

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

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718) 662-5661 ORABIMOE.Correspondence@fda.hhs.gov	DATE(S) OF INSPECTION 9/12/2022-9/15/2022
	FEI NUMBER 3009518416

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Sudhakar R Vidiyala, President and Chief Executive Officer

FIRM NAME Ascent Pharmaceuticals Inc	STREET ADDRESS 400 South Technology Drive
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CITY, STATE, ZIP CODE, COUNTRY Central Islip, NY 11722-4402	TYPE ESTABLISHMENT INSPECTED Corporate Headquarters
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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 I OBSERVED:  
OBSERVATION 1**

An application holder did not maintain a Support / Call Center or a REMS Program website, as required by your approved REMS Implementation System.

Specifically, you failed to include a REMS-specific link on your product website, <https://ascentpharm.com/products>, to the REMS Program website, [www.opioidanalgesicrems.com](http://www.opioidanalgesicrems.com).

For example, your REMS Document (09/2018), section III REMS Requirements, states “To support REMS Program operations, Opioid Analgesic Applicants must: 1. Establish and maintain a REMS Program website, [www.opioidanalgesicrems.com](http://www.opioidanalgesicrems.com). ... All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website.” However, your product website, which contains all nine products covered, <https://ascentpharm.com/products>, did not include prominent REMS-specific links to the REMS Program website, [www.opioidanalgesicrems.com](http://www.opioidanalgesicrems.com).

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Tyanna N Hadley, Investigator	<small>Tyanna N Hadley Investigator Signed By: Tyanna N. Hadley -S Date Signed: 09-15-2022 17:02:17</small> X _____	DATE ISSUED 9/15/2022

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."