DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Minneapolis District 250 Marquette Avenue Suite 600 Minneapolis, MN 55401 612-334-4100 Industry Information: www.fda.gov/oc/industry	7/28-30/10, 8/2-3, 5-6, 11, 13/10, 9/2-3/10
	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	API Manufacturer

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

Equipment used in the manufacture of API intermediates is not of appropriate design and has not been qualified to ensure it does not alter the quality of the intermediate or API.

Specifically, wet cake pancreatin (b) (4) is stored in (b) (4) drums for up to (b) (4) weeks prior to drying. When it is unloaded into the dryer a stainless steel shovel and stainless steel pitch fork is used to transfer material out of the drum. On 8/3/10 transfer of wet cake from lot #1208-1779 was observed using these utensils. Half way through the transfer, an approximately quarter inch piece of blue plastic shaving was observed in the wet cake and an approximately half inch piece of blue plastic was hanging from a gouge on the inside of the drum. The firm determined that the sharp edges of the utensils were scraping the sides of the drum and resulting in plastic shavings. An inspection of drums that had been used in production of previous lots, which had been cleaned and were ready for further use, were found to have scrapes, gouges, hanging pieces of plastic, and missing pieces out of their inner surfaces.

Additionally, (b) (4) drums are used to store wet cake pancreatin (b) (4) for up to (b) (4) weeks. These new (b) (4) drums replaced (b) (4) drums in production on 7/7/10. No extractable/leachable study has been completed on the (b) (4) drums to date.

Prior to 7/7/10, (b) (4) drums were used in production. These old drums were also observed to have scrapes, gouges, hanging pieces of plastic, and missing pieces out of their inner surfaces.

OBSERVATION #2

You did not adequately investigate a complaint that affected product quality and did not extend the investigation to other lots that may have been associated with the complaint.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Sandra A. Hughes Justin A. Boyd	Sandra A. Hughes, CSO Justin A. Boyd, CSO	09/03/2010

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Minneapolis District 250 Marquette Avenue Suite 600 Minneapolis, MN 55401 612-334-4100 Industry Information: www.fda.gov/oc/industry	7/28-30/10, 8/2-3, 5-6, 11, 13/10, 9/2-3/10
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Specifically, the SPL R&D department received a complaint that made them aware of potential Oversulfated Chondroitin Sulfate (OSCS) in Heparin finished product lot 1035-0778 on 10/9/08. The quality department did not initiate a formal investigation into this complaint until 9/9/09.

SPL concluded raw material lot #060600189 contained OSCS contamination. This raw material was used to manufacture finished Heparin API lots #1035-0778 and #1035-0780. Both lots were fully distributed. An investigation into the raw material lot and lot #1035-0778 was conducted, but not completed until 6/1/10. There was no formal investigation into lot #1035-0780.

OBSERVATION #3

You did not adequately evaluate and qualify your contract testing laboratory.

Specifically, SPL did not qualify (b) (4) per SOP 65-9663 "Qualification and Use of Contract Laboratories" prior to use. (b) (4) has been used for release testing and historical testing for (b) (4) of (b) (4) samples since 4/13/10.

OBSERVATION #4

You did not adequately evaluate your suppliers of raw ingredients.

Specifically, SOP 50-0044 "Porcine Mucosa/Hash Gut/Resin and Pancreas Gland Supplier Audits" states: "Each slaughterhouse…will be audited once every two years." At the initiation of this inspection the following approved suppliers that had not been audited within the past two years:

- (b) (4) Last audited 2/26/08
- (b) (4) Last audited 6/18/08.
- (b) (4) Last audited 6/19/08.
- (b) (4) Last audited 2/28/08.

The following slaughterhouses have recently been audited, but had exceeded the two year time frame between

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previous audits:

-(b) (4) Last audited 7/13/10 and prior to that on 3/28/08.
-(b) (4) Last audited 7/09/10 and prior to that on 5/14/08.

Further, shipments of glands that originated from (b) (4) were received 1/29/10, 6/9/10, and 6/22/10. The annual re-qualification for this supplier was not completed per SOP 76-0003 "Alternate/New Raw Material Vendor Approval and Annual Qualification".

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