

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

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 08/23/2013 - 09/03/2013*
	<small>FEI NUMBER</small> 3004668624

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Michael S. Haulsee, Owner

<small>FIRM NAME</small> The Compounding Shop, Inc.	<small>STREET ADDRESS</small> 4000 Park Street North
<small>CITY, STATE, ZIP CODE, COUNTRY</small> St. Petersburg, FL 33709-4034	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of 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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, you have not investigated and determined the root cause for any patient reported problems with your nasal preparations containing budesonide or budesonide plus another drug substance, which your pharmacy personnel had prepared and dispensed.


Your firm personnel stated that they received an unknown number of product returns pertaining to the physical appearance of nasal irrigation solutions containing budesonide which they observed that the solutions were cloudy, had precipitate or floating matter. They stated that they discarded the bottles of budesonide without conducting an investigation identifying the reason for cloudiness or floating matter in the bottles or determining whether any other batches of drug product were effected.

OBSERVATION 2

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically, you have not investigated and documented any patient reported problems with your nasal preparations containing budesonide or budesonide plus another drug substance, which your pharmacy personnel had prepared and dispensed.

Firm personnel stated that, within the last 6 months, you received approximately 3-6 complaints, including an unknown number of product returns pertaining to the physical appearance of nasal irrigation solutions containing budesonide. We were unable to verify how many complaints or what type of complaints your pharmacy has received since your firm did not investigate or determine a root cause for the complaints as stated in Observation 1.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Nicole E. Knowlton, Investigator Michael H. Tollon, Investigator	<small>DATE ISSUED</small> 09/03/2013
		

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OBSERVATION 3

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm has not established microbiological acceptance criteria and could not provide any micro test data to demonstrate that microbial quality is controlled for your nasal preparations containing budesonide, which includes irrigation solutions and sprays, which your firm dispenses. Firm personnel stated that your firm does not conduct any micro testing on your nasal solutions.

OBSERVATION 4

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

Specifically, your firm could not provide documentation covering your nasal irrigation products containing budesonide to support that microbiological quality is maintained throughout your expiration dating period, including records demonstrating antimicrobial preservative effectiveness testing. We observed prescription labeling for budesonide nasal solution products that stated to discard the product after 90 days of being dispensed or 30 days after opening of dispensed bottle which had no micro data.

*** DATES OF INSPECTION:**
08/23/2013(Fri), 08/27/2013(Tue), 09/03/2013(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nicole E. Knowlton, Investigator Michael H. Tollon, Investigator	09/03/2013

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 judgement, 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."