DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 404-253-1161 Industry Information: www.fda.gov/oc/industry	03/26/2019-04/04/2019
	FEI NUMBER 3004969894

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Danny M. Barnes, President and Chief Pharmacy Officer

FIRM NAME	STREET ADDRESS
Triangle Compounding Pharmacy Inc	3700 Regency Pkwy Ste 140
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Cary, NC 27518-8696	Producer of 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 (I) (WE) OBSERVED:

Drug product has been prepared using a method of manufacture that does not assure it meets requirements as to the safety, identity, strength, quality, and/or purity characteristics which it is purported to possess.

Specifically, up to an average of approximately 10.9% of some product lots compounded in vials supplied by your firm's chosen supplier, contained foreign matter (classified by your firm as light particles, dark particles, fibers, etc.) (b) (4) . Particles were observed in vials of finished drug units, as well as during aseptic process simulations (4 out of 4 aseptic process simulations reviewed contained vials with particulate matter, ranging from approximately 2 to 9.8% of the total simulation vials).

Finished drug units identified as containing particulate matter during your firm's visual inspection were destroyed, and the balance was dispensed. However, given the known presence of particulate matter in vials from your chosen supplier - vials which you identified as the as the primary source of particulates, you continued to use the vials for compounding.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Seneca D. Toms -S Adam R. Cooke -S3 Digitally signed by Adam R. Cooke -S3 DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Adam R. Cooke -S3, 0.9.2342.19200300.100.1.1=2001332542 Date: 2019.04.04 13:30:56 -04'00'	Seneca D. Toms, Investigator Adam R. Cooke, Investigator	04/04/2019

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."