

## Advice to members about merging ingredient names: oligofructose to fructooligosaccharide

The TGA have provided advice that an ingredient name change will be required for products on the ARTG that use the ingredient name 'oligofructose' in the formulation.

- **The name change will require sponsors to update product labels for any medicines using the name oligofructose to fructooligosaccharides by 31 December 2022.**
- **There will be no fee, sponsor action or changes to AUST L numbers associated with this change.**
- **Sponsors will be granted the option of a consent to continue to supply their affected products with existing labels using the old ingredient name for an 18-month period without a fee.**

Affected sponsors can expect to be contacted directly by the TGA over the coming week to notify them of this activity and update relevant ARTG entries. Affected sponsors are encouraged to contact the TGA prior to applying for a Section 14 consent to supply.

The TGA have advised that duplicate names will be removed from the ingredient repository and ARTG listings; and names for oligosaccharides will be aligned with those used in the scientific literature. Within the next month the TGA will:

- replace the name oligofructose with fructooligosaccharides in affected ARTG entries.
- inactivate the name oligofructose from the ingredient repository.

### Reason for the change

In 2016, the TGA updated the approved ingredient name 'oligofructose' to 'fructooligosaccharides', when used in therapeutic goods. As part of this decision, the TGA included a message within listed medicine application validation systems to inform sponsors of all new and existing listed medicine products using oligofructose in their formulations of this change.

The TGA have provided that the old ingredient name (oligofructose) is still being used in medicines on the ARTG and that this is reportedly resulting in confusion both for sponsors and consumers.

The naming reference used for this ingredient in the TGA's provides that fructooligosaccharides is the most accurate name to characterise this ingredient. It acknowledges that the name oligofructose is sometimes used to identify fructooligosaccharides derived from inulin. Therefore, the name oligofructose will remain as a synonym for fructooligosaccharides.

Members can contact TGA Names on 02 6232 8465 or email [tganames@tga.gov.au](mailto:tganames@tga.gov.au) with any questions or concerns. Alternatively, please contact CMA via [technical@cmaustralia.org.au](mailto:technical@cmaustralia.org.au).

### Resources

- TGA web page: [Consent to import, supply or export therapeutic goods that do not comply with standards - information for industry](#)