

January 31, 2019

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Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: Docket Nos. FDA-2017-E-3592 and FDA-2017-E-3616

**CITIZEN PETITION (REDACTED)**

The undersigned (“Petitioner”) submits this petition under 21 CFR 60.30(a) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to initiate an investigation by FDA of whether the Applicant for patent extension for the Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System acted with due diligence during the regulatory review period. See Docket Nos. FDA-2017-E-3592 and FDA-2017-E-3616.

All supplemental materials accompanying this submission are part of the unredacted citizen petition and this information must be treated as confidential. The unredacted citizen petition cannot be entered into the public docket because [REDACTED]

A final determination that the Applicant did not act with due diligence during the Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System regulatory review period is warranted for these reasons:

[REDACTED]

[REDACTED]

[REDACTED]

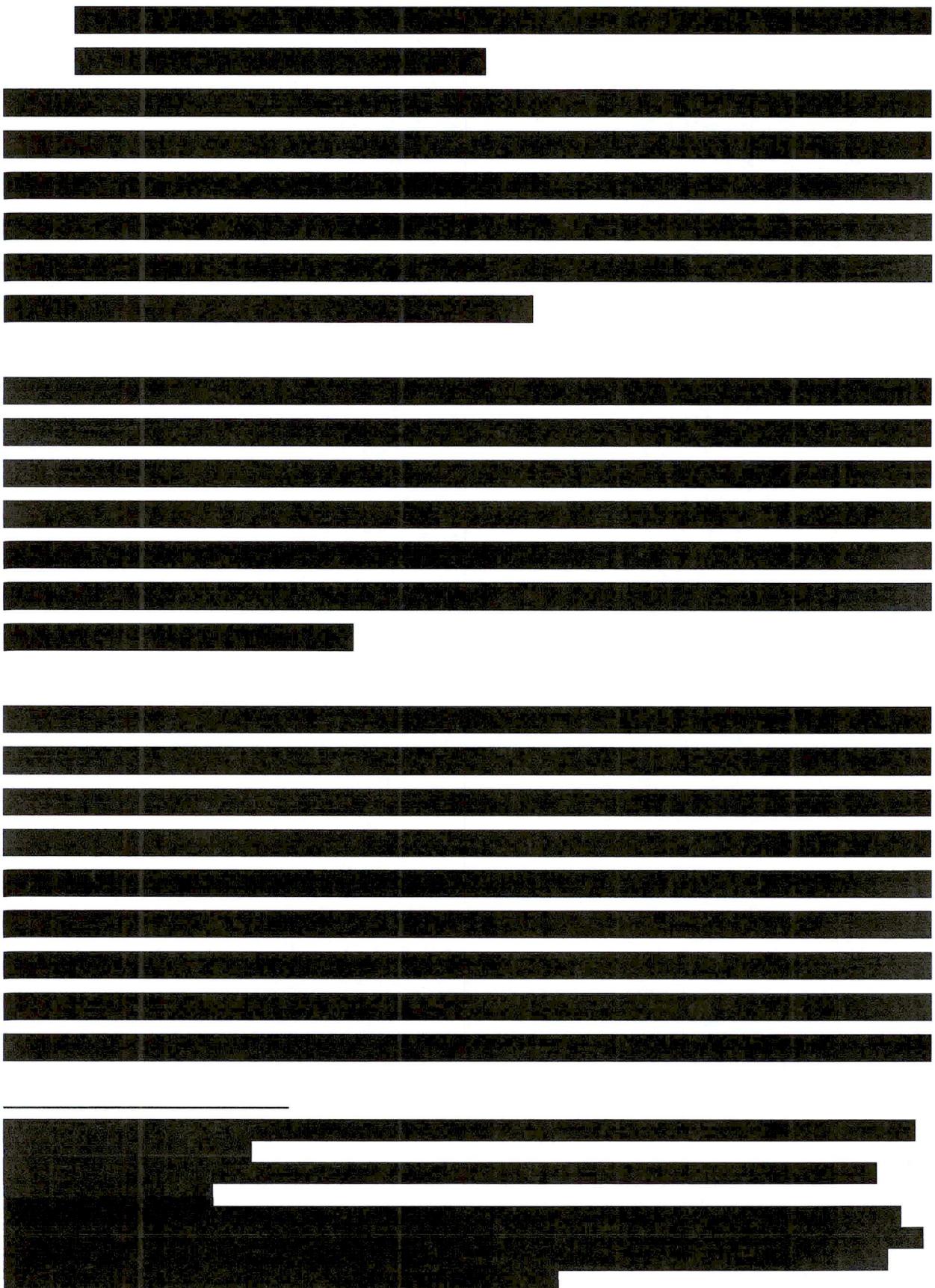
[REDACTED]

[REDACTED]

[REDACTED]

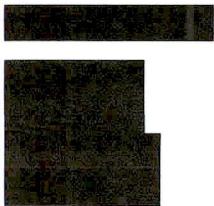
[REDACTED]

Petitioner provides a detailed explanation and supporting evidence for each of these allegations within this in the paragraphs that follow.



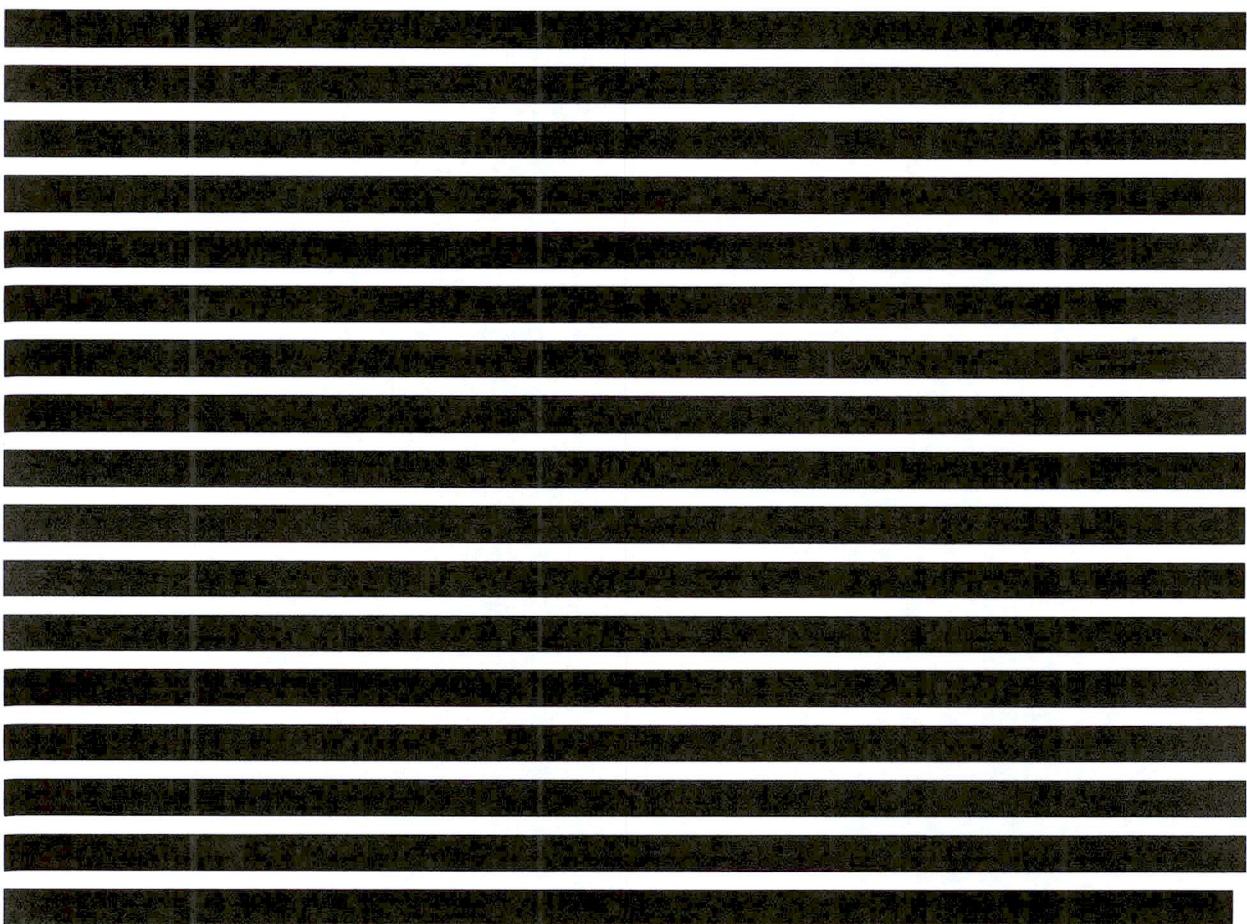
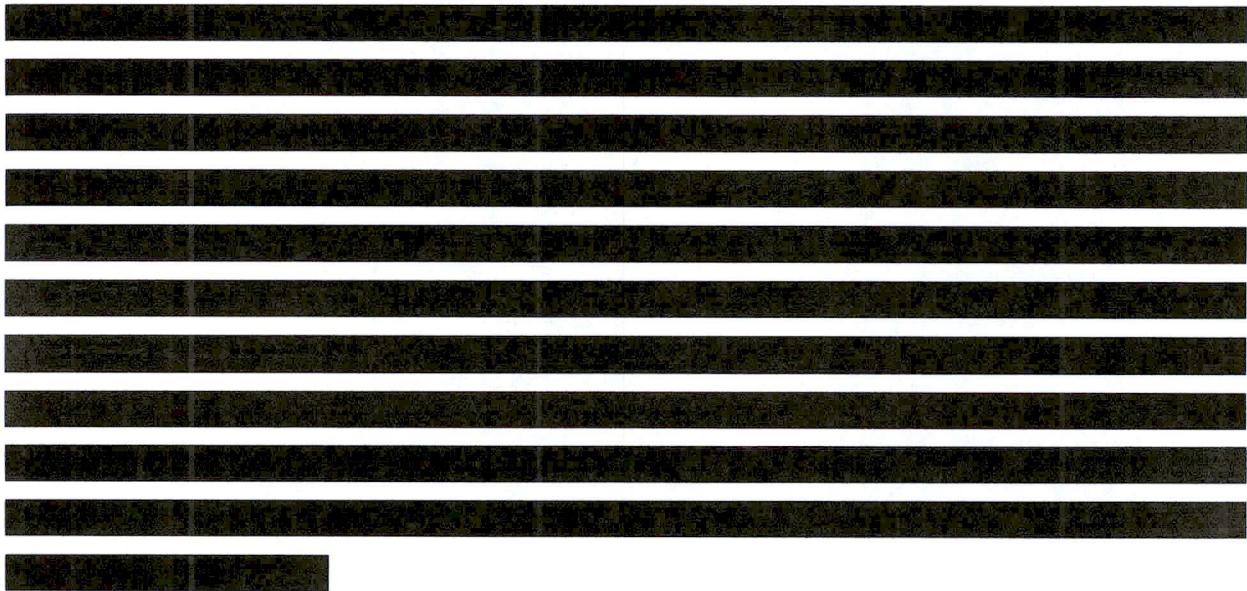
The image consists of a vertical stack of twelve horizontal black bars. Each bar has a small, thin white rectangular label positioned in the upper right area. The labels appear to be identical across all bars.

A series of five horizontal black bars, each containing a small amount of white noise or dust specks.



A horizontal strip of dark fabric with a subtle, repeating geometric pattern.

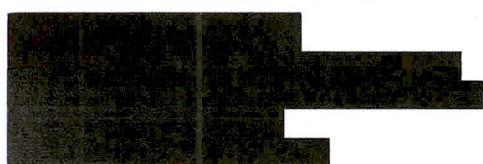




This image shows a horizontal strip of dark-colored fabric or material with a subtle, repeating geometric pattern. The pattern consists of small, light-colored shapes that create a textured, almost embossed effect across the surface. The overall appearance is that of a decorative or functional textile element.

The image consists of six horizontal panels, each showing a dark, textured surface with some very faint, illegible markings. The markings appear to be bleed-through from the reverse side of the paper, possibly from a printed page. The text is too faded to be read accurately.

The image consists of a sequence of eleven horizontal black bars of varying widths, set against a white background. The bars are arranged vertically, with the first bar at the top and the last bar at the bottom. The widths of the bars decrease from left to right, creating a visual effect similar to a digital signal or a noise pattern. The bars are thin and dark, making them stand out against the white background.



### III. CONCLUSION

The regulations at 21 CFR 60.36(b) plainly state:

*“For purposes of this part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant or applicant for patent term restoration shall be imputed to the applicant for patent term restoration.”*

[REDACTED]

[REDACTED]

[REDACTED]

The United States Supreme Court says that “the decision to grant a patent is a matter involving public rights—specifically, the grant of a public franchise.”<sup>12</sup> [REDACTED]

[REDACTED]

[REDACTED] For these reasons, a final determination that the Applicant did not act with due diligence during the regulatory review period is warranted and Applicant’s patent extension request for the Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System should be denied in its entirety.

#### **IV. OTHER REQUIRED INFORMATION**

##### **A. Environmental Impact**

The action requested in this petition is subject to categorical exclusion under section 25.30, 25.31, 25.32, 25.33, or 25.34 of Code of Federal Regulations Title 21 or an environmental assessment under section 25.40 of Code of Federal Regulations Title 21.

##### **B. Economic Impact**

Pursuant to 21 C.F.R. § 10.30, an economic impact statement will be submitted upon request of the Commissioner following review of the petition.

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<sup>12</sup> See slip op. *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 584 U.S. \_\_\_\_ (2018)

D. Certificate of Service on the Applicant for patent extension

The undersigned certifies, that Petitioner served a true and complete copy of the petition upon the Applicant by certified US mail (return receipt requested) on [REDACTED]  
to this address:

Mark Lupkowski  
Registration No. 49,010  
Attorney of Record  
275 Battery Street Suite 2600  
San Francisco, CA 94111

[REDACTED] \_\_\_\_\_ (Signature)  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]