DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. FDA, Waterview Corporate Center 10 Waterview Blvd, 3rd Floor, Parsippany, NJ 07054 973-331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	5/29/2018 - 6/1, 4, 5, 7, 12, 13, 19/2018
	FEI NUMBER 3002815949

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael Tursi, President and co-owner

FIRM NAME	STREET ADDRESS
Stokes Healthcare Inc.	8000 Commerce Parkway, Suite 600
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Mount Laurel, NJ 08054-2211	Outsourcing Facility

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) ~~HAVE~~ OBSERVED:

1. Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and the identity and strength of each active ingredient prior to release.

Specifically,
a.)Your firm does not routinely test for drug product potency. Your SOP (Sterile Compounding Finished Preparation Testing, number 9.120, Version 1.3, Step 9.7) states that potency (b) (4) of the (b) (4).

For example, no potency testing was performed on the (b) (4) units of Tacrolimus AQ 0.03% Ophthalmic Suspension, which was manufactured as "Lot 12012017@41", on 12/01/2017, with a "Use By:" date of "5/30/2018". A portion of that lot was re-labeled on 4/30/2018, as "Lot 01122018@96" with a "Use By:" date of "7/14/2018". Your facility in NJ distributed that re-labeled human drug product to a patient in (b) (6) under prescription number (b) (6).

b.)Your firm does not always submit drug product samples for sterility and endotoxin testing to your contract laboratory. Your firm performs an in-house sterility test using (b) (4) (b) (4), but that is not a validated analytical method.

For example, samples were not sent to your contract laboratory for sterility and endotoxin testing when you manufactured (b) (4) of Voriconazole 1% Ophthalmic Solution Lot 03012018@7, on 3/1/2018 with a "Use By:" date of 8/28/2018. A portion of that lot was distributed from your facility to a patient in (b) (6) under prescription number (b) (6).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Russell Glapion	Russell Glapion, Investigator	06/19/2018

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

A.)Your firm relabeled Tacrolimus Lot 12012017@41, Use By: 5/30/2018, as Tacrolimus Lot 01122018@96, Use By 7/14/2018. The product was released with a Use By date of 7/14/2018, which exceeded your stability study data by (b) (4) days.

B.)Your firm lacks stability data for all "Use By" dates being assigned to your drug products.

3. Master production and control records lack complete manufacturing and control instructions and sampling and testing procedures.

Specifically, your master batch records for all human drug products, except for one lot of Cyclosporin Olive Oil 2% Ophthalmic Solution, manufactured on 5/30/2018, as Lot R180008, Use By 08/29/2018, do not contain adequate instructions for processing steps such as: the active and excipient ingredient sequence of addition; mixing times; and in-process and finished product test requirements. For example, Tri-Mix Standard Injection Solution, Lot # 04032018@6 Use By 7/2/2018.

4. The labels of some of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) and (B). Specifically, the following information is not found on some of your drug product labels, as required by section 503B(a)(10)(A):

* The statement "This is a compounded drug";
* Name, address and phone number of the outsourcing facility;
* The statement, "Not for resale".

In addition, the following information is not found on your drug product labels, as described in section 503B(a)(10)(B):

* Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

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Examples of drug product labels that do not contain this information:
- Cromolyn sodium Preservative Free nasal solution 1%, 15 ml
- Cyclophosphamide injection solution 20 mg/ml, 4.5 ml
- Docetaxel injection solution 20 mg/ml, 0.75 ml
- Methylcobalamin injection solution 1 mg/ml, 10 ml
- Oxymetazoline pf nasal solution 0.05%, 15 ml
- Tacrolimus aqueous ophthalmic suspension 0.03%, 15 ml
- Tri-mix injection solution 30 mcg/30/3 mg/ml, 5 ml
- Tri-mix injection solution 40 mcg/30/2 mg/ml, 5 ml
- Tri-mix low injection solution 5.88 mcg/18/0.6 mg/ml, 5 ml
- Tri-mix forte injection solution 20 mcg/30/2 mg/ml, 5 ml
- Tri-mix standard injection solution 10 mcg/30/1 mg/ml, 5 ml
- Voriconazole ophthalmic solution 1%, 10 ml
- Cyclosporin olive oil ophthalmic solution 2%, 5 ml

5. Your outsourcing facility has not submitted a compounded drug product report to FDA upon initial registration as an outsourcing facility as required by section 503B(b)(2)(A).

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