



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 26, 2019

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

Sent via email to: kendallc@ada.org

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the FD seek pursuant to FD&C Act § 302(a) [21 U.S.C. §332(a)], an injunction against SDC from manufacturing or continuing to manufacture and from continuing to distribute and sell in interstate commerce SDC's plastic teeth aligner and dental impression material products. Absent such an injunction there is a likelihood that SDC's misbranding violations will continue was received by this office on 04/25/2019.

It was assigned docket number FDA-2019-P-2038. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)

