DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	09/22/2010 - 09/23/2010
	FEI NUMBER 3006043611

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Lester E. McCormick, Vice President Operations

FIRM NAME	STREET ADDRESS
Toby's Nose Filters, Inc.	3585 N Courtenay Pkwy Ste 6
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Merritt Island, FL 32953-8121	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 WE OBSERVED:

OBSERVATION 1

Procedures for device history records have not been adequately established.

Specifically, your firm has not established procedures for the compilation of design history files for your nose filter (Class 2) devices.

**** This is a repeated observation from previous FDA 483, Inspectional Observations, dated 04/03/07.**

OBSERVATION 2

A device master record has not been maintained.

Specifically, your firm has not established a device master record for your nose filter (Class 2) devices.

OBSERVATION 3

Procedures for design control have not been established.

Specifically, your firm has not established design control procedures for the manufacture of your nose filter (Class 2) devices.

**** This is a repeated observation from FDA 483, Inspectional Observations, dated 04/03/07.**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Andrea H. Norwood, Investigator Andrea H. Norwood Ashley Segura, Investigator Ashley Segura	09/23/10 09/23/2010 09/23/2010

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OBSERVATION 4

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically, your firm has not established purchasing control procedures for the manufacture of your devices including your nasal filters (Class 2) and nasal dilators (Class 1).

OBSERVATION 5

Procedures for corrective and preventive action have not been established.

Specifically, your firm has not established procedures for corrective and preventive actions for the manufacture of your nasal filters (Class 2) and nasal dilators (Class 1).

**** This is a repeated observation from FDA 483, Inspectional Observations, dated 04/03/07.**

OBSERVATION 6

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

Specifically, your firm has not established procedures for complaint handling for the manufacture of your nose filters (Class 2) and nasal dilators (Class 1).

OBSERVATION 7

Procedures for quality audits have not been established.

Specifically, your firm has not established procedures for quality audits for the manufacture of your nose filters (Class 2) and nasal dilators (Class 1).

**** This is a repeated observation from FDA 483, Inspectional Observations, dated 04/03/07.**

OBSERVATION 8

Written MDR procedures have not been developed, maintained, and implemented.

Specifically, your firm has not established procedures for Medical Device Reporting for the manufacture of your nose filters (Class 2) and nasal dilators (Class 1).

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OBSERVATION 9

Procedures for management review have not been established.

Specifically, your firm has not established management review procedures for the manufacture of your nose filters (Class 2) and nasal dilators (Class 1).

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	Andrea H. Norwood, Investigator Ann H. Norwood Ashley Segura, Investigator Ashley Segura	09/23/10 09/23/2010 09/23/2010