



Transforming smiles, changing lives.

**FOIA Confidential Treatment Requested by Align Technology, Inc.
Pursuant to 17 C.F.R. §200.83**

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Securities & Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549

May 25, 2022

Attention: Ms. Christie Wong
Mr. Michael Fay

Re: Align Technology, Inc.
Form 10-K for the Fiscal Year Ended December 31, 2021
Filed February 25, 2022
File No. 000-32259

Dear Ms. Wong and Mr. Fay:

On behalf of Align Technology, Inc. (“Align”), I respectfully submit this letter in response to the comment from the staff (the “Staff”) of Securities and Exchange Commission (the “Commission”) received by letter dated April 29, 2022, issued in response to Align’s letter dated April 21, 2022, in response to the Staff’s initial comment letter dated March 31, 2022, all relating to Align’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the “Form 10-K”) filed with the Commission on February 25, 2022.

In this letter, Align has recited the comment from the Staff in italicized, bold type and has followed the comment with Align’s response. Capitalized terms used but not defined herein shall have the meanings ascribed thereto in the Form 10-K, as applicable.

Align is requesting confidential treatment for certain figures included in Align’s response to the Staff’s comment, which have been redacted and replaced with bracketed asterisks (“[***]”). Pursuant to Rule 83 of the Commission’s Rules on Information and Requests (17 C.F.R. §200.83), Align has provided the unredacted response to the Staff under separate cover and a separate letter to the Office of Freedom of Information and Privacy Act Operations in connection with the confidential treatment request.

Form 10-K for the Fiscal Year Ended December 31, 2021

Consolidated Financial Statements

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- 1. We have reviewed your response to prior comment 1 and note that you estimate usage, which requires significant judgment. For each of the periods presented, please tell us your estimated usage rates. If multiple types of estimated usage rates are used, please explain how these were determined. In addition, tell us the approximate impact to revenue from any period over period changes in estimated usage rates.***

Response:

Align offers our Invisalign system in a variety of treatment packages which treat different severity levels of malocclusion. The packages consist of an initial set of aligners that are capable of completing the approved treatment, and for most packages, also include the option to order additional aligners if the patient's treatment deviates from the original treatment plan.

The number of optional additional aligners included in the list price and the time allowed for additional aligner order submission are defined in the terms and conditions for each product which vary by region and country.

Align has the historical experience to estimate the number of additional aligners that will be requested by our customers, which include General Practitioner dentists and Orthodontists (collectively "doctors"). The usage rate is the average number of additional aligners orders requested for each treatment and is expressed as a percentage. For example, if two additional aligners orders are delivered on average for each set of initial aligners, the usage rate is 200%.

To determine usage rates on a quarterly basis, we begin with historical information regarding the average number of additional aligners requested by doctors for treatments. We establish usage rates based on products with similar terms and conditions. In addition, we review usage rates by region, country, and doctor channels to identify if there are significant differences in usage behavior. More details about our approach by product type are discussed below:

Invisalign Comprehensive

The Invisalign Comprehensive product is used to treat a wide spectrum of mild to severe malocclusion and includes the option to order an unlimited number of additional aligners for a period of five years after the initial aligner shipment. To determine the estimated Invisalign Comprehensive additional aligner usage rates, we review the historical additional aligner usage over a five-year period from the initial aligner shipment. Five years is used since this is the length of time defined in the terms and conditions when an additional aligner order can be submitted. The number of additional aligner orders associated with each initial aligner shipment is tracked to identify customer behavior trends.

In addition to the quarterly review of existing rates, we periodically review if certain regions, countries and/or doctor channels have significantly different additional aligner usage behavior that may require new estimated usage rates to be established. As an example of a geographic difference, Japan Comprehensive has its own usage rate since doctor behavior there is different from the rest of the APAC region. In addition, we identified differing usage rate trends between our two main North American doctor channels: Orthodontists and General Practitioner dentists. Therefore, we have established six usage rates for Invisalign Comprehensive based on these identified characteristics.

Invisalign First Phase I and Invisalign First Comprehensive Phase 2

Invisalign First Phase I is specifically designed for younger patients between the ages of seven and ten years and provides early interceptive orthodontic treatment. The product includes the option to order an unlimited number of additional aligners within 18 months of shipment of the initial aligners. Invisalign First Comprehensive Phase 2 is complementary to First Phase I and is generally consistent with our Invisalign Comprehensive product. It includes the option to order an unlimited number of additional aligners within three years of shipment of the initial aligners.

To determine these estimated usage rates, we reviewed historical information for the length of time when an additional aligner can be submitted, 18 months and three years, respectively. Since doctor behavior was similar among all regions, countries, and channels, we established a global usage rate for each of Invisalign First Phase I and Invisalign Comprehensive Phase 2.

Non-Comprehensive Invisalign

Our non-comprehensive products are for less complex orthodontic cases, non-comprehensive relapse cases, or straightening prior to restorative or cosmetic treatments and include our Invisalign Express, Lite, Go, Go Plus, and Moderate products. The availability of the products, the number of additional aligners that are included in the list price, and the timing of additional aligner order submission can vary and are determined by regional and country terms and conditions. These product offerings generally provide the option to obtain one or two sets of additional aligners within a period of six months to three years from the initial aligner shipment.

To establish estimated usage rates for the non-comprehensive products, we reviewed historical trends for the length of time that an additional aligner order can be submitted. We noted that doctor behavior was generally similar across all regions, countries and channels. Therefore, usage rates were established according to the number of optional additional aligner orders included in the list price and length of time allowed to submit additional aligner orders from the initial aligner shipment date. Based on these considerations, we have established eleven usage rates for these products.

In addition to reviewing historical information by product and treatment length as outlined above, we also review doctor behavior from the last 12 months. If the review shows a change in behavior, we make further adjustments to the estimated usage rate if the changes are anticipated to be reflective of future expected behavior. Any changes in the estimated usage rates are applied prospectively at the beginning of the subsequent quarter. In addition, we compare the estimated usage rate to the actual usage rates after each quarter and no material differences have been identified to date.

Overall, we currently have 19 estimated usage rates based on the criteria outlined above. On a weighted basis, the average estimated usage rate used is [***]%, [***]%, and [***]% for the years ended December 31, 2021, 2020, and 2019 respectively.

The estimated impact to revenue as a result of period over period changes to the usage rate estimates is less than \$15 million on an annual basis for each year presented, and immaterial to our financial statements. Since usage rates are updated quarterly as needed, there is not a material cumulative impact to any one quarter.

If the Staff would like any additional information or has any further questions, please do not hesitate to contact me at (408) 470-1006.

Yours truly,

/s/ John F. Morici

John F. Morici

Chief Financial Officer and Executive Vice President, Global Finance

Cc: Joseph M. Hogan, Align Technology, Inc.
Julie Coletti, Align Technology, Inc.
Lindsey Piziali, PricewaterhouseCoopers LLP
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