DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 1201 Main Street, Suite 7200 One Main Place Dallas, TX 75202-3908 Industry Information: www fda gov/oc/industry	7/20-23; 26-28, 30; 8/3-4, 6/21
	FEI NUMBER 3016710945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Aaron M. Schneider, Director of Operations and co-owner

FIRM NAME	STREET ADDRESS
Revive Rx, LLC dba Revive Rx Pharmacy	3831 Golf Drive Suite A
CITY, STATE AND ZIP CODE Houston, TX 77018	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION #1

The certification of the ISO 5 areas was inadequate. Specifically, smoke studies were not conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions.

OBSERVATION #2

The (b) (4) used for depyrogenation of product/equipment intended to be sterile were not lethal to heat-resistant microorganisms.

Specifically,

Your firm uses a (b) (4) to depyrogenate glassware used in the preparation of your firm's sterile injectable products. However, you do not use endotoxin indicators to ensure and verify that the (b) (4) and (b) (4) used to depyrogenate glassware is adequate.

OBSERVATION #3

Media fills are not performed that closely simulate aseptic production operations, incorporating, as appropriate, worst case activities and conditions that provide a challenge to aseptic operations.

Specifically, your Media Fill Challenge log sheet documents that a total of (b) (4) vials ((b) (4) for control and (b) (4) for evaluation) will be used to conduct media fills. Review of media fills conducted since 8/2020 revealed that the media fills were not representative in that your firm failed to simulate actual production processes. For example, a typical lot of Human Chorionic Gonadotropin 12,000 IU Vial for Injection is (b) (4) vials.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Stephen D. Brown	Stephen D. Brown, Investigator	08/06/2021

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In addition, your firm does not include an evaluation of the transfer of vials to and from the ISO 5 hood to the (b) (4). For example, your firm produces several (b) (4) products at your facility including Ipamorelin and HCG.

OBSERVATION #4

Product intended to be sterile was exposed to lower than ISO 5 classified quality air.

Specifically, your firm's procedure for (b) (4) finished drug products includes (b) (4) vials under the ISO 5 laminar flow hood and then removing these vials outside of the hood to transfer into the (b) (4).

OBSERVATION #5

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. For example, your firm uses (b) (4) produced via a (b) (4) process in-house which is used as a component in various non-sterile products. Your firm has no documentation to substantiate that the (b) (4) produced by (b) (4) meets, minimally, the specifications for (b) (4) USP. Some examples of drug products which use the (b) (4) include the following: PTD- DBM 0.03%/Sodium Valproate 5% 30 ml spray and Clindamycin 1.2%/ Benzoyl Peroxide 5% Gel.

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