TABLE OF CONTENTS

SUMMARY

A follow-up inspection to a regulatory meeting conducted in June 2012 of this manufacturer of both active pharmaceutical ingredients and finished dosage prescription pharmaceuticals was conducted pursuant to a request from NWJ-CBr under FACTS Assignment ID 1513467, Operation ID 6732977. The current inspection was also part of the NWJ-DO's FY'13 Drug Workplan. Inspectional guidance was provided with CPGM 7356.002, Drug Manufacturing Inspections, and CPGM 7356.002F, Active Pharmaceutical Ingredients.

The previous inspection was a comprehensive cGMP inspection providing coverage to the Quality, Facilities and Equipment, Production, and Laboratory Control Systems. The inspection revealed the

following deficiencies: the failure to adequately perform failure investigations, inadequate cleaning of manufacturing equipment, the failure to perform temperature mapping studies for a cold-storage warehouse, the failure to maintain facilities in a state of repair, and the failure to maintain manufacturing equipment in a state of repair, the lack of manufacturing instructions and control procedures for a [redacted] (b) (4) step, the failure to label containers, the failure to validate a stability indicating test method, and the failure to validate a supplier's certificate of analysis. An FDA-483, Inspectional Observations, was issued at the close of the inspection to Dr. David P. Jacobus, President, who promised a written response to the district within 15 days.

The current inspection was a comprehensive cGMP inspection providing coverage to the Quality, Facilities and Equipment, Production, Material, and Laboratory Control Systems. Corrections to the previous FDA 483 were verified and appeared adequate. No FDA 483 was issued at the close-out meeting and only one item was discussed with the firm in relation to attaining original method validation records from a third party laboratory once they have met their record retention time frame. JPC currently retains copies of the method validation documentation.

The firm was cooperative and made no refusals. No samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	Jacobus Pharmaceutical Company Inc.
Location:	Industrial Research Laboratory Building 31 Schalks Crossing Road Plainsboro, NJ 08536
Phone:	609-921-7447
FAX:	609-799-1176
Mailing address:	PO Box 5290 37 Cleveland Lane Princeton, NJ 08590
Dates of inspection:	7/9/2013, 7/10/2013, 7/11/2013, 7/12/2013, 7/15/2013
Days in the facility:	5
Participants:	Lauren L. Vajo, Investigator

On 07/09/2013 I, Lauren L. Vajo, presented my credentials and issued an FDA-482, Notice of Inspection, to Mr. Richard W. Pursell (Plant Manager and Director Pharmaceutical Manufacturing). Dr. David Jacobus (President) and Ms. Laura R. Jacobus (Vice-President/Quality & Regulatory Affairs) were not present at the time of issuance, and Mr. Pursell indicated that he was authorized to accept the Notice.

During the inspection, Mr. Richard W. Pursell and Ms. Laura R. Jacobus (Vice-President/Quality & Regulatory Affairs) were the primary contacts at the firm. They answered questions, provided documents, and made employees available when needed. I was escorted through the facility during the walkthrough by Mr. Pursell, [redacted] (b) (6) (Quality Assurance) and [redacted] (b) (6) (Quality Assurance). Additional employees that participated in the inspection include:

- Dr. Kathy Ales, Medical Officer
- Guy Schiehser, Director of Chemistry
- Raju Shah, Director of Quality Control
- Robert J. Warman, Sr., Director of Engineering
- Gary Santonastaso, Director for cGMP Compliance
- [redacted] (b) (6)
- [redacted] (b) (6)
- Susan Kligerman, Director of Wholesale Distribution

A close-out meeting was held with the firm on 07/15/2013. No FDA 483 was issued at the close-out meeting and only one item was discussed with the firm in relation to attaining original method validation records from a third party laboratory once they have met their record retention time frame. JPC currently retains copies of the method validation documentation but originals are retained by [redacted] (b) (4)., located in [redacted] (b) (4) The following personnel were present for the close-out meeting:

- Laura R. Jacobus, Vice-President/Quality & Regulatory Affairs
- Dr. Kathy Ales, Medical Officer/Medical Affairs
- Guy Schiehser, Director of Chemistry
- Neil Lewis, Director of Chemical Manufacturing
- Raju Shah, Director of Quality Control
- Robert J. Warman, Jr., Director of Engineering
- Gary Santonastaso, Director for cGMP Compliance
- Susan Kligerman, Director of Wholesale Distribution
- Otis Forney, Deputy Director, Quality Control
- [redacted] (b) (6), Quality Assurance
- [redacted] (b) (6), Quality Assurance
- [redacted] (b) (6), Quality Assurance
- [redacted] (b) (6), Quality Assurance

This Establishment Inspection Report (EIR) was written in its entirety by Investigator Vajo.

HISTORY

Jacobus Pharmaceutical Company Inc. (hereinafter referred to as JPC) was incorporated in 1977 in the state of New Jersey and continues to operate as a privately-owned business. The Industrial Research Building at Schalks Crossing Road is the firm's sole manufacturing location. There are no related firms or subsidiaries. During the inspection, it was brought to my attention that JPC received a street number for their physical address. The address is now considered 31 Schalks Crossing Road instead of Schalks Crossing Road.

The firm's core hours of operations are [redacted] (b) (4) The firm has [redacted] (b) (4) employees, [redacted] (b) (4) of which are temporary summer interns. The firm's annual sales at this facility for 2012 were approximately [redacted] (b) (4) The firm's drug registration is active and current for 2013.

The firm contracts the following firms for coating and packaging:

Firm	Location	Service(s) Provided
[redacted] (b) (4)		

Jacobus's main customers include:

[redacted] (b) (4)

There have been no recalls or Field Alerts since the last inspection.

Changes since the last inspection include the addition of more Quality Assurance (QA) staff members in order to increase QA oversight; receiving the certificate of occupancy (COO) for the new temperature controlled warehouse; [redacted] (b) (4) [redacted] (b) (4) A detailed list of these changes has been itemized by Ms. Jacobus in

Exhibit 1 attached. The updated facility diagrams are attached as **Exhibit 2** and show airflows, personnel flows, materials (API and dosage form) flows, air handling unit zoning and pressurization.

All correspondence should be addressed to Ms. Laura R. Jacobus at the address below:
Jacobus Pharmaceutical Co., Inc.
37 Cleveland Lane
P. O. Box 5290
Princeton, NJ 08540.

INTERSTATE COMMERCE/JURISDICTION

The firm continues to operate as a manufacturer of active pharmaceutical ingredients (APIs) and prescription pharmaceuticals. The APIs manufactured at Jacobus are not sold to third party customers; they are used solely in the manufacture of JPC finished products. These products include:

- **Dapsone USP (4,4'-diaminodiphenylsulfone) 25 & 100 mg Tablets:**
  Technical grade Dapsone, USP is acquired from (b) (4) and then purified at this facility by (b) (4) steps. **Exhibit 3** shows a schematic of the API process. This purified bulk/API is then used to manufacture Dapsone 25 mg and 100 mg tablets. The tablets, after (b) (4) at this facility, are shipped to (b) (4) for blister packaging. After packaging, the finished product is shipped to (b) (4) for distribution to customers.

- **PASER® (Aminosalicylic Acid) Delayed-Release Granules (4 grams per packet):**
  The API, Aminosalicylic Acid, is manufactured by (b) (4) at the Plainsboro, NJ facility. **Exhibit 4** shows a schematic of the API process within the newly revised master batch record. It is then used in the production of PASER® granules by (b) (4) process. The (b) granules are then shipped to (b) (4) for enteric coating and then shipped to (b) (4) for packaging into individual pouches (4 grams per pouch). After packaging, the finished product is shipped to (b) (4) for distribution to customers.

Ms. Jacobus stated that greater than (b) (4) of the firm's commercial products enter into interstate commerce. She stated that approximately (b) (4) of PASER® granules are distributed domestically and that (b) (4) of Dapsone 25mg and 100mg Tablets USP respectively are distributed domestically. The majority of the PASER® granules shipped internationally are purchased by (b) (4)

The firm has (b) (4) (b) (4). Coverage was not provided to this (b) during this inspection.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

An organizational chart has been provided as **Exhibit 5**.

Dr. David P. Jacobus, President – Dr. Jacobus introduced himself on the first day of the inspection and stated that his daughter, Laura R. Jacobus is fully responsible for all GMP related activities at the firm. He currently focuses on research and development activities. He still maintains title as President of the firm.

Ms. Laura R. Jacobus, Vice-President of Quality Assurance – Ms. Jacobus provides oversight for the Quality Assurance department and all site personnel. She has the authority to make decisions and is responsible for ensuring that all regulated systems and documentation comply with the applicable regulatory requirements. Ms. Jacobus serves as the lead for all FDA and regulated audits and ensures that all registrations, notifications and approvals are submitted on time and in a complaint manner. She reports to Mr. Jacobus.

Kathy Ales, Medical Office/Medical Affairs – Ms. Ales is responsible for all medical inquiries/ complaints. She is responsible for submitting MedWatch reports, monitoring the compassionate distribution program (for both finished products) and has oversight for all clinical trial activities. She reports to Mr. Jacobus and Ms. Jacobus.

Richard W. Pursell, Plant Manager and Director Pharmaceutical Manufacturing – Mr. Pursell is responsible for both technical and scientific leadership for overall manufacturing operations for the PASER® uncoated granules and the solid, oral dosage form. He is responsible for production schedules, training of operators, investigations and corrective actions relating to manufacturing operations, and assist in regulatory inspections. During the inspection, he conducted the facility tour, explained the dosage manufacturing/purification process and went through associated records with me. He explained the [redacted] (b) (4), warehouse and storage activities, rejection activities, and shipping and distribution activities. He reports to Ms. Jacobus.

Guy Schiehser, Director of Chemistry – Mr. Schiehser is responsible for oversight for all research and development activities as well as API manufacturing/purification process activities. He is responsible for training of his staff, for investigations related to API products and processes, and provides oversight for validation and qualification activities. During the inspection, he explained the API manufacturing/purification process and went through associated records with me. He reports to Ms. Jacobus.

Raju Shah, Director of Quality Control – Mr. Shah is responsible for both technical and scientific oversight for all Quality Control (QC) laboratory operations. He is responsible for establishing specifications, standards, sampling, training, oversight for raw materials and finished dose analysis, and the stability program. During the inspection, he provided all information relating to QC activities. He reports to Ms. Jacobus.

Robert J. Warman, Jr., Director of Engineering – Mr. Warman is responsible for oversight of engineering and maintenance operations for both the bulk and solid dosage form manufacturing operations as well as the facility in general. He is responsible for conducting investigations of facility and equipment deviations and associated corrective actions if applicable. During the inspection, he assisted Mr. Pursell in explaining the [redacted] (b) (4) and providing a tour of the [redacted] (b) (4) [redacted] (b) (4) within the facility. He reports to Ms. Jacobus.

Gary Santonastaso, Director for cGMP Compliance – Mr. Santonastaso oversees facility maintenance, operations and qualification of all equipment and systems used to manufacture all JPC products. He is responsible for reviewing all current systems and equipment to ensure compliance with internal specifications and regulatory filings and documents. During the inspection, he provided me with an overview of the facility diagrams and the flows of staff, product and the air handling units. He reports to Ms. Jacobus.

Susan Kligerman, Director of Wholesale Distribution – Ms. Kligerman is responsible for all goods distribution and for maintaining documentation of all shipping records. She manages returns of products with respect to replacing expired/outdated product. During the inspection, she went through the returns process with me. She reports to Ms. Jacobus.

The following Quality Assurance personnel managed the inspectional requests and provided information relating to Quality activities:

- [redacted] (b) (6), Quality Assurance
- [redacted] (b) (6), Quality Assurance
- [redacted] (b) (6), Quality Assurance
- [redacted] (b) (6), Quality Assurance

Their responsibilities include oversight and guidance to ensure documentation associated with the manufacture and delivery of quality products is accurate, perform routine inspections, review batch records, logbooks and other GMP documentation, identify deviations and corrective and preventative actions (CAPAs) as appropriate, and participate in regulated inspections.

FIRM'S TRAINING PROGRAM

I reviewed the training SOP: QA-0015-002, "Personnel Training" (effective: 05/10/2012). The training program consists of cGMP training, on-the-job training and SOP training. In addition to reviewing training records associated with corrections to the previous FDA 483 issued on 04/16/2012, I reviewed training records for the following employees: Richard Pursell (Plant Manager and Director of Pharmaceutical), [redacted] (b) (4) (Manufacturing Operator - API) and [redacted] (b) (4) (Manufacturing Operator – Dosage Form). No deficiencies were noted.

MANUFACTURING/DESIGN OPERATIONS

As previously stated, coverage was provided to the Quality, Materials, Production, Equipment and Facilities, and Laboratory Control Systems. I covered the commercial products (PASER® granules and Dapsone tablets) including the APIs used in the manufacture of the finished dose products.

A. QUALITY SYSTEM

The Quality System was given full coverage during the current inspection. I reviewed complaints, investigations and deviations, change controls, rejected materials, relevant SOPs, and training records. I reviewed Annual Product Reviews (APRs) for the firm's 2 commercial products. There were no Field Alerts and no recalls during the current inspectional period.

B. PRODUCTION SYSTEM

The firm uses (b) (4) equipment in the manufacture of the 2 commercial products: PASER® (Aminosalicylic Acid) Delayed-Release Granules (4 grams per packet) and Dapsone USP (4,4'-diaminodiphenylsulfone) 25 & 100 mg Tablets. During my inspection, I reviewed manufacturing processes and batch records relating to both the API and finished dosage forms for both products. The firm was not manufacturing finished dose Dapsone USP 25 & 100 mg Tablets at the time of the inspection, but I was able to review previous batches made since the last inspection. JPC is currently (b) (4) and plans to start production once the (b) Production of the Dapsone API (4,4'-diaminodiphenylsulfone) is (b) (4) to support finished dosage production when (b) (4). The (b) (4) were based on corrections to the previous FDA 483. See the *Voluntary Corrections* section for further information.

C. FACILITIES AND EQUIPMENT SYSTEM

Full coverage was provided to the Facilities and Equipment system since many of the corrections to the previous FDA 483 issued included (b) (4) of the facility. Due to all the (b) (4) (b) (4) equipment was moved or new equipment was purchased, as such equipment qualifications, equipment re-qualifications and process validations and re-verifications were reviewed. See the *Voluntary Corrections* section for further information.

D. LABORATORY SYSTEM

During the walkthrough of the laboratory, I noted that equipment in use was within its calibration, and equipment outside of calibration was identified as non-operational. I noted that media, standards, and samples preparations were labeled appropriately. Coverage was provided to out-of-

specification (OOS) investigations, standard qualifications, method validations and method transfer, stability and release data.

E. MATERIAL SYSTEM

I reviewed processes and procedures relating to incoming, receiving, and shipping of materials. I also reviewed the (b) (4) and associated testing. Data relating to (b) (4) testing was performed under the Laboratory system. These items were noted on the previous FDA 483 as not being test appropriately. See the *Voluntary Corrections* section for further information.

MANUFACTURING CODES

The firm continues to assign codes per SOP: QC-0003-006, "Raw Material and Packaging Sampling Assigning (b) (4) Numbers" (effective 03/20/2013) as follows:

- (b) (4)
- (b) (4)

RECALL PROCEDURES

I reviewed the recall procedure: G-0015-002 "Recall Policy" (effective 11/06/2012). There have been no recalls since the last inspection. The firm has the ability to thoroughly trace back all of its products and components, including shipping documents, in the event of a recall.

REFUSALS

There were no refusals during the current inspection.

GENERAL DISCUSSION WITH MANAGEMENT

A close-out meeting was held with the firm on 07/15/2013. Present for this meeting were:

- Laura R. Jacobus, Vice-President/Quality & Regulatory Affairs
- Dr. Kathy Ales, Medical Officer/Medical Affairs

- Guy Schiehser, Director of Chemistry
- Neil Lewis, Director of Chemical Manufacturing
- Raju Shah, Director of Quality Control
- Robert J. Warman, Jr., Director of Engineering
- Gary Santonastaso, Director for cGMP Compliance
- Susan Kligerman, Director of Wholesale Distribution
- Otis Forney, Deputy Director, Quality Control
- [redacted] (b) (6), Quality Assurance
- [redacted] (b) (6) Quality Assurance
- [redacted] (b) (6), Quality Assurance
- [redacted] (b) (6), Quality Assurance

During my review of validation activities associated with Test method #DF-IMP-DAP-LC-1 "Determination of related Compounds in Dapsone Tablets, USP: 25mg and 100mg", I noted that the customer, [redacted] (b) (4) who performed the method validation, stated that they would maintain original records for [redacted] (b) (4) and then only by request provide copies to interested parties. I suggested to Ms. Jacobus that if [redacted] (b) (4) is destroying the original data after [redacted] (b) (4) that she may want to consider obtaining the raw data (even though she has copies currently available for review) for her own records. She agreed and stated she would make the formal request.

ADDITIONAL INFORMATION

Access to the firm's manufacturing location in Plainsboro, NJ is gained via an access road located on the northbound side of Schalks Crossing Road between Scudders Mill Road and Research Way; the access road begins immediately before an overpass. There is a white sign at the beginning of the access road that states in black letters "Industrial Research Laboratory"; the access road leads into the Plainsboro Preserve and ends at the firm.

SAMPLES COLLECTED

No samples were collected during the inspection.

VOLUNTARY CORRECTIONS

I reviewed the firm's corrective actions to the April 2012 FDA 483 issued at the close-out of the previous inspection.

Observation #1a and b:

Citation: *There is a failure to thoroughly investigate batches that do not meet specification.*

Summary and Correction: Investigations into API failed moisture content in PASER® granules lot 14269 did not extend to other batches or did not include documented evidence of a third party investigation; and [redacted] (b) (4) was the root cause of finish dose failure of PASER® Granules lot 14028 and other lots utilizing this API were not evaluated. During the current inspection I noted that any deviations and investigations that involved third party contracts were performed accordingly. A review of the Quality Agreements between these third party contractors was conducted and the agreements include statements notifying JPC of such investigations or deviations. In addition the following procedures were updated to include impact assessments that relate to third party contractors and JPC product:

- SOP G-0023-003, "Deviations" (effective: 01/25/2013)
- SOP QC-0047-007, "Laboratory Investigations" (effective: 05/23/2013)

PASER® granules lots 14269 and 14028 were placed on stability. I reviewed the stability data to date and all data met specification. All associated training records were reviewed and corrections appear adequate.

Observation #2a and b:

Citation: *Procedures for cleaning equipment used during the manufacturer of API are not followed.*

Summary and Correction: There was no visual assessment for the cleanliness of all equipment used in the manufacture of Aminosalicylic Acid (PAS API – used in PASER® Granules), specifically for JPC vessels [redacted] (b) (4). The viewing window for vessel [redacted] (b) (4) appeared to be scratched and made viewing into the vessel difficult. During the current inspection I noted that the batch records had been updated to include a start-up and shut-down approval page. These pages outlined the cleaning performed at the start of the day (before production) and at the end of the day (after production is completed) and are signed by the operator and approved by Quality Assurance. As part of the [redacted] (b) (4), these vessels were relocated and re-qualified and the viewing window for vessel [redacted] (b) (4) was replaced. In addition, cleaning procedures were enhanced to address this observation. All associated training records were reviewed and corrections appear adequate.

Observation #3a through e:

Citation: *Facilities used in the manufacturing and storage of components, APIs and in-process materials is inadequate.*

Summary and Correction: The firm utilized an outside cold storage room that lacked adequate space, was is a state of disrepair and failed to include a mapping study. The ambient storage area of this building was also in a state of disrepair. Manufacturing room [redacted] (b) (4) had exposed walls, used duct tape on the HVAC line, and had cardboard covering the vents. The walls in the [redacted] (b) (4) suite for PASER® Granules were also not suitable as they had holes in them. The Dapsone API area had residues on the floor and a hole in the ceiling. During the current inspection, Ms. Jacobus provided me with **Exhibit 6** to show the before and after pictures of the updated facility and equipment. I

confirmed that the firm no longer utilizes the outside storage facility referenced in the observation. A cold storage warehouse has been qualified and is in use. Temperature mapping studies were conducted and currently temperatures are monitored (b) (4) (captured in a logbook) and the by "Temp Tales" – temperature monitoring devices – which are downloaded and reviewed (b) (4). **Exhibit 6** pages 1 and 2 shows the before and after pictures of the newly constructed cold storage warehouse. Manufacturing room (b) (4) no longer exists due to the (b) (4); it has become part of the corridor to the (b) (4). **Exhibit 6** page 8 shows part of the corridor referenced above. Repairs were made to the (b) (4) suite for PASER® Granules as outlined in the previous EIR. As part of the (b) (4), all walls and the ceilings are made of cleanable surfaces. Of the (b) (4) areas I did not observe any defects or repairs needed in the walls and ceilings. Areas (b) (4) were well segregated from production areas to prevent any contamination. The procedure for adding (b) (4) to the Dapsone API processes was updated to control residues in the suite (the previous inspection observed (b) (4) on the floor). All associated training records were reviewed and corrections appear adequate.

Observation #4:

Citation: *Equipment used in the manufacturing of drug products are not maintained in state of repair.*

Summary and Correction: (b) (4) used in the (b) (4) of Dapsone USP was not maintained in a state of repair. During the current inspection I confirmed that this (b) (4) is no longer used. A new (b) (4) was purchased for the Dapsone suite which will be released for use when all qualifications and validations associated with the (b) (4) (b) (4). Until such times, (b) (4) is taking place.

Observation #5a and b:

Citation: *Lack of specific manufacturing instructions and control procedure.*

Summary and Correction: Deficiencies noted for the (b) (4) Dapsone (b) (4) included no routine evaluation for the removal of (b) (4), lack of adequate instructions for the (b) (4) operation, unclear procedures for gowning, and lack of procedures for glove use. In addition, there was no established final yield specification for Dapsone USP API. During the current inspection, I verified that the firm conducted (b) (4) testing for all Dapsone USP API past lots as committed in their response and I also verified that the firm is currently testing all API lots for (b) (4). In addition, I noted that the firm has purchased a new (b) (4) to (b) (4). Upon qualifications activities, it was discovered that the (b) (4) was not operating accordingly. The (b) (4) has been returned for repair and will be qualified prior to use in process validations batches needed to qualify the new equipment and (b) (4) process. The master batch record for Dapsone USP API was updated to account for this change. The following procedures were modified/created to address the gowning and glove concerns:

- SOP API-0009-002, "Sanitization of Outer Gloves Worn During Dapsone (b) (4)," (effective: 04/23/2013)

- SOP G-0004-006, "Personal Hygiene and Proper Dress" (effective: 12/31/2013)

Final yield specifications were established based on historical data. During review of the API batch records, I noted that the final yield was being calculated and captured accordingly. All associated training records were reviewed and corrections appear adequate.

Observation #6:

Citation: *Containers used during the production if drug products are not identified at all times.*

Summary and Correction: In-process PASER® lots 14563 and 14569 did not have product labels to identify the product and lot number. During the current inspection, I verified all in-process lots currently being manufactured at the time of the walk-through were labeled accordingly. SOP G0024-02, "Internal Label generation & Use" (effective: 04/24/2012) was updated to account for this observation. All associated training records were reviewed and corrections appear adequate.

Observation #7:

Citation: *Written Stability program for drug products does not include specific, meaningful and reliable test methods.*

Summary and Correction: The test method used to monitor impurities for Dapsone USP (4,4'-diaminodiphenylsulfone) 25 & 100 mg Tablets was not a stability-indicating method. The firm utilized a [redacted] method. This impurities test method, #DF-IMP-DAP-LC-1 "Determination of related Compounds in Dapsone Tablets, USP: 25mg and 100mg", is an [redacted] method and was developed by JPC but sent to [redacted] located in [redacted], for validation since JPC does not have a [redacted] detector used to determine peak purity. This validation was completed and the report approved 08/13/2012. After the method was validated by [redacted] a method transfer/qualification was conducted at JPC. I reviewed the protocol (approved 08/17/2012), report (approved 08/28/2012) and raw data and no deficiencies were noted. The method has been released and is currently in use.

Observation #8:

Citation: *Test results from component suppliers are accepted without testing each component according to the established specification without evaluating the reliability of the supplier's COA.*

Summary and Correction: [redacted] used during manufacturing of Aminosalicylic Acid USP and uncoated PASER® granules was not fully tested; only identification testing was performed. During the current inspection, I verified (through review of Certificates of Analysis and testing results) that JPC was conducting at least [redacted], full testing of the [redacted] used to [redacted] during production. Full testing is now conducted by [redacted] located in [redacted] The [redacted] is purchased from [redacted], located in [redacted]. I reviewed SOP: G-0031-005, "Vendor/Supplier Qualification and Certification" (effective 05/03/2013) which discusses qualification of suppliers and full testing requirements. No deficiencies were noted.

EXHIBITS COLLECTED

Exhibit	Description	Pages
1	List of Changes and Upgrades at the Jacobus Pharmaceutical API Facility	4
2	Revised facility diagrams	5
3	Schematic of API (b) (4) process for Dapsone USP API	1
4	Schematic of API (b) (4) process for PAS API.	1
5	Organizational Chart	1
6	Presentation of facilities renovations (pictures)	12

ATTACHMENTS

Copy of the FDA 482, Notice of Inspection, issued on 07/09/2013 (3 pages)

Lauren L. Vajo, Investigator