



MAY 30 2019

Mr. C. Michael Kendall
Sr. Associate General Counsel
American Dental Association
211 East Chicago Avenue
Chicago, IL 60610

Re: Docket Number FDA-2019-P-2038

Dear Mr. Kendall:

This letter responds to your request, dated April 25, 2019, in which you seek an injunction against SmileDirectClub, LLC (SCD) from manufacturing, distributing, or selling in interstate commerce SCD's plastic teeth aligner and dental impression material products. Requests for the agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures. *See* Title 21, Code of Federal Regulations (CFR), 10.30(k). Such matters are within the discretion of the agency.

Therefore, we are denying your request that FDA initiate enforcement action against the devices and conduct that you have alleged. An agency denial of a request to take enforcement action does not constitute final administrative action. *See* 21 CFR 10.45.

We appreciate the information that you provided. Such information is often helpful for us to identify problems with marketed products and possible violations of the laws and regulations that we enforce. We take complaints seriously, and we will evaluate this matter to determine what follow-up action is appropriate. Decisions with respect to initiating enforcement actions are generally made on a case-by-case basis.

Sincerely,

Jeffrey Shuren, MD, JD
Director

Center for Devices and Radiological Health