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: Jay Eltermann, Building 71, Room 6038 Telephone: (240) 402-9168 Industry Information: www.fda.gov/oc/industry	3-7 April 2017
	FEI NUMBER 3010353512

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Spencer Fisk

FIRM NAME	STREET ADDRESS
Novartis Pharmaceuticals Corporation	220 East Hanover Ave
CITY, STATE AND ZIP CODE Morris Plains, NJ 07959 USA	TYPE OF ESTABLISHMENT INSPECTED Gene Therapy Product Manufacturing Facility

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. Process validation for CTL-019 manufacturing (b) (4) was incomplete at the time of the inspection. Specifically,

a. The process performance qualification (PPQ) study was based on clinical batches made before the commercial process(es) were defined in the commercial master batch record (MBR).

b. Changes made to the commercial manufacturing process were not evaluated during validation including, but not limited to the following:
i. (b) (4) were not part of the PPQ study;
ii. Methods used in the PPQ study were not the same as those specified in the commercial batch record; specifically, (b) (4)

c. Hold steps are not defined in the Master Batch Record (e.g., (b) (4) (b) (4)

2. Deviations were not initiated for numerous action level excursions for microbial monitoring of (b) (4) operators during Q1-Q3, 2016 as documented in trending report (b) (4) for that period. The excursions were not investigated and the root causes were not determined.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Randa Melhem, PhD, CSO (Lead) Joan Johnson, CSO Ashley Burns, Reg. Officer Denise Gavin, PhD, Supervisory Biologist Xiaobin (Victor) Lu, PhD, Biologist	04/07/2017

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 judgement, 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."