DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	2/9/2026-2/12/2026
	FEI NUMBER 3002807038

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Anne Sjoerd Hoekstra, Plant Manager Gamma Ede

FIRM NAME	STREET ADDRESS
Synergy Health Ede BV	Morsestraat 3
CITY, STATE, ZIP CODE, COUNTRY Ede, Gelderland, 6716 AH Netherlands	TYPE ESTABLISHMENT INSPECTED Gamma Sterilizer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Production and service provision was not adequately planned, carried out, monitored, and controlled to ensure that product conforms to specification.

Specifically, the production control and monitoring procedures do not ensure that product conforms to specifications. The firm does not have adequate controls in place to identify manual entry errors that may occur during the booking of the Gamma processing run, for the received product, by the order entry operators into the ODMS system, to prevent the setup of the product to incorrect specification, resulting in underdose or overdose treatment of the product. There are no controls in place after booking/ product set to ensure the correct product specifications were selected and the product has been treated per associated validated process and specifications. The products are released based on auto batch release without any further checks or verification of product specification and set up information. The Certificate of Processing is automatically sent by the ODMS system via email to the customer and the warehouse to release the product for distribution.

OBSERVATION 2

Procedures for timely complaint handling do not adequately include requirements and responsibilities for receiving and recording information.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Maryam Tabatabaie, Investigator X Maryam Tabatabaie Investigator Signed By: MARYAM TABATABAIE -S Date Signed: 02-12-2026 11:26:47	2/12/2026

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Specifically, the complaint handling procedure does not adequately ensure that the complaints are adequately investigated and evaluated to determine the need to initiate corrections and corrective actions. The firm failed to adequately investigate and implement corrective/ preventive actions after they became aware of Customer Complaint CN-032607 involving incorrect processing specifications used for the associated product. The customer in the Netherlands reported that they had received and distributed under dosed products that were treated with incorrect Gamma dose range.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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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 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."