

FDA ADVISORY
No. **2023-2329**

14 NOV 2023

TO: ALL CONCERNED STAKEHOLDERS OF THE CENTER FOR COSMETICS AND HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES REGULATION AND RESEARCH

SUBJECT: Application Holiday

The Food and Drug Administration (FDA) will be conducting an annual inventory of pending applications for marketing authorizations lodged with the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), as well as a review of its existing processes and systems. As such, all concerned stakeholders are hereby informed of the application holiday commencing from 16 December 2023 to 15 January 2024.

For the abovementioned purpose, the FDA shall not receive the following types of applications:

1. Initial and variation applications for License to Operate (LTO) for cosmetics, household/urban hazardous substances (HUHS), household/urban pesticides (HUP), toys and childcare articles (TCCA), and pest control operators
2. Initial applications for Certificate of Product Notification (CPN) for cosmetics
3. Initial applications for Certificate of Product Registration (CPR) for HUHS and HUP products
4. Applications for the pre-approval of modified and non-standard protocols for bio-efficacy test studies of HUP products

During the application holiday, the FDA through CCHUHSRR shall continue to receive the following types of applications:

1. LTO renewal applications
2. Revalidation applications for CPNs for cosmetic products
3. All applications for CPNs for TCCA products
4. CPR Renewal and variation applications for HUP products
5. Emergency Use Permit for surface disinfectants
6. Off-label Use/ Public Health Emergency Exemption Permit for HUP products
7. Applications for other certifications and authorizations, including Sales and Promo Permits, Certificates of Free Sale, Good Manufacturing Practice Certificate, and Customs-related Clearances

The regular schedule of filing and submission of applications shall resume on 16 January 2024. For information and strict compliance of all concerned.


DR. SAMUEL A. ZACATE
Director General

