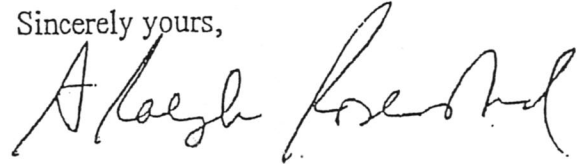


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If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and Radiological Health

FDA 0 0055