**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 109 Holton Street<br>Winchester, MA 01890<br>(781)587-7500 Fax:(781)587-7556<br>oradevices1firmresponse@fda.hhs.gov | 7/30/2024-8/2/2024 |
| | FEI NUMBER<br>3009582362 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott F. DeFelice, CEO & Chairman

| FIRM NAME | STREET ADDRESS |
|---|---|
| Oxford Performance Materials, Inc. | 30 S Satellite Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| South Windsor, CT 06074-3445 | 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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically,

Your firm's procedure "Medical Device Reporting", QMSP-1041, Rev. C, Section 5.1.4 states to submit any 5 day or 30-day MDRs as soon as possible within the required 5 or 30 calendar day timeframe. A review of all MDRs submitted since the last inspection conducted in 2017 revealed that the following MDRs were submitted past the 30-day reporting time frame as required per 21 CFR 803 and your firm's procedure.

| Complaint # | Aware Date: | MDR Submission date: | # of days to Submit MDR | # of days late: |
|---|---|---|---|---|
| 200609PI01 | 06/09/2020 | 07/23/2020 | 44 | 14 |
| 200615PI01 | 06/15/2020 | 08/14/2020 | 60 | 30 |
| 221027PI01 | 10/27/2022 | 12/01/2020 | 35 | 5 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 109 Holton Street<br>Winchester, MA 01890<br>(781)587-7500 Fax:(781)587-7556<br>oradevices1firmresponse@fda.hhs.gov | 7/30/2024-8/2/2024 |
| | FEI NUMBER<br>3009582362 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott F. DeFelice, CEO & Chairman

| FIRM NAME | STREET ADDRESS |
|---|---|
| Oxford Performance Materials, Inc. | 30 S Satellite Rd |
| CITY, STATE, ZIP CODE, COUNTRY<br>South Windsor, CT 06074-3445 | TYPE ESTABLISHMENT INSPECTED<br>Manufacturer |

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Katarzyna Plona, Investigator

X Katarzyna Plona
Investigator
Signed By: Katarzyna Plona -S
Date Signed: 08-02-2024
09:34:08

DATE ISSUED
8/2/2024

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 109 Holton Street<br>Winchester, MA 01890<br>(781)587-7500 Fax:(781)587-7556<br>oradevices1firmresponse@fda.hhs.gov | 7/30/2024-8/2/2024 |
| | FEI NUMBER<br>3009582362 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Scott F. DeFelice, CEO & Chairman

| FIRM NAME | STREET ADDRESS |
|---|---|
| Oxford Performance Materials, Inc. | 30 S Satellite Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| South Windsor, CT 06074-3445 | Manufacturer |

## Annotations to Observations

Observation 1: Promised to correct

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Katarzyna Plona, Investigator | X Katarzyna Plona<br>Investigator<br>Signed By: Katarzyna Plona -S<br>Date Signed: 08-02-2024<br>09:34:08 | 8/2/2024 |

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."