September 21, 2018

Opternative

Dear Keisha:

Opternative would find the following statement acceptable with respect to its current Denovo application currently under review at FDA.

We trust that this will be acceptable to FDA and that this statement appear on FDA's website in conjunction with the Warning Letter.

While Opternative did receive a Warning Letter from the Office of Compliance dated October 30, 2017 with reference to CMS# 532477, the company promptly responded. Opternative worked closely with the FDA to meet all regulatory requirements for full compliance and has an approved IDE which permitted it to conduct a clinical trial in close consultation with the FDA. This clinical trial was completed well ahead of the FDA's requested timeline. Opternative's DeNovo application is currently under review by FDA which is expected to be completed soon.

I look forward to hearing from you.

Steven

Steven Lee, Founder & Chief Science Officer

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