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FDA Updates Hand Sanitizer Enforcement Discretion Guidance to Provide More Information Regarding Ethanol Sourcing

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Food, Drugs, and Devices

Today, FDA issued updates to its guidance document "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)," ("Temporary Policy") and related guidance document, that primarily provide more detailed information about potential ethanol sources for companies seeking to prepare hand sanitizer or produce ethanol used in the production of hand sanitizer under the agency's COVID-19 specific enforcement discretion policies. This is the fourth update that FDA has made to these guidance documents since initially issuing them in March, with each previous update providing additional enforcement discretion regarding ethanol that can be used to produce sanitizer under the temporary policy.[1]

Overview

Most notably, the Temporary Policy now sets forth separate criteria for three different potential sources of ethanol for use in hand sanitizer: (1) ethanol produced using fermentation and distillation processes typically used for consumable goods and made in a facility used for producing consumable goods; (2) ethanol produced in facilities normally producing fuel or technical grade ethanol; and (3) ethanol derived from synthetic processes.

The first category, ethanol produced using processes typically used for consumable goods, can be used in hand sanitizer made under the Temporary Policy so long as it is made in a facility used for producing consumable goods and meets the purity and other requirements of the Temporary Policy.

The second category, ethanol produced in facilities normally producing fuel or technical grade ethanol, can be used in hand sanitizer made under the Temporary Policy only under the following circumstances:

- the ethanol is produced using fermentation and distillation processes typically used for consumable goods, and no other additives or other chemicals have been added to the ethanol;
- the ethanol meets USP or FCC grade requirements or conditions that FDA has established in new "Attachment 1" (described in more detail below); and

[1] See here for our prior client alert on FDA's Temporary Policy.

- the alcohol has been screened for any other potentially harmful impurities not specified in the USP or FCC requirements but potentially present based on the specific manufacturing environment.

The third category, ethanol derived from synthetic processes, can be used in hand sanitizer made under the Temporary Policy only if it meets USP or FCC grade.

The Temporary Policy also clarifies that its enforcement discretion only applies to hand sanitizer products that are produced under and meet all of the criteria set forth in the Temporary Policy; FDA explained that its enforcement discretion "does not reflect the risk-benefit calculus that FDA would find acceptable outside of this public health emergency and temporary policies." This means that the Temporary Policy does not apply to hand sanitizer gel, foam, or aerosol spray products, nor does it apply to hand sanitizer products that use other active or inactive ingredients, including fragrances, or are different formulations.

Attachment 1: Requirements for Ethanol Produced in Facilities Normally Producing Fuel or Technical Grade Ethanol

The Temporary Policy includes a new "Attachment 1," which establishes the following criteria for the use of fuel or technical grade ethanol that does not meet USP or FCC requirements:

- It does not contain gasoline or any of its components (e.g., n-heptane).
- Impurities meet the interim limits listed in the table below and no other potentially harmful impurities are present other than those addressed the table below. FDA notes that if a firm wishes to use or supply a fuel or technical grade ethanol that does not meet USP or FCC requirements, the firm should test the ethanol (or have a third party laboratory conduct testing) to identify the levels of impurities listed in the USP monograph as well as any other potentially harmful impurities that may be present given the manufacturing environment.

Impurity	Interim Limit under Temporary Policy
Methanol	630 ppm
Benzene	2 ppm
Acetaldehyde	50 ppm
Acetal (1,1-diethoxyethane)	50 ppm
Sum of all other impurities	300 ppm

Further, the Temporary Policy provides that fuel or technical grade ethanol that does not meet the interim limits in the above table because the sum of all other impurities exceeds the interim limit of 300 ppm can still be used so long as all individual impurities are identified and meet the interim limits in the table below.

Impurity	Interim Limit under Temporary Policy
Acetone	4400 ppm
n-propanol (1-propanol)	1000 ppm
Ethyl acetate	2200 ppm

Impurity	Interim Limit under Temporary Policy
Sec-butanol (2-butanol)	6200 ppm
Iso-butanol (2-Methyl-1-propanol)	21700 ppm
n-butanol (1-butanol)	1000 ppm
iso-amyl alcohol (3-Methyl-1-butanol)	4100 ppm
Amyl alcohol	4100 ppm

For any impurity identified not listed in Table 1 or Table 2, FDA will accept data from individual firms regarding the level for each individual impurity with information regarding the safety of each impurity, if available, for FDA's assessment regarding whether the ethanol is suitable for use under the Temporary Policy. We also note that FDA made clear that it will continue to assess these interim limits to ensure that they allow for the safe use of hand sanitizers.

Companies seeking to manufacture or market hand sanitizers under FDA's current enforcement discretion should carefully review all aspects of FDA's Temporary Policy, currently available here, and be sure to access the most up-to-date version of the Temporary Policy given the frequency of FDA updates.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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