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Healthcare & Life Sciences
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Approval to Manufacture Alcohol-Based Hand Sanitizer Extended to Traditional Drug Manufacturers License Holders

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Further to our client alert on Enhanced Measures to Facilitate the Supply of Quality Alcohol-based Hand Sanitizers (link), the Food and Drug Administration, Ministry of Public Health ("**FDA**"), has released the notification to allow alcohol-based hand sanitizers to also be manufactured by traditional drug manufacturers in addition to modern drug manufacturers and medical device manufacturers.

The FDA also released the temporary approval steps for manufacturing alcohol-based hand sanitizers which require the modern drug manufacturers, traditional drug manufacturers and medical device manufacturers to firstly apply to become approved manufacturers of alcohol-based hand sanitizers. They are then required to notify the FDA of each formula of alcohol-based hand sanitizer. These two steps must be done via the e-submission system of the Cosmetic Control Division in accordance with the requirements concerning the manufacturing of alcohol-based hand sanitizer stipulated by the FDA. In this regard, the traditional drug manufacturers will be allowed to manufacture the alcohol-based hand sanitizers for one year.

Traditional drug manufacturers can manufacture alcohol-based hand sanitizers in the areas designated for the manufacture of topical drug and at separate production times. The manufacturers must clean the manufacturing areas and conduct cleaning validation to prevent possible cross-contamination.

We will keep you informed if there are any further updates. Please contact us for more information.

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