DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/ Minneapolis District Office 250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 612-334-4100 Industry Information: www.fda.gov/oc/industry	04/27 – 05/01, 06-08/09
	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 East Main Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Waunakee, WI 53597	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Quality Systems

1. DMF 9649, dated 12/19/08, 3.2.S.2, Vol. I of II, Section 5 of 11, pages 42-44, reads in part "***(b) (4) (b) (4) (b) (4)". Furthermore, the SPL Response to FDA request for information, Item #4, dated 05/22/08, Volume I of III, page 11, reads in part "***(b) (4) (b) (4)". The DMF also does not allow for (b) (4) (b) (4) QA released blends from rejected finished APIs as follows:

   a. PEC High Lipase API, lot 1208-1433A, had high counts with spore forming bacteria (e.g. (b) (4) (b) (4) cfu/gm with a total count reportable result of (b) (4) cfu/gm. Lot 1208-1433A was rejected by QA on 09/25/07 and was reprocessed (before rejection) as API lot 1208-1486 on 02/27/07. API 1208-1486 was placed into a tote as lot 1208-1486A. API Lot 1208-1486A finished API results demonstrated (b) (4) cfu/gm (limit = (b) (4) cfu/gm). Lot 1208-1486A was **not** rejected and was reprocessed and used to manufacture three blend lots 1297-0323A, 1297-0323B, and 1297-0323C. Blend lot 1297-0323A had counts of (b) (4) cfu/gm, lot 1297-0323B had counts of (b) (4) cfu/gm (b) (4) and lot 1297-0323C had counts of (b) (4) cfu/gm. Blend lots were used as pancreatin activator and renamed 9500-0001 (spec limit NMT (b) (4) cfu/gm) with no additional testing.

   Blends 1297-0323A, 1297-0323B, and 1297-0323C were used to manufacture 1208-1651A and several other lots. Post activation of 1208-1651A had counts of (b) (4) cfu/gm prior to drying (spec is NMT (b) (4) cfu/gm), which was identified as containing (b) (4) organisms (spore-formers). Lot 1208-1651A final microbial counts were (b) (4) cfu/gm (i.e. (b) (4) cfu/gm), and product was QA released and shipped on 01/30/09.

   Lot 1297-0323B was blended on 06/05/08 from a mixture of Lots 1208-1486A, 1208-1453A, 1208-1516A and 1208-1585A. Lot 1208-1486A microbial identification was determined to be (b) (4) (b) (4) Lot 1297-0323B was documented as containing (b) (4) (i.e. spore forming organisms).

   QA released Blends 1297-0323A, 1297-0323B, and 1297-0323C as pancreatin activator 9500-0001 on 09/26/08. These three blends were used to manufacture Pancreatin Enzyme Concentrate (PEC) High Lipase 1208 and PEC 1206 API batches. Formulation 1208 lots released and shipped include 1208-1645A, 1208-1650A, and 1208-1651A.

   Other lots that used Pancreatin Activator 9500-0001 include:

   - Lot 1208-1641 renamed as Blend 1286-0163.
   - Lot 1208-1644 renamed as Blend 1286-0164.
   - Lot 1208-1646 renamed as Blend 1286-0165.
   - Lot 1208-1648 renamed as Blend 1286-0166.
   - Lot 1208-1649 renamed as Blend 1286-0168.

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	Sharon K. Thoma Marie A. Fadden	Sharon K. Thoma, Investigator Marie A. Fadden, Investigator	05/08/09

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b. PEC High Lipase API, lot 1208-1129A, was positive for (b) (4) QA rejected lot 1208-1129A on 09/23/03, but used the batch as pancreatin activator for finished API 1206 and 1208 formulations. Lot 1208-1129A was used as the starting material to manufacture several batches including 1206-1426 and 1208-1550A. Both 1206-1426 and 1208-1550A were contaminated with organisms as follows:

- Lot 1208-1550A was identified as containing (b) (4) spore-formers, and (b) (4). Lot 1208-1550A was rejected on 03/10/08. Lot 1208-1550A was named lot 9500-0006 (pancreatin activator). Lot 9500-0006 was used to manufacture several 1206 and 1208 finished API lots (e.g. 1208-1654; 1208-1655; 1206-1453A and 1206-1453B, which were later used for 1206 Blends; 1208-1652A and 1208-1653A, which were later used for 1208 Blends).
- Lot 1206-1426 initially passed total aerobic plate counts and was QA released on 02/14/08. After blending, lot 1206-1426 was retested as part of Investigation 08-QA-17-014, dated 04/14/08, and failed microbial counts at (b) (4) cfu/gm.

2. PEC High Lipase lots averaged into compliance with no investigation:
   a. Lot 1208-1613, renamed lot 1286-0158, date of manufacture 08/21/08, was released by QA on 09/17/08 per the C of A (b) (4) (b) (4). The final result was averaged into compliance and was not rejected. An investigation was not conducted for this failed final released Lipase USP result.
   b. Lot 1208-1663A, renamed lot 1286-0174, date of manufacture 02/04/09, was released by QA on 04/02/09 per the C of (b) (4) Average of all (b) (4) assays (b) (4) Units/mg) was used for the final reportable result on C of A.

3. Process Validation of Pancreatin/Pancrealipase API, Pancreatic Enzyme Concentrate (PEC) 1208 and 1206 are deficient as follows:
   a. No study has been completed to demonstrate the equivalency and/or calculation conversion from (b) (4) (b) (4) For examples, PEC 1206 page 5 of the master batch record and PEC 1208 page 11 of the master batch record.
   b. No hold time study has been conducted to determine the maximum holding times for (b) (4) (b) (4)
   c. Uniformity/Mixing studies have not been completed to date.
   d. Process validation for the 1206 formulations were conducted in 1994 for PEC 1206 Heavy and in 1996 for PEC 1206 Light. The firm has not conducted re-validation/re-qualification of the process to date. The process validation of PEC 1206 is deficient in that it has not evaluated the (b) (4) (b) (4).
   e. (b) (4) processing times and temperatures.
   f. (b) (4) processing times and temperatures.
   g. Process validation for Formulation 1208 conducted in 12/2008 allows for (b) (4) (b) (4) (b) (4) no study has been completed to evaluate the

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time/number of days used for PEC 1208 lots processed (b) (4) from 03/3/08 to present over (b) (4) days. For examples:

Lot Number	(b) (4) Date Start	(b) (4) Date Start	Total Time (days)
1208-1576	(b) (4)	(b) (4)	(b) (4)
1208-1592			
1208-1593			
1208-1594			
1208-1596			
1208-1666			
1208-1673			
1208-1675			
1208-1677			
1208-1678			
1208-1679			

4. Change control/CAPA deficiencies include the following:
   a. Change Control 08-17-0021 was evaluated to be a minor change with (b) (4) (b) (4) (b) (4) was not evaluated as a major change.
   b. No Change Control/CAPA was written prior to changing SOP 78-1000 for "SPL Metrology Program", dated 04/30/09, from changing the calibration intervals from (b) (4) months to (b) (4) months for all analytical instruments (e.g. several thermometers in the QC laboratory).
   c. No Change Control/CAPA was written or implemented for updating affected cleaning SOPs when Change Control 49-0026, dated 10/31/07, was implemented to (b) (4) (b) (4) For examples, SOP 17-0032 used for (b) (4)

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: 17-0005 at 05/08/09

(b) (4) [redacted]

5. The CGMP training presented to employees in the past year (12/08) did not include the Current Good Manufacturing Practices regarding processing of Active Pharmaceutical Ingredients in accordance with your procedure "cGMP Training Program" #50-0004, effective 7/27/07.

6. The offsite cold storage facility used for storage of pancreas glands was last audited by the firm on August 10, 1994. This cold storage facility changed ownership on 07/31/1998.

Production Systems

7. No evaluation on the suitability of plastic has been conducted to date to demonstrate there are no leachables extracted from plastic that has direct wet and dry product contact. Equipment modifications were made on (b) (4) (b) (4) [redacted] In addition, (b) (4) [redacted]

(b) (4) [redacted]

8. No disinfection study was completed to demonstrate effectiveness of cleaning agents for spore-forming organisms. For examples, (b) (4) [redacted] which are spore formers. Disinfectants/cleaning agents currently used include IPA (b) (4) [redacted] (b) (4) [redacted] In addition, OOS Investigation for Total Aerobic Microbial Count for Pancreatin Lot 1208-1550A, Protocol 08-QA-17-002, dated 03/03/08, reads in part: "***(b) (4) [redacted] ***".

9. Lack of validation and periodic re-qualification of the (b) (4) [redacted] titrator used for measuring cleaning foamer (b) (4) [redacted] which is used to clean the Grinder/Chipper (b) (4) [redacted] equipment assembly used for grinding pancreas glands. The concentration of (b) (4) [redacted] measured and mixed with water was never tested or documented to assure appropriate concentrations are measured in a reproducible fashion.

10. Lack of cleaning validation for all equipment used to process pancreatin/ pancrealipase API. Cleaning procedures are not adequate as follows:
    a. No sporocidal agent is used for cleaning, yet the firm has had high counts of spore forming organisms (e.g. (b) (4) [redacted] (b) (4) in finished API lots and/or finished APIs that were reprocessed as pancreatin activator (i.e. starting material). For examples, lots 1208-1486A, 1208-1550A, and 1206-1426, etc.
    b. No evaluation of cleaning solutions for residuals after cleaning; potential contamination of batch to batch processing by testing/swabbing for microbial presence or lack of presence after cleaning; contact time of cleaning agents, sanitizing agents, and foamers; and potential impact to product.
    c. No evaluation of cleaning agents for there ability to inactivate viruses.

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

d. Potential contamination was observed on 04/29/09 during unloading of lot 1208-1685 from the freeze dryer and the loading of 1206-1469 into freeze dryer (b) (4) immediately following the unloading of lot 1208-1685. (b) (4) was observed to contain left over pancreatin/pancrealipase between the drying processes of both lots. A vacuum with hose and brush head was used to clean excess product on the front of the shelves and floor in front of (b) (4) The vacuum brush was later observed to be sitting in an adjacent room on a table, uncovered and not sent or scheduled for cleaning.

e. On 04/29/09, the freeze dryer (b) (4) located in (b) (4) was observed to contain product from prior manufacturing run(s) in the freeze dryer on freeze dryer shelves and equipment. The equipment is not routinely cleaned and was said to be cleaned on occasion normally every (b) (4) whereas the freeze dryer is used (b) (4) times a week. (b) (4) There

(b) (4)

f. On 04/29/09 in (b) (4) where delumping, metal detection and product transfer from the second level into a drum/tote on the first/ground level occurs, the chute that comes in direct contact with product was covered with a plastic bag and the bag and chute contained excessive dry material from a previous run. This chute/equipment is not routinely cleaned of excess dry material, which may lead to commingling of lots.

g. There is no cleaning procedure in place for freeze dryer (b) (4) used for dedicated PEC 1208 runs. (b) (4) has not been cleaned with cleaning agents, sanitizers, and/or IPA to date and there is no routine scheduled cleaning process of the freeze dryer between lots of APIs processed.

h. Cleaning of production tanks do not always follow written procedures i.e. tanks (b) (4) cleaned per procedure 17-0020 specify "(b) (4)" The cleaning logs for tanks (b) (4) (b) (4) demonstrate that the tanks were not cleaned after (b) (4)

i. There is no written procedure on cleaning Freezer (b) (4) and no cleaning log maintained that documents dates the freezer is cleaned.

11. On 04/29/09 at the completion of freeze drying run 1208-1685, potential contamination of product was observed as follows:

a. Operators were observed to unload trays from the freeze dryer, stack them directly on top of each other/product, and cram them onto/between shelves on a cart also placing the top tray with product in direct contact with cart shelves. Wet cake product on the trays came into direct contact with the bottom of plastic trays that were previously placed directly on freeze dryer shelves.

b. The cart was moved to an adjacent (b) (4) and was not covered in this staging area. The cart sat in (b) (4) from approximately 10 a.m. to 1:30 p.m. uncovered (b) (4) (b) (4)

12. An operator was observed on 04/29/09 to have an earring in his left ear uncovered by his hair net during the unloading of lot 1208-1685, during stacking of trays on top of each other onto the cart; and with placement of wet cake product lot 1206-1469 into plastic trays and loading of trays into (b) (4)

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Equipment & Facilities

13. No IQ/OQ/PQ performed for Freezer (b) (4) installed in 1992. No temperature mapping of the (b) (4) has been completed to date. Firm has (b) (4) temperature probes, (b) (4) (i.e. the one closest to the door of the walk-in freezer) was last calibrated on 01/10/07 and was not placed out of service until on or about 04/30/09. The currently used temperature probe, (b) (4) was not calibrated to a national standard for its intended use at freezer storage temperatures between -10 to -25°C (set point -14.4°C).

14. Equipment is not adequately maintained as follows:
    a. On 04/28/09, Tank (b) (4) was observed to be leaking from the manhole seal on the top of the tank. The seal was observed to be damaged and in need of replacement. The firm's SOP for preventive maintenance (PM) only includes (b) (4) No other PM is performed on Tank (b) (4)
    b. On 04/28/09, the (b) (4) was observed to be leaking oil on top of the centrifuge. Paper towels were placed on top of the oil. SOP 20-2022 for PM on the Centrifuge does not include checking for seal leaks.
    c. Per SOP 17-0005 for "Unloading/Loading/Cleaning (b) (4) ", dated 05/02/08, the chamber vacuum release cartridge is to be "replaced (b) (4) ". The cartridge was not replaced between 01/16/08 through 02/15/09. The cartridge was replaced only once on 02/16/09 per the cleaning lot and dates between 01/16/08 and 03/23/09.
    d. Per SOP 17-0043 for "(b) (4) Dryer Cleaning/Loading/Unloading Procedures", dated 05/02/08, the chamber vacuum and condenser release cartridges for (b) (4) are to be "replaced (b) (4) ". The cartridges were not documented as being replaced in 2007 and 2008. A cartridge was last replaced on 02/16/09, but it was not described (e.g. chamber or condenser).

15. Cleaning Logs and Cleaning documented in Manufacturing Instructions (i.e. Batch Records) lack a second signature verifying cleaning was completed as follows:
    a. (b) (4) Equipment and Facility Cleaning/Use Log: sweeping and mopping, and soaking utensils on 03/28/08, 03/31/08, 04/04/08, 04/07/08, *** 04/16/08, 08/08/08, 08/22/08, etc.; and cleaning (b) (4) shelves per SOP 17-0103 per SOP 07-0111.
    b. Pancreatin Delumper, (b) (4), per the Equipment and Facility Cleaning/Use Log per SOP 170036 (12/10/07 through 01/21/08). There is no documentation of cleaning from 03/06/08 to present recorded in the log per SOP 17-0036 for "Operating and Cleaning Metal Detector (b) (4) Delumper", dated 05/20/08. An example, Manufacturing Instruction (page 28 of 44) for 1208-1458 lacks a double signature.
    c. Cleaning and Use Log for Poly Drums from 01/16/08 to 01/25/08 lacks a double signature. An example, Manufacturing Instruction (page 27 of 44) for 1208-1458 lacks a double signature for cleaning drums.
    d. (b) (4) Dryer Equipment and Facility Cleaning/Use Log has no cleaning recorded in the log for all of 2008 and 2009. Per SOP 17-0043 for (b) (4) Dryer Cleaning/Loading/Unloading Procedures", dated 05/02/08, cleaning is to be recorded in the Cleaning/Use logbook (Form 21-0300).

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Laboratory Systems

16. As of 04/30/09, the Process Validation stability batches (i.e. 1208-1628, 1208-1629, and 1208-1630) have not been pouched/packaged and placed up on stability into stability chambers. These batches were manufactured in September 2008.

17. (b) (4) batches currently in the stability chamber for product codes 1206 and 1208 were manufactured from October 2003 to date and were placed in the stability chamber (b) (4) after the date of manufacture.

18. Secondary standards for Amylase and Protease were qualified against the USP reference standard in May 2006. The bulk product used as the secondary standard was originally manufactured in June 2000. This bulk product now has a two year expiration date, whereas the secondary standard does not include an expiration date.

19. There is no procedure that describes system suitability requirements for the Gas Chromatography (GC) system.

20. GC method used is not included in raw data for each analysis.

21. Preparation of Acacia Solution was given the wrong expiration date by the analyst for two months after the DRAFT procedure "USP Lipase Activity of Pancreatin" #65-1252 effective 1/10/08 was changed (i.e. the Acacia Solution expiration previously had been 2 months, the modified procedure updated the Acacia Solution expiration to 14 days).

22. Thermometers on a (b) (4) calibration schedule and not calibrated on a periodic basis (at a minimum annually) included the following:
    a. Refrigerator (b) (4) used for storage of (b) (4) test organism stock cultures used Thermometer (b) (4) which was last calibrated on 08/30/04. The calibration sticker read due in "08/09".
    b. (b) (4) total thermometers used in the QC laboratory. For examples, (b) (4)

Material Systems

23. Pancreatic activator (starting material) is used in multiple PEC 1206 and 1208 batches. Qualification of the material does not include analysis for (b) (4)

24. Lack of traceability of approximately (b) (4) lbs of pancreas glands found in Freezer (b) (4) on 04/28/09 that was not labeled and was stored on top of boxes of pancreas glands, receiving #090300185, unwrapped and exposed to the environment.

25. Firm does not monitor the temperature of the outsourced company trucks that transfer pancreas glands from (b) (4) cold storage facility to SPL. Firm has not conducted a transfer study of glands to assure proper storage conditions of glands when initially received by firm from the cold storage facility (b) (4) and when transferred from the firm to the cold storage facility for temporary storage when Freezer (b) (4) is cleaned and/or undergoing maintenance. Traceability of pancreas glands/lots that are transferred to the cold storage facility is not easily retrieved since there is no QA "approved" procedure or log maintained.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Sharon K Thoma Marie A. Fadden	Sharon K. Thoma, Investigator Marie A. Fadden, Investigator	05/08/09

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/ Minneapolis District Office 250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 612-334-4100 Industry Information: www.fda.gov/oc/industry	04/27 – 05/01, 06-08/09
	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 East 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 WE OBSERVED:

26. No holding time studies have been conducted to date on pancreas glands in quarantine at the cold storage facility to evaluate the maximum hold time.

27. No written procedure describing rejection of glands.

28. Process water used for the production of Pancreatin/Pancrealipase has not been validated in that:
    a. On and before 04/28/09, the sample port in room (b) (4) is hot process water for cleaning; production uses domestic cold water for processing.
    b. There is no scientific basis for the (b) (4) sampling frequency and the location of the sample ports.
    c. Sample locations are not identified on the CAD diagram.
    d. Sample locations are not physically identified at the sampling ports.
    e. The effect of the chlorine in city water on the product has not been evaluated.

DMF 9649 Deficiencies

29. There is no name and address of the outside storage cold facility listed in the DMF.

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