

**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: www.fda.gov/oc/industry	DATE(S) OF INSPECTION February 22- March 02, 2023
	FEI NUMBER 1000630279

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Amir London, Chief Executive Officer

FIRM NAME Kamada Ltd.	STREET ADDRESS Beit Kama
CITY, STATE AND ZIP CODE MP Negev, Israel, 8532500	TYPE OF ESTABLISHMENT INSPECTED Drug substance and Drug Product 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. Adequate process validation for (b) (4) used during the (b) (4) step was not performed. Failure to validate (b) (4) for (b) (4) resulted in mishandling of (b) (4) (b) (4) improper assembly and disassembly of the (b) (4) insufficient (b) (4) (Deviation MDR-42123).

2. Internal SOPs, recommendations of the equipment's manufacturer and process control procedures in execution of various production and process control functions are not followed, and non-validated "amended" procedures are used when equipment and processes fail. No data package is sent to FDA/CBER to demonstrate that safety, purity, potency, and effectiveness of product manufactured using these amended processes are equal to or greater than product manufactured by the licensed process. Specifically,

a. During Cytogam manufacturing run, non-qualified (b) (4) to the (b) (4) step during manufacturing of the lot (b) (4) led to about (b) (4) and difficulties in sample collection. The impact of this unqualified amended procedure on the manufacturing process has been insufficiently evaluated.

b. The unvalidated fourth version of the (b) (4) in the Production of Cytogam" SOP (b) (4) was used during the manufacturing of the PPQ lots (b) (4) while the unvalidated fifth version of this SOP with major revisions including (b) (4) (b) (4) procedure of the (b) (4) was used to manufacture the PPQ lot (b) (4). The impact of these changes on the manufacturing process have not been validated.

c. After (b) (4) at the (b) (4) resulted in (b) (4) failing (b) (4) to reach the (b) (4) (a critical parameter), the (b) (4) was approved to proceed to the next stage during manufacturing of the (b) (4) PPQ lot (Deviation MDR-43906). The impact of this amended procedure on the manufacturing process has been insufficiently evaluated, and no CAPA was issued.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE /s/	EMPLOYEE(S) NAME AND TITLE (Print or Type) Pete Amin, Consumer Safety Officer Prajakta Varadkar, Biological Reviewer Olga Simakova, Biologist	DATE ISSUED 02/03/2023
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3. Facilities are not in state of good repair. For example

a. Twenty incidents of power outages were noted in last three years caused by incidents within the company including a recent power outage noted January 2023. As of this inspection, preventive actions including (b) (4) (b) (4) are still pending.

b. There were multiple incidents of water leaks (the number of leaks were 11 in 2021 and 4 in 2022) that penetrated the production areas. Several Corrective and preventive actions (CAPA) were taken to address the issue. However, two leakage incidents occurred again in January 2023. The completion of the repair of the (b) (4) (b) (4) to prevent rain penetration preventive actions are pending as of this inspection.

c. There are twenty pressure differential excursion related deviations documented (last two years) in the production areas, one of the root causes was operators not closing the production areas door properly or blocking the air shutter in the vial preparation room. CAPA 46034 was open on 03/02/2023 during this inspection.

4. During observation of aseptic filling setup procedure, the followings were noted in filling suite (b) (4) (room (b) (4)):

a. Product spill incident during PPQ (b) (4) run required an additional intervention in the critical filling areas including removal of glass bottles, cleaning the product spill, and cleaning the filling areas (2022). (b) (4) additional media fill study were performed in 2022, however these additional interventions was not captured as part of the several media fill study performed after this incident in 2022.

b. The trash bin partially blocked the air return grill, filling suite used (b) (4) of recirculating air.

c. Current routine monitoring procedure for the critical areas during aseptic filling setup does not include the monitoring during (b) (4) connection to product transfer line. Firm initiated a CAPA during last day of this inspection.

5. Failure to establish adequate written procedures for the labelling of the (b) (4) (drug substance) to assure the proper labelling and to prevent mix ups of the drug substance stored in multi-product facility.

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Specifically, Form TR-P-518, (b) (4) - Final Concentration in (b) (4) and (b) (4),
ver 20, Effective Date: March 15, 2021, does not include sufficient instructions for completing the label, such as
circling or making the name of the (b) (4) product.

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PAGE

EMPLOYEE(S) SIGNATURE

/s/

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Pete Amin, Consumer Safety Officer
Prajakta Varadkar, Biological Reviewer
Olga Simakova, Biologist

DATE ISSUED

02/03/2023

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."