DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Industry Information: www.fda.gov/oc/indnstry	10/25-11/2, 11/6-7, 9 & 13/2012
	FEI NUMBER 3005115360

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: E. Michael Pruett, Managing Partner

FIRM NAME	STREET ADDRESS
Dyna Labs, LLC	2327 Chouteau Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
St. Louis, MO 63103	Contract Testing Laboratory

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

Test procedures relative to appropriate laboratory testing for sterility are not followed. Specifically,

A. Certificates of Analysis (CofA's) your firm issues to customers for sterility testing cite USP <71> as the method used for testing. This was observed during the inspection in our review of 16 CofA's for sterility testing. However, your firm is not following USP<71> when testing these products for sterility assurance. USP <71> specifies the number of articles to be tested based on the overall batch size of the drug product. USP <71> also specifies the number of articles to be tested when the batch size is unknown. Your Quality Assurance Lead stated your firm does not require batch size information from clients for samples tested per USP <71>, nor is this information routinely shared with your firm.

Your firm recommends to customers to follow USP<71> for sampling products for sterility testing; however there are no documents, correspondences, or procedures in place to guarantee your customers routinely submit the required number of articles for sterility testing, whether or not this is for initial sample submission or customer-requested re-test.

B. In addition, your firm did not assure the required number of articles specified per USP <71> were submitted for testing and re-testing of drug product glutathione/vitamin C/DMSO 1.25%/1.25%/6.25%, lot (b) (4) on 8/15/2012 and 8/20/2012, respectively.

C. Your written procedure MIC-SOP-0016 reads "The client must specify if re-testing can occur from the original sample or if they are sending in a new sample from the same lot. Re-testing can only be justified in the event of a proven lab OOS. New results cannot replace previous OOS results." The procedure does not define "proven lab OOS," nor does it describe the criteria for invalidating an OOS test result not shown to be a "proven lab OOS."

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		Steven D. Kehoe, Investigator Eric M. Padgett, Investigator Matthew H. Hunt, Investigator Kallol Biswas, Chemist Jeremy W. Rotton, Microbiologist	11/13/2012

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D. Also, your firm has not performed validation of sterility testing for currently-tested drug products containing any of (b) (4) different active ingredients, for clients including (b) (4).

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically,

A. Your firm does not keep a written procedure or work instruction for performing potency analysis of drug products with active ingredient methylprednisolone.

B. For potency analysis of drug products performed at your firm, sample calculations are not described within analytical worksheets or written procedures to show how calculations should be performed. There is no written instruction for performing drug product bag volume corrections as part of the calculation to obtain the correct potency assay value. This was observed during review of the following investigation reports (IRs) and test results for (b) (4) products on 10/29/12:

IR (b) (4) methylprednisolone lot (b) (4) 1/31/2012
IR (b) (4) penicillin G, lot (b) (4), 10/3/2012
IR (b) (4) remifentanil, lot (b) (4), 9/6/2012
IR (b) (4), morphine sulfate, lot (b) (4), 9/21/2012
IR (b) (4), cefazolin, lot (b) (4), 6/11/2012
IR (b) (4), cefepime, lot (b) (4), 5/8/2012
IR (b) (4), epinephrine, lot (b) (4), 5/8/2012

C. The description of the sample preparation in sample test schedules reviewed for the above analyses lacks detailed instructions for sample handling prior to testing, and lacks a description of the type of autopipette used, the type of glassware needed, or any other details on how the sample was prepared. Also, there are no written

instructions for protecting methylprednisolone drug product tested by your firm, from degradation known to occur during sample preparation.

D. Additionally, your firm does not record the actual numerical value of laboratory measurements performed in drug product analysis. For testing performed for clients including (b) (4) since January 2012, 4 of 9 sample test schedules reviewed reported precision of autopipettes to two decimal places when the actual precision of the equipment only extends to one decimal place.

(i). For example, we observed the pipette used for sample preparation of Methylprednisolone SOD Succinate 80 mg added to 50 mL NS, Lot # (b) (4) (identified as (b) (4) Calib date (b) (4) only delivers sample volume accurate to tenths of a microliter. However, the theoretical amount of sample to deliver (reported to hundredths of a microliter) was documented rather than the actual volume delivered by the autopipette.

OBSERVATION 3

The accuracy and sensitivity of test methods have not been established or documented. Specifically,

A. Analytical methods for two of the seven (b) (4) products (remifentanil and cefepime) reviewed alongside potency assay out of specification investigations did not have appropriate validation data to support the method. Your firm did not provide accuracy and recovery results with the validation documentation, and only listed linearity data.

B. Your firm provided a list of (b) (4) currently used analytical methods requiring remediation to their current validation package, to include accuracy and recovery data with the method. This list includes analytical methods for methylprednisolone, remifentanil and cefepime, all of which are (b) (4) products.

OBSERVATION 4

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Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals. Specifically,

Your firm does not periodically validate the suppliers' Certificates of Analysis (CofA's) for components used in sterility testing of drug products. For example, (b) (4) and (b) (4) purchased from (b) (4) and filtration funnels purchased from (b) (4) are accepted on CoA, and your firm does not currently perform periodic validation of the information on these CofA's.

Additionally, your firm does not have a written procedure in place describing periodic validation of the information stated on component suppliers' CofA's.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established. Specifically,

Your firm's environmental monitoring (EM) program described in MIC-SOP-0125 specifies the establishment of alert and action levels (based on USP <1116>) as well as procedures to follow when EM results exceed the action and/or alert levels. However, we observed the EM reporting forms included action level limits only.

Furthermore, while your firm does take corrective actions in cases where EM results are out of specification (e.g., re-cleaning the clean room suite. personnel gowning requalification, re-monitoring of the clean room suite), these actions are not documented or correlated to the specific EM excursions. During our review of October 2012 EM reports for your facility, we observed the following action level excursions:

10/4/12: 15 CFU recovered from gowning room wall
10/5/12: 34 CFU recovered on mask plate
10/8/12: 20 CFU recovered from splitting room floor
10/10/12: 30 CFU recovered from testing room floor

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No documentation of the corrective actions performed following these excursions was provided by your firm.

Additionally, MIC-SOP-0125 describes the procedure for trending of EM data; however, no trending reports were available upon request.

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