



FDA U.S. FOOD & DRUG
ADMINISTRATION

August 5, 2019

Mr. David Scott
Senior Director Commercial Services
Hologic Ltd.
Appleton Place, Appleton Parkway
Livingston, West Lothian, EH54 7EZ
United Kingdom

Dear Mr. Scott:

The Food and Drug Administration (FDA) acknowledges receipt of your letter dated April 11, 2019, which responds to the Form FDA 483, issued at the conclusion of the March 7, 2019 through March 11, 2019, FDA inspection of Hologic Ltd. located in Livingston, United Kingdom.

Your response and proposed corrective actions have been reviewed by FDA and appear adequate. Your response will be placed in your firm's permanent file, and corrective actions will be reviewed and assessed during the next inspection.

Sincerely,

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

cc:

Scott Wadsworth
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Somerset, NJ 08873

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