DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	9/21/2017-9/29/2017* FEI NUMBER 3007067755

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Wendy A. Strgar, CEO

FIRM NAME	STREET ADDRESS
Good Clean Love, Inc.	207 W 5th Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Eugene, OR 97401-2604	Medical Device Specifications Developer

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

Records of complaint investigations do not include required information.

Specifically,

a. For seven (7) complaint files identified as investigated of 20 complaint files since 2016 reviewed, your firm did not document the lot coding applied to each device, or attempts to obtain this lot coding. Your firm's *Quality System Practices*, section *Complaint Files*, required your firm to document complaint investigations, including any identifying numbers/lot codes/dates for the device.

b. For seven (7) of the reviewed complaint files since 2016 where the customer reported a burning sensation when using one of your firm's devices and provided a lot code for the device, your firm did not document the results of investigation into the device reported by the complainant.

OBSERVATION 2

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

Specifically,

Your firm's *Quality System Practices*, section *Handling of Customer Complaints*, required your firm to evaluate complaints to determine if they require an MDR report. Review of 20 complaints since 2016 for your firm's devices found none of the 20 complaint records documented the evaluation of the complaints to determine if the complaint represented an event required to be reported as an MDR as of 09/21/2017.

OBSERVATION 3

Written MDR procedures have not been developed.

Specifically,

Your firm's *Quality System Practices*, section *Reporting an adverse event to the FDA (death or serious injury)* did not include procedures or requirements for the following as of 09/21/2017:

a. Evaluation, identification, and submission of events which reasonably suggest a device that you market has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to death or serious injury, if the malfunction were to recur.

b. Submission of complete supplemental or follow-up reports within 30 calendar days of obtaining information required to be submitted which was not known or was not available to you when you submitted the initial report.

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c. Submission of complete 5-day reports within 5 work days of receiving a written request for such reports from the FDA.

d. Submission of required reports in an electronic format.

OBSERVATION 4

Procedures for corrective and preventive action have not been adequately established.

Specifically,

a. Your firm's *Quality System Practices*, section *Corrective and Preventive Actions (CAPA),* did not include procedures for the analysis of sources of quality data to identify quality problems other than nonconforming devices as of 09/21/2017.

b. Your firm's *Quality System Practices*, section *Corrective and Preventive Actions (CAPA)*, required verification of each action plan to ensure all tasks are completed and effective. Review of all three (3) corrective and preventive actions identified as implemented since 2015 found that one (1) of three (3) records, initiated 07/09/2015, was not fully implemented and the effectiveness of the activities was not documented as of 09/21/2017. The corrective action dated 07/09/2015 was opened to address an increase in customer complaints from two lot codes of your firm's Almost Naked Personal Lubricant. Your firm identified actions including (b) (4) the pH specification for the device from (b) (4) to (b) (4). Your firm documented that verification included correlating complaints with ongoing check and specifications in batch records, and signed identifying the actions as effective without a date prior to 09/21/2017. Your firm did not document updated production specifications for the Almost Naked Personal Lubricant requiring a range of (b) (4) until 09/21/2017, and did not document analysis of complaints for the Almost Naked Personal Lubricant device correlated to batch records until 09/22/2017.

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OBSERVATION 5

Document control procedures have not been adequately established.

Specifically,

Your firm's *Quality System Practices*, section *Change records*, required your firm document a description of document changes, identification of the documents or labels, the signature of the approving individual(s), the approval date, and when the changes become effective. As of 09/21/2017, your firm had not documented changes to *Quality System Practices*, the signature of the approving individual(s), the approval date, or when the changes became effective since the creation of the document in 2015. Your firm identified changes were made to the document as recently as 09/20/2017. *Quality System Practices* includes your firm's written procedures for corrective and preventive actions, complaint handling, medical device reporting, and design controls.

OBSERVATION 6

Procedures for design change have not been adequately established.

Specifically,

Your firm had not established procedures for design changes as of 09/21/2017, including requirements for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

OBSERVATION 7

Procedures for design input have not been adequately established.

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Specifically,

Your firm's *Quality System Practices*, section *Design input*, identified documenting design inputs on the design plan; these procedures did not include processes for addressing incomplete, ambiguous or conflicting requirements, and do not require documentation of the review and approval of design inputs. Your firm had not documented design input requirements, including the review and approval of the design inputs, for the design of the Restore Moisturizing Personal Lubricant device cleared under K162207 as of 09/21/2017.

OBSERVATION 8

Procedures for design verification have not been adequately established.

Specifically,

Your firm's *Quality System Practices*, section *Design quality procedure*, identified design verification as part of your firm's design process, and required your firm to confirm design specifications and review and approve the design. Your firm had not documented verification of the device design, including confirmation that design outputs met input requirements, for the Restore Moisturizing Personal Lubricant device cleared under K162207 as of 09/21/2017.

OBSERVATION 9

Procedures for design review have not been adequately established.

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Specifically,

Your firm's *Quality System Practices*, section *Design quality procedure*, identified as containing design review procedures, did not include requirements that these reviews include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed as of 09/21/2017. Your firm had not documented a design review for the design of the Restore Moisturizing Personal Lubricant device cleared under K162207 as of 09/21/2017.

OBSERVATION 10

A device master record has not been maintained.

Specifically,

Your firm had not established a device master record for the Restore Moisturizing Personal Lubricant device, first manufactured in June 2015, as of 09/21/2017.

Annotations to Observations

Observation 1:	Reported corrected, not verified
Observation 2:	Reported corrected, not verified
Observation 3:	Reported corrected, not verified
Observation 4:	Reported corrected, not verified
Observation 5:	Reported corrected, not verified
Observation 6:	Reported corrected, not verified
Observation 7:	Reported corrected, not verified
Observation 8:	Promised to correct
Observation 9:	Promised to correct
Observation 10:	Promised to correct

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9/21/2017(Thu), 9/22/2017(Fri), 9/26/2017(Tue), 9/29/2017(Fri)

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