DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	11/19/2018-11/29/2018* FEI NUMBER 3012981036

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Raymond Bray, Vice President of Operations

FIRM NAME	STREET ADDRESS
Belluscura LLC	5504 Democracy Dr.
CITY, STATE, ZIP CODE, COUNTRY Plano, TX 75024	TYPE ESTABLISHMENT INSPECTED 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

The evaluation of potential suppliers was not documented.

Specifically, your firm did not document the evaluation of its suppliers to ensure that all purchased or otherwise received products and services conform to specified requirements.

During an inspection of your firm I observed that in section 7.5.1 of QSP 012-01, Supplier Evaluation Approval, it states that a supplier survey questionnaire (Attachment 2) is sent to the prospective supplier to be completed and sent back to Belluscura before the audit. Mr. Raymond Bray, Vice President of Operations, stated that an attachment 2 was never sent to (b) (4) and (b) (4).

Section 7.5.1 also states that Operations and QA shall determine supplier ratings and either approve or choose not to approve the supplier for use by using the rating system in QSP-012-01. The decision is then required to be documented on the Supplier Summary Rationale form (Attachment 3). Mr. Bray stated that there is no record of an evaluation being done on (b) (4) and (b) (4).

Your suppliers' evaluations were not documented using Attachments 2 and 3 as required by QSP 012-01.

*DATES OF INSPECTION

11/19/2018(Mon), 11/20/2018(Tue), 11/21/2018(Wed), 11/26/2018(Mon), 11/27/2018(Tue), 11/28/2018(Wed), 11/29/2018(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeremy L Stukes, Investigator	X Jeremy L Stukes Investigator Signed By: Jeremy L. Stukes -S Date Signed: 11-29-2018 14:19:58	11/29/2018

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Jeremy L Stukes, Investigator

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Investigator
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Annotations to Observations

Observation 1:

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