

ANNEX

Frequently-Asked Questions (FAQs) on FDA Circular (FC) No. 2022-001

1. **I was able to secure both a License-to-Operate (LTO) for my establishment to manufacture rubbing alcohol products with concentrations of 70% and beyond and the corresponding Certificate of Product Notification (CPN), following the interim guidelines (FDA Circular No. 2021-004).**

- a) **What will happen to my LTO and CPN?**

Your LTO and CPN will be recognized as valid only until its validity date but not exceeding 31 December 2022. Until this date, you may still, under the provisional authorization, produce and market your products. However, after this period, your provisional LTO and CPN will be considered invalid. Thus, you must immediately cease any production and sale of your products under these authorizations.

- b) **Can I apply for a major variation for an additional product line to include cosmetic products and be able to continue our LTO as a cosmetic manufacturer?**

Yes, you may apply for a major variation for an additional product line to include cosmetic products in your current provisional authorization, to be able to continue to engage in the manufacture of cosmetic products. Applications for a major variation for an additional product line to include cosmetic products must be filed by 30 June 2022 to ensure continuity of your authorization. Please note that applications for this purpose received after 30 June 2022 will not be accommodated, wherein, applicants will be advised to file for an initial application for a Cosmetic Manufacturer LTO.

2. **My CPN for rubbing alcohol products with concentrations of 70% and beyond, issued under the interim guidelines, has a validity beyond 31 December 2022, can I still exhaust my products beyond this date?**

No, your CPN will automatically be considered invalid beyond 31 December 2022, thus, your products will be considered unauthorized. It is expected that your products should be removed at the retailer level, and the necessary inventory and recall of these products have been performed by the said date. Any unauthorized products that are found in the market beyond 31 December 2022 will be subject to penalties and sanctions, following due process.

3. I still want to continue to produce and sell rubbing alcohol products beyond 31 December 2022, what are my options?

You may only produce and market rubbing alcohol products which are duly-authorized. Depending on the alcohol content, intended use and claimed benefits of your product, you may secure:

- An LTO as a drug manufacturer and a Certificate of Product Registration (CPR) as a household remedy, if the product you intend to manufacture and distribute contains 70% and beyond alcohol concentration, and is intended to be used as a rubbing alcohol for the prevention, management, or treatment of diseases. You may submit your applications with the Center for Drug Regulation and Research (CDRR) beginning 01 July 2022.
- An LTO as a cosmetic manufacturer and a CPN as a cosmetic product, if the product you intend to manufacture and distribute contains less than 70% alcohol or is an alcohol-based product, and has cosmetic claims. You are advised to refer to the ASEAN Cosmetic Claims Guidelines (Appendix III of the ASEAN Cosmetic Directive) for the guidance on allowable and prohibited claims.

4. My product is a rubbing alcohol with concentration of 70% and beyond, can I still continue to market these as cosmetics?

You may only market these products as cosmetics until 31 December 2022, provided that you have valid authorizations issued under FC No. 2021-004. Please see response to FAQ no. 1.

5. Can I still renew my authorizations originally issued under FC No. 2021-004?

The Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) will receive and process applications for renewal or revalidation of previously-issued authorizations under FC No. 2021-004 until 30 June 2022. Beyond this date, new applications will not be received and the received applications will automatically be disapproved. You are advised to file any application within sufficient timelines before this date to avoid unacceptance or disapprovals.

6. My CPN for Rubbing Alcohol is about to expire before 01 July 2022 but I want to exhaust my products in the market until the end of December, should I still reapply for CPN to exhaust the stocks by 31 December 2022?

Yes, you may still reapply for a CPN of rubbing alcohol before 01 July 2022. See response to FAQ Nos. 1 and 5.

7. Can I still apply for an initial LTO as a cosmetic manufacturer of rubbing alcohol products with concentrations of 70% and beyond before 01 July 2022?

The CCHUHSRR will no longer accommodate initial applications for a provisional LTO for manufacturers of rubbing alcohol products with concentrations of 70% and beyond, twenty (20) working days before 01 July 2022. This is in view of the insufficient period of time to completely process the application for both the provisional LTO and the corresponding initial CPN.

8. Can I still apply for a major variation for an additional product line in my existing LTO to include rubbing alcohol products with concentrations of 70% and beyond before 01 July 2022?

The CCHUHSRR will no longer accommodate major variation applications for an additional product line for manufacturers of rubbing alcohol products with concentrations of 70% and beyond, twenty (20) working days before 01 July 2022. This is in view of the insufficient period of time to completely process the application for both the provisional LTO and the corresponding initial CPN.