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End Is Near For Distributing OTC Hand Sanitizers Manufactured Under Temporary US Guidance

by Hannah Daniel

The 31 March cut-off date brings to a comparatively low-profile end a well-chronicled saga of FDA acting to increase OTC hand sanitizer production as consumer demand soared in response to COVID-19.

Manufacturers have until the end of March to distribute any alcohol-based OTC hand sanitizers made under temporarily relaxed guideance the Food and Drug Administration allowed starting in March 2020.

The 31 March cut-off date brings to a comparatively low-profile end a well-chronicled saga of the FDA acting to increase and accelerate OTC hand sanitizer production as consumer demand soared in response to COVID-19.

In stores and online for weeks following the onset of the novel coronavirus pandemic in 2020, consumers found empty shelves looking for hand sanitizers, products typically not among the most in-demand consumer health items. Store shelves also were empty where consumers looked for personal care products continually in demand but not subject to the FDA's regulatory oversight, toilet paper.

All hand sanitizers not made in compliance with the FDA's good manufacturing standards and not distributed by the deadline should be destroyed; manufacturers should keep records of product disposals, the agency stated in a 25 March announcement.

However, the FDA says it doesn't intend to object if retailers continue selling inventories of hand sanitizers produced consistent with its temporary guidance.

But it also reminds manufacturers that alcohol-based hand sanitizers made since 1 January to be

sold in the US must be fully compliant with the agency's current GMPs and the alcohol used in the product must be compliant with the US Pharmacopeia's monograph.

The temporary guidance easing standards for OTC hand sanitizer production was withdrawn at the end of 2021. (Also see "*US FDA Plans Year-End Rinse Of Temporary Policy Easing Standards For OTC Sanitizer Production*" - HBW Insight, 12 Oct, 2021.)

Easing standards for making the products didn't come without consequences. The FDA in August 2020 needed to clarify its original document with information on the preparation, compounding and manufacturing of alcohol-based sanitizer after widespread reports of OTC sanitizers found to contain methanol as well as being packaged in inappropriate containers and mis-labeled. (Also see "*US FDA Clarifies Testing In Sanitizer Production Temporary Guidances To Tighten Compliance*" - HBW Insight, 10 Aug, 2020.)

Methanol contamination and other problems that followed the eased manufacturing standards prompted the FDA in July 21 to create an import alert category to block all OTC hand sanitizers made in Mexico from reaching the US, the agency's first-ever countrywide import alert. (Also see "*US FDA Adds Hand Sanitizer Import Alert Category After COVID-19 Production Surge Turned Deadly*" - HBW Insight, 18 Sep, 2020.)

When the FDA announced in November it would pull the temporary guidance at the end of the year, it stated that 94% of hospital systems responding to a July 2021 survey reported the majority of their current hand sanitizer product is produced by traditional manufacturers. The agency also noted media reports "indicate that there is now a surplus of hand sanitizer products on retail shelves."

It added that even though the novel coronavirus pandemic continued, with the Omicron variant driving an increase in late 2021, data indicated supply from traditional manufacturers has increased; demand for alcohol-based hand sanitizer has significantly decreased; and most consumers and health care personnel are no longer having difficulty accessing alcohol-based hand sanitizers.

The American Cleaning Institute and the Consumer Healthcare Products Association couldn't agree more with the FDA's findings. (Also see "*Trade Groups Push US FDA To Close Window On Loosened OTC Sanitizer Production Standards*" - HBW Insight, 29 Apr, 2021.)

The two trade groups asked the FDA in April 2021 to withdraw the temporary guidances, saying they "were extremely concerned with ongoing reports of products with dangerous ingredients entering the US market that both jeopardized public health and required significant FDA oversight and resources."

Entries into the US hand sanitizer market in response to the FDA's encouragement also created a temporary glitch in the agency's first-ever notice for OTC monograph user fees published in late 2020. (Also see "*US OTC Monograph Facilty Fees Increase With Pandemic-Inspired Sanitizer Makers Exempted*" - HBW Insight, 25 Mar, 2021.)

After businesses that began making sanitizers in response to the COVID-19 pandemic initially were made subject to the facility fees in the FDA's first notice, the agency replaced it with a second notice in March 2021 omitting companies that entered the OTC drug market to produce only hand sanitizer products on or after Jan. 27, 2020.