**BACKGROUND:**

Late yesterday afternoon, Brian Harrison, HHS Chief of Staff, issued the following statement that they have withdrawn the Notice published in the Federal Register re OTC Monograph Drug Facility Fees and directed FDA to cease enforcement of these fees. HHS Tweet: Https://Twitter.Com/Spoxhhs/Status/1344782160084037639?S=21

Full HHS Statement:

Good Afternoon – early in the COVID-19 pandemic many small businesses across the country joined the fight to combat the virus and keep Americans safe – that included distilleries that augmented their operations to produce hand sanitizer, an important asset in the battle to deter the spread of COVID. In March, the Food and Drug Administration (FDA) issued a guidance document – the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) – which provides flexibility for those entities capable of producing hand sanitizer to rapidly enter the market. In the guidance, the FDA stated it "does not intend to take action against firms that" produce hand sanitizer products – which are classified as over-the-counter drugs – during the COVID-19 Public Health Emergency, provided the firm's activities are consistent with the guidance. Importantly, the guidance contains no discussion regarding user fees or any indication such fees would be due by these entities, many of which would be entering the drug manufacturing business for the first time. Nevertheless, on December 29, the FDA posted an over-the-counter drugs user fee notice that imposes a significant financial burden on these small businesses.

This action was not cleared by HHS leadership, who only learned of it through media reports late yesterday. HHS leadership convened an emergency meeting late last night to discuss the matter and requested an immediate legal review. The HHS Office of the General Counsel (OGC) has reviewed the matter and determined that the manner in which the fees were announced and issued has the force and effect of a legislative rule. Only the HHS Secretary has the authority to issue legislative rules, and he would never have authorized such an action during a time in which the Department is maximizing its regulatory flexibility to empower Americans to confront and defeat COVID-19. Because HHS OGC has determined the notice is really a legislative rule and that no one at FDA has been delegated authority to issue such a rule, the notice is void. HHS leadership, based on this legal opinion, has ordered the Federal Register Notice to be withdrawn from the Federal Register, meaning these surprise user fees will not need to be paid.

"Small businesses who stepped up to fight COVID-19 should be applauded by their government, not taxed for doing so. I'm pleased to announce we have directed FDA to cease enforcement of these arbitrary, surprise user fees. Happy New Year, distilleries, and cheers to you for helping keep us safe!" – Brian Harrison, HHS Chief of Staff

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