



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, ILLINOIS 60604**

DATE: JUN 25 2019

SUBJECT: CLEAN AIR ACT INSPECTION REPORT
Scientific Protein Laboratories LLC (SPL), Waunakee, Wisconsin

FROM: Albana Bega, Environmental Engineer
AECAB (MI/WI)

THRU: Sarah Marshall, Section Chief
AECAB (MI/WI)

TO: File

BASIC INFORMATION

Facility Name: Scientific Protein Laboratories LLC (SPL)

Facility Location: 700 E Main Street, Waunakee, Wisconsin

Date of Inspection: May 3, 2019

EPA Inspector(s):

1. Albana Bega, Environmental Engineer
2. Alexandra Letuchy, Environmental Engineer

Other Attendees

1. Bruce A. Greer, P.E., Manager – Environmental Health and Safety, SPL
2. Kevin R. Tebrinke, P.E., Vice President, Engineering, Maintenance & Health and Safety, SPL

Contact Email Address: greerb@splpharma.com

Purpose of Inspection: CAA compliance

Facility Type: bulk pharmaceutical ingredient manufacturing

Regulations Central to Inspection: Synthetic Minor, Non-Part 70 Operation Permit

Arrival Time: 09:30

Departure Time: 13:00

Inspection Type:

- ☒ Unannounced Inspection
☐ Announced Inspection

OPENING CONFERENCE

- ☒ Credentials Presented
☒ CBI warning to facility provided

The following information was obtained verbally from Mr. Greer and Mr. Tebrinke unless otherwise noted.

Company Ownership: In 2014 SPL was acquired by the Chinese company Shenzhen Hepalink Pharmaceutical Co., Ltd.

Process Description: SPL is a bulk product biopharmaceutical manufacturing company of active pharmaceutical ingredients. It is a global supplier of Heparin and Pancreatin enzymes. SPL claimed its process information as confidential business information.

TOUR INFORMATION

EPA toured the facility: Yes

The facility was operating normally at the time of inspection.

Data Collected and Observations: The following were observed during the tour:

- Raw material warehouse
- Heparin line
- Tank farm

Photos and/or Videos: were not taken during the inspection.

Field Measurements: were not taken during this inspection.

RECORDS REVIEW

- Heparin Process Line P05 - Figure No. 4
- Pancreatin Line 2 - Figure No. 5
- Milling P25 - Figure No. 7

CLOSING CONFERENCE**SIGNATURES**

Report Author: Asger Date: 6/25/19
Section Chief: [Signature] Date: 6/25/19