

EX REQ ACCEPTANCE PHASE METRICS

Data as of: 03/31/2022

| Metric | Product Category | FY 2020 (Oct 2019 - Sept 2020) | FY 2021 (Oct 2020 - Sept 2021) | FY 2022 Total To-Date (Oct 2021 - Mar 2022) |
|-----------------------------|------------------------|-----------------------------------|-----------------------------------|--|
| Accepted* | Cigar | 73 | 136 | 36 |
| | Cigarette | 221 | 209 | 226 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 6 |
| | Roll-Your-Own | 10 | 2 | 0 |
| | Smokeless | 2 | 1 | 3 |
| | Waterpipe | 126 | 252 | 203 |
| | Total | 432 | 600 | 474 |
| Refuse-to-Accept* (RTA) | Cigar | 2 | 82 | 1 |
| | Cigarette | 17 | 44 | 18 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 0 |
| | Roll-Your-Own | 4 | 0 | 0 |
| | Smokeless | 0 | 0 | 3 |
| | Waterpipe | 0 | 565 | 541 |
| | Total | 23 | 691 | 563 |
| Total Applications Received | Cigar | 157 | 167 | 18 |
| | Cigarette | 247 | 439 | 43 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 6 |
| | Roll-Your-Own | 14 | 2 | 0 |
| | Smokeless | 2 | 5 | 2 |
| | Waterpipe | 126 | 1,553 | 187 |
| | Total | 546 | 2,166 | 256 |

*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: 03/31/2022

| Metric | Product Category | FY 2020 (Oct 2019 - Sept 2020) | FY 2021 (Oct 2020 - Sept 2021) | FY 2022 Total To-Date (Oct 2021 - Mar 2022) |
|---|------------------------|-----------------------------------|-----------------------------------|--|
| Number of Displine Reviews completed* | Cigar | 33 | 2178 | 126 |
| | Cigarette | 860 | 669 | 185 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 0 |
| | Roll-Your-Own | 32 | 6 | 0 |
| | Smokeless | 5 | 0 | 0 |
| | Waterpipe | 103 | 692 | 82 |
| | Total | 1,033 | 3,545 | 393 |
| Deficiency letters issued* | Cigar | 0 | 84 | 0 |
| | Cigarette | 2 | 20 | 0 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 0 |
| | Roll-Your-Own | 4 | 2 | 0 |
| | Smokeless | 1 | 0 | 0 |
| | Waterpipe | 0 | 5 | 0 |
| | Total | 7 | 111 | 0 |
| Environmental Information Request letters issued* | Cigar | 1 | 55 | 0 |
| | Cigarette | 23 | 11 | 0 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 0 |
| | Roll-Your-Own | 0 | 0 | 0 |
| | Smokeless | 0 | 0 | 0 |
| | Waterpipe | 25 | 0 | 0 |
| | Total | 49 | 66 | 0 |

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|-------------------------|------------------------|-----------------------------------|-----------------------------------|--|
| Found Exempt Orders* | Cigar | 0 | 66 | 0 |
| | Cigarette | 183 | 117 | 17 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 0 |
| | Roll-Your-Own | 6 | 0 | 0 |
| | Smokeless | 1 | 0 | 0 |
| | Waterpipe | 29 | 130 | 0 |
| | Total | 219 | 313 | 17 |
| Not Exempt Orders* | Cigar | 7 | 4 | 0 |
| | Cigarette | 62 | 10 | 0 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 0 |
| | Roll-Your-Own | 0 | 0 | 0 |
| | Smokeless | 1 | 0 | 0 |
| | Waterpipe | 0 | 0 | 0 |
| | Total | 70 | 14 | 0 |
| Withdrawn by Applicant* | Cigar | 0 | 0 | 19 |
| | Cigarette | 0 | 1 | 0 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 0 |
| | Roll-Your-Own | 4 | 0 | 0 |
| | Smokeless | 0 | 0 | 0 |
| | Waterpipe | 0 | 1 | 1 |
| | Total | 4 | 2 | 20 |

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|----------|------------------------|-----------------------------------|-----------------------------------|--|
| Closure* | Cigar | 0 | 0 | 0 |
| | Cigarette | 0 | 0 | 0 |
| | ENDS | 0 | 0 | 0 |
| | Heated Tobacco Product | 0 | 0 | 0 |
| | Other | 0 | 0 | 0 |
| | Pipe | 0 | 0 | 0 |
| | Roll-Your-Own | 0 | 0 | 0 |
| | Smokeless | 0 | 0 | 0 |
| | Waterpipe | 0 | 0 | 0 |
| | Total | 0 | 0 | 0 |

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