

Conclusions

- While different products within the ONP category show some commonality in terms of user behaviour, for some user and use characteristic variables there are major differences between brands
- Findings demonstrate the importance of conducting independent user surveys for each brand in order to accurately inform an APPH determination. While the literature may be informative, FDA will likely require brand- and SKU-specific data
- Online surveys of convenience samples of established product users can provide a cost-effective and timely method of collecting brand- and SKU-specific data to support PMTA submissions
- Data can also help identify whether additional, more rigorous studies of user behavior are warranted and inform the design of such studies e.g., time in mouth to justify controlled use period in abuse liability studies or pouches per day for toxicological risk assessments

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