DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/3/2026-3/6/2026
	FEI NUMBER 3022069968

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mandeep Singh, Global Patient Safety

FIRM NAME	STREET ADDRESS
Ascendis Pharma LLC	1000 Page Mill Rd
CITY, STATE, ZIP CODE, COUNTRY Palo Alto, CA 94304-1019	TYPE ESTABLISHMENT INSPECTED PADE

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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of the information.

Specifically,

On 13 Jun 2025, the firm received a spontaneous consumer report (case (b) (6)) describing hospitalization following Yorvipath use. The firm's own triage, completed 16 Jun 2025, identified the case as serious (hospitalization), unexpected, and expedited. The firm subsequently classified case (b) (6) as non-valid on the basis that no patient identifier was available. The firm's own case narrative documented a single patient's sequential 12-day clinical course including laboratory values, emergency care at a hospital, and inpatient treatment — meeting the threshold for an identifiable patient. No 15-day expedited report was submitted to FDA for case (b) (6)

Furthermore, internal firm correspondence dated 18 Jun 2025 confirms that the firm applied the same non-valid classification collectively to three additional adverse event reports from the same social media source, each previously identified by the firm's own operations team as individual patient adverse event reports, on the basis of absent reporter email address and patient details — without individual medical review of each case.

OBSERVATION 2

There are no written procedures for the surveillance, receipt, evaluation and reporting of post-marketing adverse experiences to FDA.

Specifically,

No written procedures to ensure systematic surveillance, receipt, and reporting of post-marketing adverse experiences identified through social media monitoring to FDA for SKYTROFA and YORVIPATH.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Scott N Lim, Consumer Safety Officer Kristin M Abaonza, Investigator X Scott N Lim Consumer Safety Officer Signed By: 2002619245 Date Signed: 03-06-2026 14:48:34	3/6/2026

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X Kristin M Abaonza
Investigator
Signed By: KRISTIN M. ABAONZA -S
Date Signed: 03-06-2026 14:51:29

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Scott N Lim, Consumer Safety Officer
Kristin M Abaonza, Investigator

X Scott N Lim
Consumer Safety Officer
Signed By: 2002619245
Date Signed: 03-06-2026 14:48:34

DATE ISSUED
3/6/2026

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."