

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax: (949)608-4417 | DATE(S) OF INSPECTION 11/2/2021-11/10/2021* |
| | FEI NUMBER 3014745182 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George M. Hiers IV, Owner and Pharmacist-in-Charge

| | |
|--|--|
| FIRM NAME Hiers Enterprises, LLC dba Northwest Compounding Pharmacy | STREET ADDRESS 1350 NE Stephens St Ste 42 |
|--|--|

| | |
|---|---|
| CITY, STATE, ZIP CODE, COUNTRY Roseburg, OR 97470-6410 | TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products |
|---|---|

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

You produced hazardous drugs without providing adequate containment and cleaning of utensils to prevent cross-contamination.

Specifically,

On 11/03/21 I observed inadequate utensil cleaning practices and inadequate containment conditions surrounding the compounding of drug product creams, troches, liquid suspensions, and suppositories, some of which contained hormones. These practices and conditions included the following:

a) I observed a Pharmacy Technician weigh out raw materials and compound multiple drug product lots using a (b) (4) to weigh out all materials for all lots, while cleaning the (b) (4) by (b) (4) and wiping it on a single visibly soiled cloth towel. The Technician did not clean utensils or equipment with a deactivating or oxidizing agent to clean the (b) (4) or area work surfaces following the compounding of products containing hormones. The lots that were observed to be prepared under these conditions are as follows, and were prepared in the following order:

- Estradiol/Progesterone/Testosterone (b) (4) 2.25/175/7 mg troches, lot 11032021@ (b) (4)
- Metronidazole in HRT 0.75% cream, lot 11022021@ (b) (4)
- Baclofen/Diclofenac/Gabapentin/Lidocaine/Prilocaine 2/3/1/2/2% cream, lot 11022021@ (b) (4)

| | | | |
|---------------------------------|---|---|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Christopher R Czajka, Investigator | Christopher R Czajka Investigator Signed By: Christopher R. Czajka Date Signed: 11-10-2021 115 : 7 X | DATE ISSUED 11/10/2021 |
| | | | |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax: (949)608-4417 | DATE(S) OF INSPECTION 11/2/2021-11/10/2021* FEI NUMBER 3014745182 |
|---|--|

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George M. Hiers IV, Owner and Pharmacist-in-Charge

| | |
|--|--|
| FIRM NAME Hiers Enterprises, LLC dba Northwest Compounding Pharmacy | STREET ADDRESS 1350 NE Stephens St Ste 42 |
|--|--|

| | |
|---|---|
| CITY, STATE, ZIP CODE, COUNTRY Roseburg, OR 97470-6410 | TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products |
|---|---|

b) I observed a Pharmacy Technician perform compounding of multiple drug product lots containing (b) (4) hazardous chemicals in the firm's general lab area, which is equipped with no air quality or flow control measures. The lots that were observed to be prepared under these conditions, along with specific observations made about each preparation, are as follows:

- Estradiol/Progesterone/Testosterone ((b) (4)) 2/200/4 mg troches, lot 11022021@((b) (4)) observed the weighed-out Estradiol, Progesterone, and Testosterone (b) (4) in the open lab.
- Progesterone/Testosterone ((b) (4)) 275/10 mg troches, lot 11022021@((b) (4)) - I observed the weighed-out Estradiol, Progesterone, and Testosterone (b) (4) in the open lab.
- Amitriptyline/Ketamine/Lidocaine 5/15/5% cream, lot 11022021@((b) (4)) observed the (b) (4) (b) (4) in the open lab for (b) (4) along with the other (b) (4) in the open lab.
- Estradiol/Progesterone/Testosterone ((b) (4)) 2.25/175/7 mg troches, lot 11032021@((b) (4)) observed the Estradiol, Progesterone, and Testosterone (b) (4) lab for (b) (4) in the open lab, and (b) (4) in the open lab.
- Estradiol/Testosterone 2/8 mg suppositories, lot 11032021@((b) (4)) observed the Estradiol, and Testosterone (b) (4) left sitting in the (b) (4) in the open lab for (b) (4) in the open lab.

c) On 11/03/21 I observed compounding utensils and other equipment that had been used in the compounding of multiple drug products that day placed in a (b) (4) solution which did not

| | | | |
|---------------------------------|---|---|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Christopher R Czajka, Investigator | Christopher R Czajka Investigator © gred By: Christopher R. Czajka Date © gred: 11-10-2021 115 : 7 X _____ | DATE ISSUED 11/10/2021 |
| | | | |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax: (949)608-4417 | DATE(S) OF INSPECTION 11/2/2021-11/10/2021* |
| | FEI NUMBER 3014745182 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George M. Hiers IV, Owner and Pharmacist-in-Charge

| | |
|--|--|
| FIRM NAME Hiers Enterprises, LLC dba Northwest Compounding Pharmacy | STREET ADDRESS 1350 NE Stephens St Ste 42 |
|--|--|

| | |
|---|---|
| CITY, STATE, ZIP CODE, COUNTRY Roseburg, OR 97470-6410 | TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products |
|---|---|

cover all product contact surfaces. When the solution was first prepared in your firm's lab sanitation sink (b) (4), the level of the solution failed to reach the entire inside product-contact surface of a plastic (b) (4) submerged in the solution, leaving part of this item unsanitized. (b) (4) (b) (4), I observed the level of the solution had lowered, further uncovering the inside of the same jar as well as leaving inside product-contact surfaces of several other utensils uncovered, including but not limited to the following: (b) (4), (b) (4) plastic measuring cylinders, (b) (4) glass mortars, and (b) (4) glass beakers. The complete product contact surfaces of these items were not exposed to the (b) (4) solution for the (b) (4) window required by your cleaning procedure.

OBSERVATION 2

You produced beta-lactam drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

Your firm performs compounding of drug products containing (b) (4) beta-lactam antibiotics amoxicillin and cephalexin without adequate containment, segregation, or cleaning procedures to prevent cross-contamination with other drug products compounded at your facility. Between the dates of 08/01/21 and 10/31/21, your firm compounded the following product lots containing amoxicillin or cephalexin (b) (4) in the same open lab area in which all other non-capsule dosage form drug products are compounded, using equipment and utensils that are shared with non-beta lactam drug products:

- Amoxicillin/Clavulanate 75 mg/mL liquid, lot 08192021@ (b) (4), 28 mL, exp 09/18/21
- Amoxicillin 100 mg/mL suspension, lot 08272021@ (b) (4), 45 mL, exp 09/10/21
- Cephalexin 250 mg/mL suspension, lot 09092021@ (b) (4), 30 mL, exp 09/23/21
- Amoxicillin Clav/Enronfloxin in Triple Fish 100/20 mg/mL liquid, lot 10122021@ (b) (4), 60 mL, exp 11/11/21

| | | | |
|---------------------------------|---|--|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Christopher R Czajka, Investigator | Christopher R Czajka Investigator S. grad. By: Christopher R. Czajka Date S. grad: 11-10-2021 115 : 7 X | DATE ISSUED 11/10/2021 |
| | | | |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | | |
|---|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax: (949)608-4417 | | DATE(S) OF INSPECTION 11/2/2021-11/10/2021* |
| | | FEI NUMBER 3014745182 |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED George M. Hiers IV, Owner and Pharmacist-in-Charge | | |
| FIRM NAME Hiers Enterprises, LLC dba Northwest Compounding Pharmacy | STREET ADDRESS 1350 NE Stephens St Ste 42 | |
| CITY, STATE, ZIP CODE, COUNTRY Roseburg, OR 97470-6410 | TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products | |

OBSERVATION 3

Personnel did not change gloves frequently enough to prevent contamination.

Specifically,

On 11/03/21, I observed a Pharmacy Technician weigh out raw materials and compound Gabapentin 50 mg/mL liquid suspension lot 11022021@^{(b)(4)} while wearing a pair of (b)(4) gloves. I subsequently observed the same technician perform the following actions in the order listed without changing her gloves:

- Clean and rinse compounding utensils in the lab sanitation sink
- Dry her gloved hands on a visibly soiled cloth towel kept near the lab sanitation sink
- (b)(4) Estradiol/Progesterone/Testosterone (b)(4) 2/200/4 mg troches, lot 11022021@^{(b)(4)} into (b)(4)
- (b)(4) Progesterone/Testosterone (Natatroche) 275/10 mg troches, lot 11022021@^{(b)(4)} into (b)(4)
- Clean and rinse (b)(4) beakers in the lab sanitation sink
- Dry her gloved hands on a visibly soiled cloth towel kept near the lab sanitation sink
- Weigh raw materials and compound Enalapril 10 mg/mL liquid suspension, lot 11022021@^{(b)(4)}
- Clean the analytical balance on the compounding bench using (b)(4) and a visibly soiled cloth towel kept near the balance
- Weigh raw materials and compound Amitriptyline/Ketamine/Lidocaine 5/15/5% cream, lot 11022021@^{(b)(4)}
- Clean the analytical balance on the compounding bench using (b)(4) and the same visibly soiled

| | | | |
|---------------------------------|---|---|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Christopher R Czajka, Investigator | Christopher R Czajka Investigator Signed By: Christopher R. Czajka Date Signed: 11-10-2021 115 : 7 X | DATE ISSUED 11/10/2021 |
| | | | |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax: (949)608-4417 | DATE(S) OF INSPECTION 11/2/2021-11/10/2021* |
| | FEI NUMBER 3014745182 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George M. Hiers IV, Owner and Pharmacist-in-Charge

| | |
|--|--|
| FIRM NAME Hiers Enterprises, LLC dba Northwest Compounding Pharmacy | STREET ADDRESS 1350 NE Stephens St Ste 42 |
|--|--|

| | |
|---|---|
| CITY, STATE, ZIP CODE, COUNTRY Roseburg, OR 97470-6410 | TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products |
|---|---|

cloth towel used to clean the balance (b) (4)

- Weigh raw materials and compound Estradiol/Progesterone/Testosterone ((b) (4)) 2.25/175/7 mg troches, lot 11032021@^{(b)(4)}
- Remove suppository molds containing Lidocaine/Hydrocortisone 2.5%/25 mg suppositories, lot 11022021@^{(b)(4)} from the firm's refrigerator, open the molds, and place the finished suppositories in a plastic bottle for delivery to a patient with her hands
- Prepare a (b) (4) solution in the lab sanitation sink and place suppository molds in the solution
- Dry her gloved hands on a visibly soiled cloth towel kept near the lab sanitation sink
- (b) (4) Estradiol/Progesterone/Testosterone ((b) (4)) 2.25/175/7 mg troches, lot 11032021@^{(b)(4)} into (b) (4)
- Weigh raw materials and compound Metronidazole in HRT 0.75% cream, lot 11022021@^{(b)(4)}
- Clean the analytical balance on the compounding bench using (b) (4) and the same visibly soiled cloth towel used to clean the balance (b) (4)
- Weigh raw materials and compound Baclofen/Diclofenac/Gabapentin/Lidocaine/Prilocaine 2/3/1/2/2% cream, lot 11022021@^{(b)(4)}

***DATES OF INSPECTION**
11/02/2021(Tue), 11/03/2021(Wed), 11/04/2021(Thu), 11/09/2021(Tue), 11/10/2021(Wed)

| | | | |
|---------------------------------|---|---|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Christopher R Czajka, Investigator | Christopher R Czajka Investigator Signed By: Christopher R. Czajka Date Signed: 11-10-2021 115 : 7 X _____ | DATE ISSUED 11/10/2021 |
| | | | |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."