DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S Food & Drug Administration 250 Marquette Avenue Suite 600 Minneaplois, MN 612-334-4100	11/30 &12/1-4, 7, 8 & 15/2009
	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 Waunakee, WI 53597	TYPE OF ESTABLISHMENT INSPECTED API Manuacturer

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 OBSERVED:

1) Not all deviations from normal production are documented and explained in the MI or other documents. example

a) It was noted that pancreatin batch 1206-1495, load #2,) was loaded into dryer (b) (4) as observed on 1DEC2009, with (b) (4) trays partially filled and extending off of the shelves by 5"- 6". It was stated by management that this has reportedly occurred on several occasions in the past. The amount loaded was (b) (4) kg per MI. The most recent validation for this dryer shows the maximum load (by weight) is (b) (4) kg. Current version of SOP 17-0005 still shows the former amount, (b) (4) kg, is allowed, yet as shown in this instance, (b) (4) kg would not fit normally into the dryer. No deviation or discrepancy was written into the MI.

2) Not all materials (ingredients, starting materials) are stored in a manner to prevent degradation, contamination, and cross-contamination. example

a) Starting material (bulk raw, frozen pancreas glands in cardboard cartons and totes) are received into the firm at the loading dock, taken directly from vehicles on a wooden pallet using a fork lift vehicle and after cursory examination are moved to the freezer, room (b) (4) Review of this room on the first day of the inspection, 30NOV2009, found the freezer floor to appear dirty (discolored), we noted several small pieces of wood from damaged pallets, a very heavy layer of black dust like material on the top layer of several pallets of goods, dark material on the plastic hanging curtains and what appeared to be some sort of particulate from blowers located above.

The firm routinely de-boxes frozen blocks of glands during spare time and re-stacks them onto these same wooden pallets, with only a layer of unfolded card board from one of the cartons between them and the wooden pallet and on the top and with plastic stretch wrap around the sides. Large damaged areas of the plastic and too small cardboard liners expose the open blocks to the described dust and pallets.

3) Process validation efforts are not always suitable in that critical parameters / attributes are sometimes missed and not covered or not well expressed in SOP's. examples

a) Protocol (b) (4) - Process Validation: Blending of Pancrelipase (b) (4) states, "(b) (4) (b) (4) (b) (4)". As of this inspection, a protocol for the blending of pancrelipase has yet to be executed.

b) There is no validation for the blending of sucrose with finished product.

c) Freeze Dryer validation does not specify tray orientation and it was noted in one instance a batch (lot 1206-1495, load #2, 1DEC2009) was loaded into dryer (b) (4) with (b) (4) trays partially filled and extending off of the shelves by 5"- 6". It was stated by management that this has reportedly occurred on several occasions in the past. Amount loaded was (b) (4) kg per MI. The most recent validation for this dryer shows the maximum load (by weight) is (b) (4) kg. Current version of SOP 17-0005 still shows the former amount of (b) (4) kg is allowed. Yet as shown in this instance, (b) (4) kg would not fit normally into the dryer.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Sandra A Hughes Justin A. Boyd Charles R Cote	Sandra A Hughes, CSO Justin A. Boyd, CSO CHARLES R COTE, CSO	15 December 2009

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4) Written cleaning procedures for equipment including dryers, tanks, blenders and rooms include a description of the approved cleaning method, however in each case reviewed, including SOP 17-032 regarding cleaning of pancreas grinding equipment, the procedure describes the use of appropriate cleansers and sanitizers and describing each in very generic terms, such as "a liquid, non-phosphated, chlorinated alkaline cleanser, but it does not specify which cleanser by brand and name.

5) Equipment is not always maintained suitably or kept in a manner to protect from contamination after cleaning but prior to use. Examples

a) Sampling cups for in-process samples (b) (4) were noted to be stored either hanging from a hook in the open process area (with very visible heavy residue inside the shorter handled cup, or laying on the cat walk and building beams.
b) Buckets used to hold RM's calcium sulfate and sodium bicarbonate noted stored on end or upside down on catwalk or other equipment (bucket for anti foam on wheel barrel handle, beneath floor broom storage).
c) Oil drip of about 1' wide noted along entire side, top to bottom, of tank (b) (4)
d) During the walk through on 01DEC2009 we observed an approximate one inch unknown brown chunk hanging off of the gasket seal on tank (b) (4) On tank (b) (4) a rust like substance was observed around the opening of the tank lid.
e) Badly peeling paint on pipes located above open raw gland grinding station.

6) Analytical equipment not always calibrated before use. Probes used in oven (b) (4), used to dry samples for analysis, are not calibrated. Also, this activity is not described in an SOP.

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