March 20, 2020

Dockets Management
**Docket Number: FDA-2020-D-1106**
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: **Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry**
**Docket Number: FDA-2020-D-1106**

Dear Sir/Madam:

Our nation's compounding pharmacists are thankful for the opportunity afforded by the FDA to prepare alcohol-based hand sanitizers for consumer use for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020 because of the public health emergency posed by the coronavirus (COVID-19). As compounders who do this every day for our nation's patients, we are offering to serve as a resource to FDA for consultation prior to issuance of future emergency guidance documents to ensure that the formulas and information provided are sufficient to meet public need.

*Challenges yet remain with the guidance, which if not addressed by FDA in a timely manner, will limit the effectiveness of FDA's guidance and pharmacy compounders' ability to be helpful in COVID-19 prevention efforts.* Compounding pharmacists at our organizations have already contacted FDA's compounding team with inquiries at compounding@fda.hhs.gov. In order to receive a consistent response from FDA, our organizations have compiled a number of pertinent questions on the guidance. Here are a number of significant issues/ questions for clarification our organizations respectfully request FDA's compounding team take quick action to address:

- The FDA guidance does not address shipping/reselling/distribution of compounded hand sanitizers. Can FDA provide clarification on shipping/reselling/distribution – as well as labeling if reselling and distribution are allowed – to maximize availability of this necessary product?
- FDA's guidance does not preempt state law, and some state boards of pharmacy have yet to issue state-specific emergency orders allowing compounding of certain alcohol gels.

Could FDA provide clarification to the state boards of pharmacy to issue orders that align with FDA's clarified guidance where needed under state law and regulations?

- FDA's guidance does not address reported shortages of the 75% isopropyl alcohol (IPA) required in the FDA specifications, without which our members are unable to compound sanitizers as the FDA guidance intends. These IPAs are not available from distributors and wholesalers and additional steps to secure these products, such as neutral spirits, (27 CFR § 5.22 - The standards of identity.) for compounding pharmacies may be necessary. FDA should consider allowing compounders further flexibility to meet the consumer need. For example, allowing pharmacists to exercise professional judgment with the use of food-grade products for compounding hand sanitizers, as well as allowing flexibility in formulas as long as the final concentration of alcohol is >60%.
- Pharmacies are having trouble getting 99% IPA and ethyl alcohol from their suppliers. Our members are able to get ethyl alcohol from liquor stores but it is not USP grade. Can FDA provide our members with an acceptable formula from FDA using 70% IPA or for other hand sanitizers with antiseptic properties such as benzalkonium chloride?
- The guidance requires "Sterile distilled water or boiled cold water." Boiled cold water would not be USP grade. Our members recommend boiled purified water rather than boiled tap water. Can FDA clarify how long does the water need to be boiled?
- Can FDA provide clarity regarding the labeling in the guidance? Under inactive ingredients, the guidance states to label the product as "purified water USP," yet, this is not one of the required ingredients.
- The guidance does not specify beyond use expiration dates (BUDs). Can FDA clarify that the default BUD is 30 days and/ or is there guidance on how to extend these BUDs?
- The guidance does not address the differences between using the pharmaceutical-grade active and inactive ingredients, which are significantly more expensive than what could be obtained commercially. Can FDA prioritize the availability of both pharmaceutical-grade and commercially available ingredients to meet demand?
- We are receiving numerous inquiries from our members on what compounders should do as standard cleaning and disinfecting agents are increasingly not available. Can FDA offer guidance?
- Has FDA considered adding language to the guidance to extend applicability beyond the current crisis to meet ongoing hygiene challenges to prevent future pandemics?

Our organizations thank FDA's compounding team for your quick actions issuing this guidance to respond to this crisis. If these issues can be addressed promptly, the aim of FDA's March 14 guidance can be achieved much more quickly, and FDA's and pharmacy compounders' role in COVID-19 prevention will have immediate and substantive impact in communities across America.

Our organizations welcome the opportunity to meet with FDA for regular productive and proactive dialogue with our nation's compounders as this crisis continues. We all want to help get ahead of this current public health emergency and address potential patient needs. Compounding pharmacists are trained, prepared, and stand ready to help in the event certain

FDA-approved products go into shortage. We recognize that the current situation limits an in-person meeting, however, we are happy to meet with FDA through virtual meeting technologies.

We look forward to hearing from you soon to clarify this guidance and continuing to work with you on the ongoing issues required to prevent the spread of COVID-19.

Sincerely,

American Pharmacists Association
Alliance for Pharmacy Compounding
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

CC: The Honorable Stephen M. Hahn M.D., Commissioner, FDA