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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| New Orleans District Office<br>404 BNA Dr., Suite 500<br>Nashville, TN 37217<br>615-366-7801<br>Industry Information: www.fda.gov/oc/industry | 05/16-24/2016 |
| | FEI NUMBER<br>3004034796 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Tommy T. Simpson, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Delta Pharma, Inc. | 114 West Mulberry St. |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Ripley, MS 38663 | 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) (WE) OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically,

1. Your firm receives non-sterile (b) (4) for use in the production of finished injectable drug products. You (b) (4) ; however, you have not performed any testing or validation to determine if (b) (4) is acceptable, and if so (b) (4) . Also, you do not have a specific procedure for cleaning the (b) (4) after use.

2. Per the firm's SOP, media fills will be performed every (b) (4) . Media fills have not been performed by (b) (4) operators who perform aseptic operations. One employee conducted a media fill on (b) (4) ; however, it did not simulate the firm's actual processes.

3. Sterilization (b) (4) for your (b) (4) have not been validated. Your firm uses the (b) (4) to (b) (4) finished injectable products and to sterilize stoppers, vials, and tubing for use in the production of finished injectable products.

4. Depyrogenation processes using an (b) (4) have not been validated. Your firm uses this (b) (4) to depyrogenate finished product containers (10mL glass vials) and glassware used in production. Also, your firm uses industrial grade (b) (4) to clean glassware used in processing of injectable drug product.

5. The firm's incubator used to incubate environmental monitoring media has not been validated for use and is not continuously monitored for temperature.

**This is a repeat observation from previous FDA inspections ending on 10/02/2013, 09/17/2010, 10/17/2007, & 03/10/2004**

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|---|---|---|---|
| | Marvin D. Jones | Zada L. Giles, Investigator<br>Marvin D. Jones, Investigator | 05/24/2016 |

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OBSERVATION 2
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,
1. Personnel monitoring is not performed for each production of injectable drug product.

2. Viable air monitoring was not performed during the initial clean room certification dated (b) (4) or during the two following certifications dated (b) (4)

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

4. Your firm does not perform positive or negative controls for environmental microbial testing.

**This is a repeat observation from FDA inspection ending 10/02/2013**

OBSERVATION 3
Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically,
There are no written procedures or records which demonstrate the following equipment has been calibrated:
1. The (b) (4) used for the (b) (4)

2. The (b) thermometer in the incubator used for the incubation of environmental monitoring samples.

3. (b) (4) thermometers located in the refrigerator used for environmental media storage and in the refrigerator used for storage of finished product that requires refrigeration.

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|---|---|---|---|
| | Mary D. Jones | Zada L. Giles, Investigator<br>Marvin D. Jones, Investigator | 05/24/2016 |

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4. Scales used in weighing out ingredients for sterile processing.

5. The pH meter used to test the finished product before being filled into glass vials.

**This is a repeat observation from FDA inspections ending on 09/17/2010 and 10/02/2013**

OBSERVATION 4
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 products produced. You have not performed any testing to ensure the preservatives you add to your multi-dose vials remains effective through your expiration date.

OBSERVATION 5
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 glassware and containers/closures on site. The mixing glassware is stored in the (b) (4) room and the containers/closures for finished injectable product are stored in the ante room. Both are stored still (b) (4). You have not conducted hold time studies for glassware or containers/closures to determine how long these can be stored and still remain sterile for use.

OBSERVATION 6
Batch production and control records do not include complete information relating to the production and control of each batch.

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Specifically,
Your firm's batch records lack the following information:
1. The individual who performs each step in the processing does not sign off on the batch record. The (b) (4) [redacted] however, the firm's (b) (4) [redacted] performs these processing steps.

2. On processing steps where a time limit is established, start and stop times are not recorded to ensure the time limit was met. Also, on steps that require heating, no temperature range is defined.

3. The batch production record states the theoretical and actual yield; however, the percentage of yield is not calculated and an acceptable range is not identified.

OBSERVATION 7
Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your firm's gowning requirements for personnel involved in the processing of sterile drug products do not include forehead or eye covers.

OBSERVATION 8
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 stability testing that has been performed did not include stability indicating tests such as impurities and degradents.

OBSERVATION 9
The labels of your outsourcing facility's drug products does not include information required by sections 503B(a)(10)(A) and (B).

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Specifically,
the following information is not found on your drug product labeling:

• The statements, "This is a compounded drug" and the date the drug was compounded, are not on your drug product labels.
Examples of drug products that do not contain this information:
o Dexamethasone Acetate Suspension, USP 8mg/ml
o Betasone SA-6 6mg/ml
o Benadram 50mg/ml
o Delta MP-100 100mg/ml

• In addition, information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.
Examples of drug products that do not contain this information:
o Deltalone-40 40mg/ml
o Betasone 3mg/ml
o Bromphed 10mg/ml
o Prometh 50mg/ml

• Further, the route of administration is not present on one of your outsourcing facility's drug product label.
o Betasone 3mg/ml

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