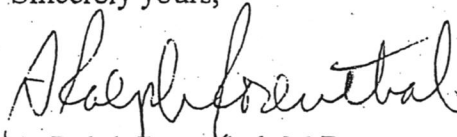


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If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

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

Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear, Nose and
Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

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