

# ENZYMOTEC LTD.

## **FORM 6-K** (Report of Foreign Issuer)

Filed 05/10/17 for the Period Ending 05/10/17

Telephone	972747177177
CIK	0001578809
Symbol	ENZY
SIC Code	2833 - Medicinal Chemicals and Botanical Products
Industry	Commodity Chemicals
Sector	Basic Materials
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 6-K**

**Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
under the Securities Exchange Act of 1934**

**For the month of May 2017**

**Commission File Number: 001-36073**

**ENZYMOTEC LTD.**

(Translation of registrant's name into English)

**Sagi 2000 Industrial Area  
P.O. Box 6  
Migdal Ha'Emeq 2310001, Israel**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F       Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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Enzymotec Ltd. (the “**Company**”) is issuing this Form 6-K to inform the market of certain regulatory developments, including the recent inclusion of certain of its products on Import Alert# 66-41 (the “**Import Alert**”) issued by the U.S. Food and Drug Administration (the “**FDA**”).

On May 5, 2017, the FDA issued an Import Alert called “Detention Without Physical Examination of Unapproved New Drugs Promoted In The U.S.” that included the Company’s Vayarol®, Vayarin® and Vayacog® products, which are labeled and sold as “medical foods” in the United States (the “**Products**”). In addition, on May 9, 2017, the Company became aware that following a facility inspection held during August 2016 at the facilities of a supplier to the Company such supplier received a warning letter from the FDA, on May 4, 2017. The warning letter referenced Vayarin® as well as products of other manufacturers, alleging that Vayarin® is a “new drug” within the meaning of Section 201(p) of the Federal Food, Drug, and Cosmetic Act.

The Company remains committed to its medical food business in the United States and believes that the science and evidence behind its Products support their labeling, claims and regulatory classification. As indicated by the Company in its annual report on Form 20-F filed on March 16, 2017, there exists a risk that the FDA may take the position that one or more of the Products is not eligible to be classified as a “medical food.” The Company recognizes the trust that doctors and customers have placed in its Products. The Company is prepared to defend its position that the Products are properly sold as “medical foods” and are not subject to the drug provisions of the law, and intends to engage in discussions with the FDA as soon as possible to understand the reasoning for the agency’s action and affirm the classification of the Products as “medical food,” while continuing its U.S. activities and the sales of its Products.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**EYZMOTEC LTD.**

Dated: May 10, 2017

By: /s/ Oren Bryan

Name: Oren Bryan

Title: Chief Financial Officer

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