COPY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Carolyn Renshaw, Building 71 Rm. 4042 Telephone: (240) 402-7343 Industry Information: www.fda.gov/oc/industry	11/06/2023 to 11/10/2023
	FEI NUMBER 1000110954

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jon Tucker, Site Leader

FIRM NAME	STREET ADDRESS
Wyeth Pharmaceutical Division of Wyeth Holdings LLC	4300 Oak Park Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sanford, NC 27330	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.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. There is no (b) (4) test on the incoming starting material (b) (4) used for the manufacturing of Fidanacogene Elaparvovec.

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Add Continuation Page

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SEE REVERSE OF THIS PAGE

EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
JieHe, Lead CSO Kevin Matthews, CSO Jianyang Wang, Biologist Ronit Jolles-Mazor, Senior Staff Fellow	11/10/2023