

Say goodbye to
RED DYE

#40



ORA-Blend[®]
ORA-Blend[®] SF
ORA-Sweet[®]
ORA-Sweet[®] SF

Dear Pharmacist,

This letter is to serve as notification regarding updates to Type IV Drug Master File (DMF) 14443, ORA Brand of Oral Pharmaceutical Vehicles (ORA-Blend[®], ORA-Blend[®] SF, ORA-Sweet[®], and ORA-Sweet[®] SF). Please note this letter pertains to all ORA products, except ORA-Plus[®] listed in DMF 14443. Therefore, some updates described within may not apply to the specific product or products you purchase.

ORA-Sweet[®], ORA-Sweet[®] SF (473 mL and 150 mL), ORA-Blend[®] and ORA-Blend[®] SF Updates are the following:

The FD&C Red #40 dye was removed from the berry citrus flavor. The ORA labeling will continue to read “berry citrus flavor (contains FD&C Red #40)” until labeling inventory has been depleted at which point, the notification letters will no longer be sent along with the product. These ORA products do NOT contain red dye #40.

Drug Master File No. 14443 “ORA Brand of Oral Pharmaceutical Vehicles” will be updated with these changes.

Contact Padagis with any questions or concerns at (866) 634-9120.

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