

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	DATE(S) OF INSPECTION 9/17/2018-11/19/2018* FEI NUMBER 3010087152
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Ms. Ashley M. Downing, Co-Owner

FIRM NAME Downing Labs, LLC	STREET ADDRESS 4001 McEwen Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75244-5020	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:  
OBSERVATION 1**

Equipment was not disinfected prior to entering the aseptic processing areas.

Specifically, your firm's pharmacy I.V. support staff and pharmacy technician failed to disinfect:

1. A (b) (4) beaker containing (b) (4) liquid EDTA Disodium drug product.
2. A pair of scissors utilized to open packages in the ISO 5 environment.
3. (b) (4) utilized to (b) (4) in the ISO 5 environment.

These pieces of equipment were utilized during the production of EDTA Disodium 150mg/ml, 50 ml volume, Batch #'s S10242018@13 and S10242018@14, Manufacture Date 10/25/2018.

**OBSERVATION 2**

The ISO 5 classified aseptic processing areas had difficult to clean equipment or surface.

Specifically, your ISO 5 processing suite has a (b) (4) installed partially in the ISO 5 area where the cabinet of the equipment has air vents that are not easily cleaned and disinfected. Also, there is a fan unit inside the (b) (4) cabinet which creates a risk of spreading particles in the ISO 5 environment.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Scott T Ballard, Investigator Jason R Caballero, Investigator	<small>Scott T Ballard Investigator Signed By: Scott T Ballard-S Date Signed: 11-19-2018 10:58:11</small> X	DATE ISSUED 11/19/2018

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	DATE(S) OF INSPECTION 9/17/2018-11/19/2018* FEI NUMBER 3010087152
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Ms. Ashley M. Downing, Co-Owner

FIRM NAME Downing Labs, LLC	STREET ADDRESS 4001 McEwen Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75244-5020	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

There are no environmental monitoring samples collected from the (b) (4) cabinet and most difficult-to-clean portions of this equipment.

**OBSERVATION 3**

Results of stability testing are not used in determining appropriate storage conditions.

Specifically, your firm is assigning Beyond Use Dates (BUDs) to sterile human drug products for a time period that extends past failing test data for potency and particulates.

Product Name	Lot #	Date Compounded	Labeled BUD	Qty Distributed	Concern
TNPDR Buffered and Preserved for injection	S01172018a2	17-Jan-18	22-Feb-18	(b) (4)	>6000 count particulates at 30 days
Folic Acid 10mg/mL - 30 mL for injection	S12142017a1	27-Dec-17	16-Feb-18		53% sub-potent at 35 days
L-Glutathione 200mg/mL - 50mL for injection	S12132017a2	14-Dec-17	2-Mar-18		50% sub-potent at 65 days
Dexamethasone 250mg/mL, 30mL for injection	S12112017a1	11-Dec-17	26-Feb-18		BUD 15 days beyond passing results; 80% sub-potent at 92 days

**OBSERVATION 4**

Your facility was designed and/or operated in a way that permits poor flow of materials.

Specifically, your pharmacy technician failed to clear equipment wrappers and used wipes out of the ISO 5 environment during the production of EDTA Disodium 150mg/ml, 50 ml volume, Batch #'s S10242018@13 and S10242018@14, Manufacture Date 10/25/2018. These sterile equipment wrappers and sterile wipes were used and stayed present in the ISO 5 environment throughout production.

**\*DATES OF INSPECTION**

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Scott T Ballard, Investigator Jason R Caballero, Investigator	Scott T Ballard Investigator Signed By: Scott T Ballard-S Date Signed: 11-19-2018 10:58:11 X _____	DATE ISSUED 11/19/2018

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

DISTRICT ADDRESS AND PHONE NUMBER

4040 North Central Expressway, Suite 300  
Dallas, TX 75204  
(214)253-5200 Fax: (214)253-5314

DATE(S) OF INSPECTION

9/17/2018-11/19/2018\*

FEI NUMBER

3010087152

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Ms. Ashley M. Downing, Co-Owner

FIRM NAME

Downing Labs, LLC

STREET ADDRESS

4001 McEwen Rd Ste 110

CITY, STATE, ZIP CODE, COUNTRY

Dallas, TX 75244-5020

TYPE ESTABLISHMENT INSPECTED

Producer of Sterile Drugs

9/17/2018(Mon), 9/18/2018(Tue), 9/19/2018(Wed), 9/20/2018(Thu), 9/21/2018(Fri), 9/24/2018(Mon),  
9/28/2018(Fri), 10/16/2018(Tue), 10/22/2018(Mon), 10/23/2018(Tue), 10/24/2018(Wed),  
10/25/2018(Thu), 10/30/2018(Tue), 11/01/2018(Thu), 11/16/2018(Fri), 11/19/2018(Mon)

**SEE REVERSE  
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE:

Scott T Ballard, Investigator  
Jason R Caballero, Investigator

Scott T Ballard  
Investigator  
Signed By: Scott T Ballard-S  
Date Signed: 11-19-2018 10:58:11

X

DATE ISSUED

11/19/2018