DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/18/2016-3/29/2016* FEI NUMBER 3006164918

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sam C.H. Ching, R. Ph. , Pharmacist	
FIRM NAME Reliable Rexall-A Compounding Pharmacy	STREET ADDRESS 801 Irving St
CITY, STATE, ZIP CODE, COUNTRY San Francisco, CA 94122-2310	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

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 WE OBSERVED:

OBSERVATION 1

No appropriate investigation was conducted when a returned drug product appeared to implicate associated batches of drug products.

Specifically,

Your firm received returned Rx# (b) (7)(C), (b) (6) for Biotin 100 mg Capsules with a letter detailing an adverse reaction, which involved hospitalization the patient experienced by taking this medication produced in your facility. On March 21, 2016, you shipped the returned prescriptions and your firm's finished product lots listed below to (b) (4) for destruction, instead of conducting the investigation as described in your firm's written procedures.

- Rx (b) (7)(C), (b) (6) CAP- Aminopyridine SR 2.5mg (b) (4) capsules
- Rx (b) (7)(C), (b) (6) CAP-Biotin 100 mg (b) (4) capsules
- Rx (b) (7)(C), (b) (6) CAP- Aminopyridine 10.1 mg (b) (4) capsules
- Biotin Lot #(b) (4) (b) (4) capsules
- Biotin Lot # (b) (4) (b) (4) capsules

Your firm failed to conduct an investigation to ensure that the drug product met the minimum standards for integrity, potency, quality and labeled strength. You did not subject the capsules to examination, testing or other investigations to prove that the drug product met all the necessary parameters or find the

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root cause of the discrepancy. Your firm failed to follow the investigation procedure outlined in section 8.c of "Compounding Policies & Procedures-Reliable Drug PHY 46431," dated 04/01/2014.

Additionally, your firm does have written operating procedures for complaint receiving, handling, and processing and does not maintain any complaint records. Your firm does not maintain any records of investigations for any returned drug products produced at your facility.

OBSERVATION 2

Results of stability testing are not used in determining expiration dates.

Specifically,

Section 2(d)(iv) of "Compounding Policies & Procedures-Reliable Drug PHY 46431", dated 04/01/2014 states "The expiration date of the final product (b) (4)

a) During our review of your firm's production formula worksheets from 07/2015 to 03/2016, we found instances where you manipulated expiration dates of ingredients to extend the expiration date of the drug products. The revised expiration dates were not a result of a new lot of material received at the facility, but were arbitrarily chosen by you. Representative examples identified during our inspection are categorized and summarized as follows:

   Revisions of expiration dates of active and inactive ingredients:

   i. According to your firms Audit Log Report, on 02/16/2016 at 12:07 PM, Ching, Sam changed the expiration date of 4-Aminopyridine Reagent Lot# (b) (4) , Exp.

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(b) (4) to 02/12/2017. The revised expiration date allowed the production software to move forward with the batches and the 4-Aminopyridine Reagent Lot# (b) (4) no longer had the shortest expiration date.

4-Aminopyridine Reagent Lot# (b) (4), Exp. (b) (4) was used in the following (b) (4) lots of Aminopyridine drug products:

(b) (4)

ii. According to your firms Audit Log Report, on 12/31/2015 at 4:17 PM, Ching, Sam, changed the expiration date of (b) (4) USP Lot # (b) (4) from (b) (4) to 12/19/2016. The revised expiration date allowed the production software to move forward with the batches and the (b) (4) USP Lot # (b) (4) no longer had the shortest expiration date. (b) (4) USP Lot # (b) (4), Exp. (b) (4) was used in the following twelve (12) lots of drug products:

- Testosterone 100 mg capsules, Lot #01262016@3
- Testosterone 2% cream, 20 mg, Lot #02222016@1 and Lot #01152016@1
- Testosterone 4 mg capsules, Lot #02242016@2
- Testosterone 1 mg capsules, Lot #01112016@3
- Estriol 2 mg Cream, Lot #02082016@1 and Lot #02192016@1

- TRIE 2 mg /DHEA 8 mg/TE 0.1 mg/PG 100 mg Peterson Cream , Lot #12212015@3, , Lot #011162015@2,and Lot #02222016@6
- Monobenzone 20% cream, Lot #03102016@2
- Progesterone 100 mg.ml cream, Lot #07062015@5

Section 2.d.vi.1 states "Beyond use dating should not exceed 180 days and should be in accordance with 2.d.iv.1."

b) Review of your logged Formula Worksheets and prescription labels show that a definitive correlation between the prescription and the corresponding formula worksheet cannot be made. The expiration dates written on the prescription labels are between 180 days and 365 days after the date the prescription label is printed. The date on the label corresponds to when the label was printed, and not when the prescription was filled or when the lot was made. The expiration dates on the prescription labels are not consistent with the Beyond Use Date assigned on the Formula Worksheets. There is no reference made to the corresponding lot number to ease traceability to the batch record that contains the Beyond Use Date. Representative examples identified during our inspection are summarized as follows:

- Biotin 100 mg Capsule Prescription Label# (b) (7)(C), (b) (6) is dated 02/04/2016, and displays an expiration date of 02/03/2017.
- Biotin 100 mg Capsule Prescription Label# (b) (7)(C), (b) (6) is dated 02/16/2016 and displays an expiration date of 02/15/2017.

Your records show that between (b) (4), four (4) lots of Biotin 100 mg Capsules were made, totaling (b) (4) capsules. Three prescriptions were filled between

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(b) (4), where (b) (4) capsules were dispensed. Your firm failed to relate which Lot of Biotin below was used to fill the prescription listed above.

Lot Number	Quantity Made	Beyond Use Date
Lot # 01152016@2	(b) (4)	07/13/2016
Lot # 01262016@2	(b) (4)	07/24/2016
Lot # 01262016@4	(b) (4)	07/24/2016
Lot # 01282016@4	(b) (4)	07/26/2016

OBSERVATION 3

Failure to reject any lot of components that did not meet the appropriate written specifications for identity, strength, quality, and purity.

Specifically,

a) Section 3.a.i. of your firm's procedure entitled "Compounding Policies & Procedures-Reliable Drug PHY 46431," dated 04/01/2014 states (b) (4)

"

On 03/18/2016 and 03/21/2016, during the inspection, we observed the following expired active and inactive raw materials and finished products in your inventory:

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- (b) (4) , Lot: (b) (4) Expires:(b) (4)
- Betamethasone (b) (4) Lot: (b) (4) , Exp. (b) (4)
- (b) (4) , Lot: (b) (4) Expires: (b) (4)
- Fluocinonide (b) (4) , Lot: (b) (4) EXP. (b) (4)
- Methimazole, USP (b) (4) Lot: (b) (4) Exp. (b) (4)
- (b) (4) , Lot: (b) (4) Expires: (b) (4)
- Progesterone USP (b) (4) Lot # (b) (4), (b) (4)
- Tertracaine USP Lot # (b) (4) E.D. (b) (4)
- (b) (4) , Lot#(b) (4) Exp: (b) (4)
- (b) (4) , Lot (b) (4) Expires: (b) (4)
- (b) (4) Lot: (b) (4) Expires: (b) (4)
- (b) (4) , Lot:(b) (4) Expires: (b) (4)
- (b) (4) Lot: (b) (4) Expires: (b) (4)

b) We observed many active and inactive raw materials and finished products in your inventory that were missing information such as Lot number and/or expiration dates. For example: (b) (4) , Lot# (b) (4) (used in Biotin 100 mg capsules). We also observed a glass bottle of the controlled substance "codeine phosphate 10 mg/guaifensin 200 mg" in the compounding area with no lot number and expiration date.

In addition, your firm stores antique bottles of raw materials on the very top of your shelves. You stated that these materials are for "Display only". However, when we asked you to locate the Thymol used in producing Thymol 4% Chloroform 4% Liquid (Lot 02122016@2), you brought us the bottle of Thymol from that was located in the Display only area. The bottle was not labeled with lot number and expiration date information.

c) On 3/24/2016, we observed a brown paper bag in the retail area of your pharmacy on the second

shelf from the bottom underneath a handwritten piece of paper that read "million". The brown paper bag contained (b) (4) unlabeled individual (b) (4) jars of an unidentified ointment. You informed us that the containers contained "Million 6 20-5-0.1-0.5-5-0.2%" and were not produced for an individual patient but rather for office use.

d) On 03/21/2016, we observed Dr. Ching mixing ingredients as part of the manufacturing process of finished product "CAP-T4 LEVOTHYROXINE 50 MCG CAPSULES, Lot # 03172016@1. One of the ingredients used was (b) (4) Lot # (b) (4) The labeling on the bottle did not contain the expiration date. On 3/24/2016, Dr. Ching provided the batch record for capsules Lot # (b) (4) , which read "(b) (4)) Lot # (b) (4) Exp. Date: 03/15/2017". According to your firms Audit Trail, on 03/19/2015, CHING, SAM changed the expiration date for Lot # (b) (4) from 03/15/2016 to 03/15/2017, without having any supporting documents to support the new expiration date.

OBSERVATION 4

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,

a) You do not conduct any in process testing during production of your capsules to assess the particle size distribution and homogeneity of the blends.

b) Your firm failed to establish adequate blending times for each drug product.

c) Section 8.a.iv of "Compounding Policies & Procedures-Reliable Drug PHY 46431," dated 04/01/2014, states "Potency testing of compounded formulation (b) (4) "

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You failed to perform weight variation testing, content uniformity testing and/or potency testing on each lot of drug products prior to release, to ensure that every dosage form contains equal amounts of drug substance.

OBSERVATION 5

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

Section 8.a.v. of your firm's procedure, entitled "Compounding Policies & Procedures-Reliable Drug PHY 46431", dated 04/01/2014 states "*The final compounded product* (b) (4) ."

On 03/24/2016, we observed the "pharmacy technician" fill, label and dispense two prescriptions (Rx (b) (7)(C), (b) (6) and Rx (b) (7)(C), (b) (6) without the pharmacist conducting and documenting his review on the log sheet.

OBSERVATION 6

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically,

Your firm does not conduct at least one specific test to verify the identity testing on each active pharmaceutical ingredient or component used for any of your drug products manufactured at your facility.

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OBSERVATION 7

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

During the inspection, we reviewed Formula Worksheets for Biotin 100 mg Capsules from July 2015 to March 2016.

- Your firm failed to have an adequate Master Formula and written procedures for the drug products produced at your facility. The Master Formula does not provide detailed instructions on how to produce your Biotin 100 mg capsules such as the preparation of raw materials, listing the ingredients in order of addition, and the duration of mixing the blend.
- Your firm uses "(b) (4) ", which (b) (4) . However we have observed inconsistencies and additional handwritten calculations on the Formula Sheet after it has been created. You do not document the rationale in changing the formulation after printing out the worksheet.
- Your reference formulations are often different from how you actually make the product. For example on 03/18/2016 we observed that the Biotin 100 mg capsules, Lot# 01152016-2 appeared pink although the corresponding Formula Worksheet states that (b) (4) was used in the formulation.

OBSERVATION 8

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Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

a) Your firm has failed to establish and maintain written procedures describing the requirements for the calibration of the balances and calibration weights used at the facility.

b) You firm failed to complete qualification and calibration of the (b) (4) balance used to weigh active and inactive ingredients for the production of drug product at your facility.

c) Your daily verification of conformance is inadequate because the one (1)-(b) (4) scale calibration weight used is not calibrated. Additionally, we observed the handling the scale calibration weight with your bare hands and storing it on the counter, which could affect the integrity of the calibration.

***DATES OF INSPECTION**
3/18/2016(Fri),3/21/2016(Mon),3/22/2016(Tue),3/23/2016(Wed),3/24/2016(Thu),3/25/2016(Fri),3/28/2016(Mon),3/29/2016(Tue)

3/29/2016

X Kristin M Abaonza
Kristin M Abaonza
Investigator
Signed by: Kristin M. Abaonza -S

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