UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 26, 2013

INTEGRA LIFESCIENCES HOLDINGS CORPORATION
(Exact name of Registrant as specified in its charter)

Delaware	**0-26224**	**51-0317849**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

311 Enterprise Drive **Plainsboro, NJ**	**08536**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (609) 275-0500

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On November 26, 2013, the United States Food and Drug Administration (the "FDA") completed an inspection of the regenerative medicine facility in Añasco, Puerto Rico (the "Añasco Facility") of Integra LifeSciences Corporation, a wholly-owned subsidiary of Integra LifeSciences Holdings Corporation (the "Company"). The Añasco Facility is operating subject to an FDA warning letter dated February 13, 2013 (the "Warning Letter") that relates to quality systems and compliance issues. The inspection began on October 25, 2013 and focused primarily on the issues raised in the Warning Letter. At the end of the inspection, the FDA issued a new Form 483 with six observations, relating to Corrective and Preventative Action ("CAPA"), quality system procedures and instructions, procedures pertaining to complaints, procedures pertaining to checking and maintaining equipment, procedures for finished device acceptance and procedures to prevent contamination of equipment or products. Of these, the FDA designated the first observation, related to CAPA, and the third observation, related to complaint procedures, as repeat observations. The FDA did not issue repeat observations about validated processes, document control procedures, process control procedures or schedules for the adjustment, cleaning and maintenance of equipment The Company had committed to several corporate-wide corrections and additional site corrections and will continue to complete these within the timeframes provided to the FDA in order remediate the observations that the FDA has made. A copy of the FDA Form 483 is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1* Food and Drug Administration Form FDA-483, dated November 26, 2013, relating to the inspection of the Añasco Facility

* Application has been made to the Commission for confidential treatment of certain provisions of this exhibit. Omitted information for which confidential treatment has been requested has been filed separately with the Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

Date: December 3, 2013

By: /s/ Peter J. Arduini
Peter J. Arduini
Title: President and Chief Executive Officer

EXHIBIT INDEX

Exhibit Number	Exhibit
99.1*	Food and Drug Administration Form FDA-483, dated November 26, 2013, relating to the inspection of the Añasco Facility

* Application has been made to the Commission for confidential treatment of certain provisions of this exhibit. Omitted information for which confidential treatment has been requested has been filed separately with the Commission.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

466 Fernandez Juncos Ave.
San Juan, PR 00901-3223
(787)-474-9500 Fax: (787) 729-6809
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

10/24/2013 - 11/26/2013*

FEI NUMBER

3000204775

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Jose F. Carrero, Plant Manager

FIRM NAME

Integra Neurosciences PR, Inc.

STREET ADDRESS

Carr 402 Norte Km 1.2

CITY, STATE, ZIP CODE, COUNTRY

Anasco, PR 00610

TYPE ESTABLISHMENT INSPECTED

Medical Device 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Corrective and preventive action activities and/or results have not been adequately documented.

Specifically,

A. Corrective and Preventive Actions executed on site and documented in CAPA files in accordance with approved procedure H6-055 do not always include documented evidence to support activities executed with corrective and preventive actions (CAPA) that addresses actual/potential/other undesirable conditions in order to prevent recurrence, as described on the procedure's purpose. For example:

1. CAPA 83945, issued on 02/17/13 to conduct a comprehensive evaluation of the Añasco Collagen processes due to Bacterial Endotoxin Test (BET) Out of Specification (OOS) results reported from December 2012 to February 2013 on Collagen Products, does not include supportive evidence to determine the adequacy of Laboratory (Micro) operations during the course of the investigation. As part of the CAPA file, a comprehensive review of the Manufacturing Areas and Microbiology Laboratory was conducted. The CAPA file documents the Laboratory was ruled out as the source of the OOS in lieu of procedures and practices executed on site for testing and sample preparation. However, this inspection disclosed the Laboratory has no formal procedure for aseptic techniques, procedures for BET test do not include complete documentation of activities conducted during routine tests, and equipment used during routine BET test is not adequately qualified.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Noreen Muniz, Investigator

DATE ISSUED

11/26/2013

Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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2. CAPA #78620 was issued on 11/14/12 to document the effort initiated on site for the assessment of current practices vs. procedures in place, and reports a comprehensive evaluation of all procedures and tests associated to Chem/Micro Laboratories. The CAPA file reports only minimum corrections on BET Testing Method 1034, SOP H7-402 for Depyrogenization of Equipment, and SOP H7-064, Block Heater Operation. However, this inspection disclosed that the before mentioned procedures are not adequate to ensure that all activities conducted for sample testing in accordance with TM1034 are consistently executed and documented.

Inadequate documentation of CAPA activities and results is a repeat observation for the site as reported during FDA inspections conducted in 10/ 2009 and 11/2012.

B. In addition:

Stability failures evaluated on a Validation Assessment conducted on 2013 as reported for lots of [redacted] under Protocol # HSPR06-042, Stability Program for [redacted] in 2010, failed to include a comprehensive evaluation of production data or actions needed (if any) to support product-transfer activities. OOS investigation 08-004/08-010 and CAPA 08-006/08-010 were issued with the original protocol to investigate Shrink Temperature failures reported at 12,24 and 30 months for products claiming a 24-month shelf life with no root cause identified. On 08/22/2013, an Addendum to the Stability Protocol was issued to clarify that the OOS investigations and CAPA files should not have been generated as the shrink temperature tests were conducted for information only and to be documented “as reported”. (Shrink Temperature is a release test for the product and was reported as important to demonstrate that sufficient cross-linking occurred during the manufacturing process to ensure appropriate absorption rate in use.)

OBSERVATION 2

Quality system procedures and instructions have not been established.

Specifically,

Integra World Wide Corporate Guidance # WWCG-005, Stability Guidance for Bovine Collagen Medical Devices, was issued on 07/13 to provide guidance on the Stability Program requiring one lot per product be entered into the program on an annual basis. The local Stability Program procedure H7-014 failed to include the requirement of the annual lot on the stability program, prior to this inspection. Approximately 764 lots of collagen-based medical devices have been released in 2013 and over 300 lots of Collagen Products (including : 510K/Duragen,[redacted] PMA/Helitene, [redacted]) were manufactured after July 2013, but not a single lot of referenced products has entered the stability program prior to this inspection for production executed in 2013. No additional stability data studies for regular (annual production) production are currently ongoing for the referenced products as the firm’s practice is to enter validation lots (if any) on the stability program or to enter one lot per family until expiration-not by production year.

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OBSERVATION 3

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

Not all complaint investigations conducted and documented on site in accordance with approved procedure H7-700, Complaint Investigation, include documented evidence to support findings and conclusions or are investigated consistently. For example, complaint reports of Fever/Discomfort and membrane failures for Collagen products were not always investigated consistently or included tests on retain samples. The results obtained at release were used to support lack of testing (even though the complaint report was received over 2 years after the release date). In addition, the documented justification for not testing retain samples (for complaints reporting fever) was “the reported condition cannot be identified with a visual inspection of the product”. Reference Complaint files: PR ID #92395/2013-07-00087(07/2013); PR ID #96519/2013-09-00182 (09/2013); PR ID #89125/2013-05-00217(05/2013)

Inadequate complaint handling procedures is a repeat observation for the site as reported during FDA inspection conducted 11/2012.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Noreen Muniz, Investigator

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TYPE ESTABLISHMENT INSPECTED

Medical Device Manufacturer

OBSERVATION 4

Procedures to ensure equipment is routinely checked and maintained have not been adequately established.

Specifically,

1. Depyrogenization cycles executed in glassware used by the Microbiology Laboratory for routine Bacterial Endotoxin (BET) Testing of Collagen products (e.g.: Helistat, [redacted] Duragen) and instruments used in manufacturing operations are not adequately validated to ensure that the cycles used on site are reproducible and can in fact remove pyrogens from glassware or parts depyrogenized. For example, the most recent protocol executed on site as described under protocol INPR13-034, Annual Revalidation of Depyrogenization Oven Located in Chemistry Laboratory, dated 03/15/13, was found inadequate as follows:

a. Glassware and Manufacturing equipment intended for de-pyrogenization have never been spiked with endotoxins to confirm that the executed cycle reported as the annual “revalidation” in fact can remove endotoxins from treated units after execution.

b. Holding time for de-pyrogenized glassware and tools has not been challenged to justify the lack of expiration date on loads (items) treated for use during routine BET testing / manufacturing operations or current storage conditions (laboratory space/shelves).

b. No information is included on the protocol or associated procedure to describe the configuration of 50 pieces of glassware including beakers, scissors and lime tubes to justify this as a representative or worst case load, and does not include how the load was charged at the Oven during cycle validation. A similar approach is in place for the manufacturing load (reported as infusion pumps and pressure testers).

c. The reproducibility of the de-pyrogenization cycle is not demonstrated as the firm’s practice is to validate the de-pyrogenization cycles (as described) with a single run at 200 Deg C and a single run at 250 Deg C, each cycle with a different load configuration.

d. No continuous monitoring evidence is maintained during the annual re-validation or during routine cycle execution to confirm if in fact the required temperature was achieved within one hour for the successful execution of de-pyrogenization cycles.

2. The most recent certification of the Laminar Flow Hood CN-1521, used for sample preparation during routine Bacterial Endotoxin Tests (BET) on collagen products (e.g.: Helistat, [redacted] Duragen) was not conducted under routine operational conditions, as documented on 02/2014. The most recent certification was conducted on an empty laminar flow hood, reported as the practice on site. However, during this inspection I observed that routine sample preparation at the same laminar flow hood is conducted at the hood’s edge (less than 6 inches from intake air), and observed a large manifold and a balance inside the hood, which are placed at the working level directly in front of the working area used for the preparation of samples for BET Testing, thus partially blocking Clean Air supplied via HEPA filters at the hood.

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3. The most recent annual qualification of the Block Heater Model 2097.4 used routinely during BET testing (TM1034) on site to maintain samples at a prescribed temperature for testing, and documented on 05/14/13 with protocol INPR13-075, Annual Revalidation of Block Heater located in Microbiology Laboratory, failed to include documented evidence to support the reliability and consistency of the equipment's performance as used during routine operations. The qualification included tests of each of the four heat zones one at a time for a single hour each. However, a visit to the laboratory conducted during this inspection disclosed that all four heat zones are used simultaneously for extended periods of time (over two full shifts or more).

4. Laboratory balance CN0723, OHAUS SP-402, reported for exclusive use for BET testing, is calibrated in accordance with the site's calibration program by an external contractor within the range of 10g to 400g (10,20,100, 400g)) with a single measuring point. However, daily verification activities conducted by the Laboratory in accordance with SOP #H6-007, Balance Calibration Check and Weighing, include the verification of three points, including 0.0g, 1.0g and 400g. No documented evidence is available on site to support the firm's claim of the balance never used under the l00g range. TM 1034,BET Testing Method for Collagen Products, require the use of a composite samples of 2.7g for product Duragen.

OBSERVATION 5

Procedures for finished device acceptance have not been adequately established.

Specifically,

1. Not all activities conducted during testing for Bacterial Endotoxins (BET) conducted on finished products manufactured on site as described on Testing Method 1034 for all Collagen products (e.g.: Helistat, Helitene, [redacted] are fully documented as executed or are fully described on the procedure to ensure test method is executed aseptically and documented consistently. In addition, measurements of pH conducted on sample extracts required by the procedure are not documented or conversion factors conducted for products tested with a sample composite as reported with a formula of grams/volume specifically for Duragen products.

2. Procedure H7-402, Depyrogenization of Equipment, established on site for glassware used for routine BET testing and manufacturing equipment, does not include any instruction on how to operate the only oven available on site at the Chemistry Laboratory (and on site) for this purpose or how to load materials per cycle to ensure that loads are executed as validated. The current procedure does not ensure continuous monitoring activities, or include verification/conversion of oven readings reported on Degrees Fahrenheit on depyrogenization cycles validated at Degrees Celcius.

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Medical Device Manufacturer

3. Procedure H7-064, Block Heater Operation, established on site for the use of Heat Blocks used for routine tests such as Bacterial Endotoxin Testing on Collagen Products (TM1034} does not include specific instructions on how to operate Block Heater 2097.4 to set temperature required for execution (as this heat block model does not include a temperature indicator display or setting).

OBSERVATION 6

Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically,

Procedures for monitoring and testing of production water, reported as Purified Water during this inspection, do not include accurate and consistent identification of sampling points. A review of associated procedures during this inspection (SOP H7-029, Microbiological and Chemical Analysis of Process Water; SOP H7-036, Microbiological and Chemical Millipore Process Water Specification; and SOP# H5-003, Product Water System Operation) disclosed that sampling points' identification in all three documents referring to the same water system do not always match to ensure samples are always collected from the same point during routine monitoring activities.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Noreen Muniz, Investigator

DATE ISSUED

11/26/2013

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct

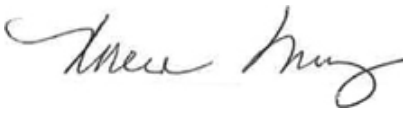
*** DATES OF INSPECTION:**

10/24/20l3(Thu), 10/25/2013(Fri), 10/28/2013(Mon), 10/29/2013(Tue), 11/04/20I3(Mon), 11/05/2013(Tue), 11/06/2013(Wed), 11/07/20I3(Thu), 11/08/2013(Fri), 11/13/2013(Wed), 11/14/2013(Thu), I1/15/2013(Fri), 11/25/2013(Mon), 11/26/2013(Tue)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Noreen Muniz, Investigator



DATE ISSUED

11/26/2013

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

FORM FDA 483 (9/08)