DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	6/2/2026-6/3/2026
	FEI NUMBER 3008654268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David M. Holch, Quality Manager

FIRM NAME	STREET ADDRESS
Pregis Protective Films & Coatings LLC	515 Enterprise St
CITY, STATE, ZIP CODE, COUNTRY Aurora, IL 60504-8143	TYPE ESTABLISHMENT INSPECTED Contract 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

One or more processes for risk management in product realization have not been adequately documented.

Specifically, your organization manufactures the (b) (4) and failed to maintain risk management documentation. The following was not documented:

a. Your organization does not have a risk management procedure that details the risk management activities to be conducted throughout the lifecycle of your (b) (4) that identifies the criteria for risk acceptability and methods to determining severity of harm and probability of occurrence.
b. Your organization did not conduct a risk assessment of the (b) (4) that identified potential hazards and product impact associated with the device and the manufacturing process under normal and reasonably foreseeable misuse conditions. Your organization also did not document risk control measures to reduce risk to acceptable levels.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shawn Choi, Investigator X Shawn Choi Investigator Signed By: 2004265134 Date Signed: 06-03-2026 11:40:05	6/3/2026

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shawn Choi, Investigator X Shawn Choi Investigator Signed By: 2004265134 Date Signed: 06-03-2026 11:40:05	6/3/2026

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."