routinely require the documentation of mixing speeds, mixing times, and specific equipment (or type) used throughout the process. For example:

i. The compounding log sheet for Medroxyprogesterone Acetate Suspension for Injection, 200mg/ml, lot 20121219@273 (Exp: 06/17/2013, veterinary) requires the technician to perform activities such as: (b) (4) (b) (4) (b) (4) (b) (4) No details regarding vessel size, mixing speeds and times, duration and speed of and actual pump speed were recorded by the technician in the record.

ii. The compounding log sheet for Guaifenesin 5% (in Dextrose 5%) Solution for IV Infusion, Preservative Free, 1000ml, lot 20130104@363 (Exp: 04/04/2013, veterinary) requires the technician to perform activities such as: (b) (4) (b) (4) No details regarding initial volume of (b) (4) used, (b) (4) setting used, size of beaker and vessel used, order of addition of ingredients, mixing

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speeds, and mixing times were recorded by the technician in the record.

Observation 11

The system used to manage changes to formulations and processes is not always effective. Formulation Change Request 1875 was implemented approximately on 3/26/2012, to modify the formulation of Medroxyprogesterone Acetate Suspension for Injection, 200mg/ml, following the compounding of batches that could not be filled into vials. Multiple ingredients were changed, including the preservative system, from (b) (4) (b) (4) Although the compounding batch log sheet was updated to reflect the formula change, the preservatives listed on the label for the product were not subsequently changed to reflect the difference.

More than 7 months later and after the initiation of this inspection, Change Request 2027 was issued (11/15/2012), to correct the labeling; however, approximately 22 lots with potentially incorrect labeling have been produced and remain within expiry.

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