

## EX REQ ACCEPTANCE METRICS

Data as of: 4/1/2021

| Metric                      | Product Category | FY 2020 Total<br>(October 2019 - September 2020) | FY 2021 Total To-Date<br>(October 2020 - March 2021) |
|-----------------------------|------------------|--|--|
| Accepted*                   | Cigarette        | 221  | 63   |
|                             | Roll-Your-Own    | 10   | 0  |
|                             | Smokeless        | 2  | 0  |
|                             | ENDS             | 0  | 0  |
|                             | Cigars           | 73   | 6  |
|                             | Pipe             | 0  | 0  |
|                             | Waterpipe        | 126  | 34   |
|                             | Other            | 0  | 0  |
|                             | <b>Total</b>     | <b>432</b>                                       | <b>103</b>   |
| Refuse-to-Accept* (RTA)     | Cigarette        | 17   | 0  |
|                             | Roll-Your-Own    | 4  | 0  |
|                             | Smokeless        | 0  | 0  |
|                             | ENDS             | 0  | 0  |
|                             | Cigars           | 2  | 82   |
|                             | Pipe             | 0  | 0  |
|                             | Waterpipe        | 0  | 0  |
|                             | Other            | 0  | 0  |
|                             | <b>Total</b>     | <b>23</b>  | <b>82</b>  |
| Total Applications Received | Cigarette        | 247  | 114  |
|                             | Roll-Your-Own    | 14   | 0  |
|                             | Smokeless        | 2  | 0  |
|                             | ENDS             | 0  | 0  |
|                             | Cigars           | 157  | 81   |
|                             | Pipe             | 0  | 0  |
|                             | Waterpipe        | 126  | 783  |
|                             | Other            | 0  | 0  |
|                             | <b>Total</b>     | <b>546</b>                                       | <b>978</b>   |

\*Please note that some metrics can change as FDA is processing an extremely large number of applications that move through many steps during the review process. The data reported here is generally accurate to within 10%.

EX REQ REVIEW AND ACTION METRICS

Data as of: 4/1/2021

| Metric  | Product Category | FY 2020 Total<br>(October 2019 - September 2020) | FY 2021 Total To-Date<br>(October 2020 - March 2021) |
|---|------------------|--|--|
| Number of Displine Reviews completed*             | Cigarette        | 860  | 402  |
|   | Roll-Your-Own    | 32   | 0  |
|   | Smokeless        | 5  | 0  |
|   | ENDS             | 0  | 0  |
|   | Cigars           | 33   | 951  |
|   | Pipe             | 0  | 0  |
|   | Waterpipe        | 103  | 467  |
|   | Other            | 0  | 0  |
|   | <b>Total</b>     | <b>1,033</b>                                     | <b>1,820</b>   |
| Deficiency letters issued*                        | Cigarette        | 2  | 20   |
|   | Roll-Your-Own    | 4  | 0  |
|   | Smokeless        | 1  | 0  |
|   | ENDS             | 0  | 0  |
|   | Cigars           | 0  | 7  |
|   | Pipe             | 0  | 0  |
|   | Waterpipe        | 0  | 5  |
|   | Other            | 0  | 0  |
|   | <b>Total</b>     | <b>7</b>   | <b>32</b>  |
| Environmental Information Request letters issued* | Cigarette        | 23   | 0  |
|   | Roll-Your-Own    | 0  | 0  |
|   | Smokeless        | 0  | 0  |
|   | ENDS             | 0  | 0  |
|   | Cigars           | 1  | 55   |
|   | Pipe             | 0  | 0  |
|   | Waterpipe        | 25   | 0  |
|   | Other            | 0  | 0  |
|   | <b>Total</b>     | <b>49</b>  | <b>55</b>  |

\*Please note that some metrics can change as FDA is processing an extremely large number of applications that move through many steps during the review process. The data reported here is generally accurate to within 10%.

## EX REQ REVIEW AND ACTION METRICS

Data as of: 4/1/2021

| Metric                  | Product Category | FY 2020 Total<br>(October 2019 - September 2020) | FY 2021 Total To-Date<br>(October 2020 - March 2021) |
|-------------------------|------------------|--|--|
| Found Exempt Orders*    | Cigarette        | 183  | 68   |
|                         | Roll-Your-Own    | 6  | 0  |
|                         | Smokeless        | 1  | 0  |
|                         | ENDS             | 0  | 0  |
|                         | Cigars           | 0  | 66   |
|                         | Pipe             | 0  | 0  |
|                         | Waterpipe        | 29   | 97   |
|                         | Other            | 0  | 0  |
|                         | <b>Total</b>     | <b>219</b>                                       | <b>231</b>   |
| Not Exempt Orders*      | Cigarette        | 62   | 10   |
|                         | Roll-Your-Own    | 0  | 0  |
|                         | Smokeless        | 1  | 0  |
|                         | ENDS             | 0  | 0  |
|                         | Cigars           | 7  | 0  |
|                         | Pipe             | 0  | 0  |
|                         | Waterpipe        | 0  | 0  |
|                         | Other            | 0  | 0  |
|                         | <b>Total</b>     | <b>70</b>  | <b>10</b>  |
| Withdrawn by Applicant* | Cigarette        | 0  | 0  |
|                         | Roll-Your-Own    | 4  | 0  |
|                         | Smokeless        | 0  | 0  |
|                         | ENDS             | 0  | 0  |
|                         | Cigars           | 0  | 0  |
|                         | Pipe             | 0  | 0  |
|                         | Waterpipe        | 0  | 1  |
|                         | Other            | 0  | 0  |
|                         | <b>Total</b>     | <b>4</b>   | <b>1</b>   |

\*Please note that some metrics can change as FDA is processing an extremely large number of applications that move through many steps during the review process. The data reported here is generally accurate to within 10%.

EX REQ REVIEW AND ACTION METRICS

Data as of: 4/1/2021

| Metric   | Product Category | FY 2020 Total<br>(October 2019 - September 2020) | FY 2021 Total To-Date<br>(October 2020 - March 2021) |
|----------|------------------|--|--|
| Closure* | Cigarette        | 0  | 0  |
|          | Roll-Your-Own    | 0  | 0  |
|          | Smokeless        | 0  | 0  |
|          | ENDS             | 0  | 0  |
|          | Cigars           | 0  | 0  |
|          | Pipe             | 0  | 0  |
|          | Waterpipe        | 0  | 0  |
|          | Other            | 0  | 0  |
|          | <b>Total</b>     | <b>0</b>   | <b>0</b>   |

\*Please note that some metrics can change as FDA is processing an extremely large number of applications that move through many steps during the review process. The data reported here is generally accurate to within 10%.