

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA/CBER/OCBQ/DMPQ 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Carolyn Renshaw, Building 71 Room 4042 Telephone: 240.402.7343 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 05/01/2023-05/05/2023
	FEI NUMBER 3008455069

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Lisa McClintock, Vice President / Site Head**

FIRM NAME Bristol Myers Squibb (BMS)	STREET ADDRESS 38 Jackson Road
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CITY, STATE AND ZIP CODE Devens, Massachusetts 01434	TYPE OF ESTABLISHMENT INSPECTED Drug Product Manufacturer
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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) (WE) OBSERVED:

The quality system failed to fully investigate all manufacturing deviations and component failures.

Specifically, between 07/01/2022 and 12/31/2022, 337 deviations were reported as no impact. These deviations were associated with (b) (4) leaks, deviation from procedures, (b) (4) disconnection from (b) (4) equipment excursions, environmental monitoring excursions, among others. Since the Quality Unit assessed these deviations as no impact they failed to investigate the root causes in order to address with the appropriate corrective and preventative actions. Although these deviations were trended for area or department, the possibility of a shared root cause and potential trend was not identified.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) ZHONGREN WU, CSO Nirjal Bhattacharai, Branch Chief Greerme Price, Lead Biological Res. Viviana Ramirez, CSO	DATE ISSUED May 5, 2023
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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."