DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US FOOD + DRUG ADMINISTRATION 250 MARQUETTE AVE, SUITE 600 MINNEAPOLIS, MN 55401 612-334-4100	2/9,10,12,13,17,19 + 3/2,4/2009
	FEI NUMBER 2111173

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: DAVID G. STRUNCE, PRESIDENT and CEO

FIRM NAME	STREET ADDRESS
Scientific Protein Laboratories, LLC	700 E Main Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Waunakee, WI 53597	Pharmaceutical Manufacter

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

The 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.

(1) Firm does not always follow written MI (batch record) or protocal. Documentation is not always adequate.

Examples: In step (b) (4) of the MI guides the operator to (b) (4) (b) (4). MI states "(b) (4) (b) (4). There is no documentation as to why this is done.

- Cleaning of tanks in MI includes documentation of initials but no date or time. As a result of this inspection, the MI has been updated to include this information.
- Cleaning of perastaltic transfer pump not always logged. Review of Heparin Cleaning solution formulation documentation log from 10/31/08 to present shows of (b) (4) batches, (b) (4) lack written verification for one cleaning (MI calls for (b) (4) cleanings/batch), (b) (4) lack any written verification of any cleaning. Since this finding, the MI was reportably updated to include initial/date/time. SPL also updated appropreate SOP to reflect solution prep and documentation.
- Cleaning of probes used in the lyophilization unit is not documented.
- Cleaning of the disposible trays (using (b) (4)) is not documented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Charles R Cole S Hughes	CHARLES R COLE Investigator Sandra A Hughes Investigator	3-3-2009

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- rinsing of the (b) (4) % HCL solution container is not documented.

(2) Cleaning Validation Studies for the (b) (4) appears to have flaws in their execution + evaluation.

Example - (b) (4) for documentation of cleaning including micro testing. (b) (4) cleaning validation report dated 3/2008 reveals one post cleaning swab @ (b) (4). Colonies were not identified or speciated as mandated per the protocol. The final report states the colonies were identified but no results were available.

- (b) (4) for % recovery of microorganisms from ss surfaces. Spiked recovery studies using (b) (4) (b) (4) included (b) (4) tests, each test includes a (b) (4) (b) (4). Reported results appear to indicate the (b) (4) (b) (4). All (b) (4) data sets were reportedly averaged by the firm to show (b) (4) % recovery. This result was accepted as a suitable method for recovering microorganisms.

(3) The firm does not include (b) (4) testing in its finished product release specification for Heparin Sodium. Testing for (b) (4) but no specification is in place. Final steps in the process use (b) (4) (b) (4).

(4) Quality of management review and approval of documents, procedures changes etc is questionable after finding serveral incidents or incorrect or inadequate data/reports being reviewed and signed

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Examples – Cleaning Validation deviation incorrectly states (b) (4)

– The two most recent annual ~~quality~~ product reviews failed to report all deviations incurred during that time period.

– Change control document signed 10/29/08 for the MI 1037 which requested (b) (4) of the heparin did not reference supportive data for the change but instead stated "(b) (4)" as the justification. This was not questioned by management who approved the document.

– The document covering suitability of results for (b) (4) testing for the (b) (4) samples sent to a contract lab in 2002 includes an incorrect calculation which was not caught during the review.

(5) Contract Lab Audits - Prior to Feb 2009 the firm had no written guidance or SOP regarding Qualifications or Auditing of Contract Laboratories. Currently the firm utilizes (b) (4) Contract Labs.

(6) Material Supplier Audits - Although firm makes periodic audits of starting material suppliers they do not always make timely follow-up to known reported deficiencies.

Example – Audit report dated 3/3/2008 for (b) (4) includes concerns of lack of equipment maintenance, supervision and a corroded roof above the digester unit. No evidence of follow-up was available. This firm is currently being used as a supplier.

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