DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New Orleans District 404 BNA Drive BLDG 200, STE 500 Nashville, TN 37217 (615) 366-7801 Industry Information: www.fda.gov/oc/industry	02/13-15/2017; 02/23/2017
	FEI NUMBER 3004034796

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tommy T. Simpson, President

FIRM NAME	STREET ADDRESS
Delta Pharma, Inc.	114 W. Mulberry Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Ripley, MS 38663	Outsourcing Facility

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

Observation 1
Procedures designed to prevent microbiological contamination of drug product purporting to be sterile do not include validation of sterilization process.

Specifically,
a) Your firm receives non-sterile (b) (4) for use in the production of finished injectable drug products. However, you have not validated your process for sterilizing the (b) (4). Additionally, it is a practice of your firm to (b) (4) (b) (4) of finished injectable drug products. However, you have not validated your process for cleaning and sterilizing the (b) (4).

b) Your firm receives non-sterile wipes, sponges, and mop heads used for cleaning the ISO 5, ISO 7, and ISO 8 classified areas. You have not validated your process for sterilizing wipes, sponges, and mop heads. Additionally, you have not validated your process for cleaning and sterilizing the reused wipes, sponges, and mop heads.

c) Media fills have not been performed by all operators who perform aseptic operations. Additionally, media fill procedures do not simulate actual processing, including but not limited to the largest batch size, and all process manipulations.

d) Your firm uses an (b) (4) for sterilization of (b) (4) used in the production of injectable drug products. However sterilization (b) (4) have not been validated.

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		Brandon C. Heitmeier, Investigator Shelby N. Marler, Investigator Diane P. Goyette, Regulatory Counsel	02/23/2017

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e) Your firm uses an (b) (4) to depyrogenate (b) (4) sodium chloride (NaCl), however this process has not been validated.

f) Post production (b) (4) performed by your firm have repeatedly failed to meet the (b) (4) manufacturer's specifications for (b) (4). No investigations were performed and the batches were released for distribution. The following batches all had recorded (b) (4) below the specification (list is not all inclusive):

-Benadram lot 04-11/23/16
-Bromphed lot 09-10/20/16
-Prometh lot 07-11/08/16
-Betasone SA-6 lot 11-06/23/16
-Delta MP-100 lot 24-11/30/16
-Dexamethasone Acetate Suspension lot 02-08/31/16
-Dexamethasone Acetate Suspension lot 02-08/04/16
-Deltalone lot 08-08/23/16

g) (b) (4) are not performed for (b) (4) nitrogen gas used in aseptic processing.

This is a repeat observation from FDA inspections ending on 05/24/2016 and 10/02/2013

Observation 2
Drug product containers and closures were not clean, sterilized, and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, depyrogenation (b) (4) using an (b) (4) have not been validated. Your firm uses this (b) (4) to depyrogenate finished product containers (amber glass vials) and glassware used in the production of finished injectable products. Also, your firm uses household dish soap to clean glassware but this cleaning process

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has not been validated.

Observation 3
Clothing of personnel engaged in the processing of injectable drug products is not appropriate for the duties they perform.

Specifically, your firm uses powdered sterile gloves during the production of injectable drug products.

This is a repeat observation from FDA inspections ending on 05/24/2016 and 10/02/2013

Observation 4
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,
a) Personnel monitoring is not performed for each production of injectable drug product. There are no recorded logs of glove tip monitoring (b) (4) , logs periodically mention (b) (4) , however logs do not specify (b) (4) or which operator the sample is from. Furthermore, the logs do not specify the date environmental sample was read, the incubation temperature of the sample, or the person recording the information. No environmental monitoring has been recorded since 11/23/2016. However your firm produced (b) (4) of sterile product since 11/23/2016.

b) Your firm does not perform active viable air monitoring during production of sterile drug products.

c) Your firm has not established microbial limits for environmental monitoring in your ISO 5 laminar flow hood, buffer room, or ante room.

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Observation 5
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, cleaning and disinfection procedures are inadequate for aseptic process areas. Pre-production cleaning/disinfection of the ISO 5, ISO 7, and ISO 8 areas were observed on 02/13/2017. During this cleaning operation we observed that the operators failed to clean the kick plate (section of flooring that rises up the wall approximately 6 inches) in the ISO 7 and ISO 8 areas. One operator failed to clean the wheels on the LAFH and prep table in the ISO 7 area. Additionally, during cleaning of the return vent in the ISO 7 area the operator dropped a wipe on the floor and then picked it up and continued to use it. The floor had not yet been cleaned/ disinfected. Also, a stool located in the ISO 7 area was observed to leak brown colored fluid on to the floor after cleaning it with sporicide.

Observation 6
Aseptic processing areas are deficient in that walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically, chips and scratches were observed on the east and west walls of the clean room (ISO7). Approximately, 7 chips and scratches were found during visual inspection of the clean room on 02/14/2017. Additionally, approximately, 3 brown colored stains were observed on the clean room floor (ISO7) on 02/14/2017.

This is a repeat observation from FDA inspection ending on 05/24/2016

Observation 7
There is a failure to thoroughly review unexplained discrepancies 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.

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Specifically, Dexamethasone Acetate Suspension, USP lot 02-07/12/16 failed to meet specifications for potency/ purity. Lot 02-07/12/16 was discarded however your firm's quality unit did not conduct an investigation in response to this failure and your firm lacks written procedures for discrepancy investigations.

Observation 8
Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically, there are no records which demonstrate the following equipment has been calibrated:
1) The (b) (4) used for (b) (4)
2) Pressure gauges used to monitor pressure differentials in the ISO 7 and ISO 8 areas
3) (b) (4) thermometers used to monitor temperatures for media storage and incubation of EM samples.
4) Scales used for weighing out bulk drug ingredients and components
5) pH meter used (b) (4)

This is a repeat observation from FDA inspections ending on 05/24/2016 and 10/02/2013

Observation 9
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,
Your firm adds preservatives to all injectable drug products produced. However, you have not performed any testing to ensure the preservatives remain effective throughout the labeled shelf life of the product.

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Observation 10
There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm does not have a written stability protocol and testing performed to date did not include stability indicating tests.

This is a repeat observation from FDA inspection ending on 05/24/2016

Observation 11
Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,
Your firm sterilizes and depyrogenates product containers, closures, and glassware used injectable drug production. These items are stored (b) (4) or (b) (4) . After depyrogenation this items are held in unclassified areas until used in drug production. Hold times studies have not been performed for all storage conditions. Additionally, the (b) (4) completed on (b) (4) did not include growth promotion of the media used and the test media was not stored and transported to the lab under controlled storage conditions.

This is a repeat observation from FDA inspection ending on 05/24/2016

Observation 12
The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A).

Specifically, the statement, "Not for resale," is not on your drug product labels. Labels for the following drug products do not contain this statement:

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- Dexamethasone Acetate Suspension, USP 8mg/ml
- Betasone SA-6 6mg/ml
- Benadram 50mg/ml
- Delta MP-100 100mg/ml
- Deltalone-40 40mg/ml
- Betasone 3mg/ml
- Bromphed 10mg/ml
- Prometh 50mg/ml

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