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Pharmacy
Compounding



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[Submitted electronically to compounding@fda.hhs.gov]

March 26, 2020

Food and Drug Administration (FDA)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Compounding Products in Shortage or Anticipated to be in Shortage During the National Emergency

On behalf of America's compounding pharmacists, we write to urge FDA to help us provide urgently needed compounded products to patients and fill a critical supply chain need for certain over-the-counter (OTC) and prescription products during the current COVID-19 public health emergency.

As this health crisis continues, pharmacies, wholesalers and manufacturers are experiencing or are likely to experience shortages of critical OTC and prescription drug products that are needed for patient care. Compounders stand ready to provide needed medications for COVID-19 treatment and drugs in shortage in the U.S. as a result of this global crisis. We seek specific FDA enforcement discretion to compound these products and provide health care professionals and patients safely compounded versions of the medications they need.

We ask FDA to engage with the pharmacy compounding community now in identifying drugs in shortage or anticipated to be in shortage and work with us to ensure that timely FDA guidance is clear and thorough regarding scope of authority, formulas, information, and ingredients.

Because we understand that FDA staff is in emergency response mode, we provide the following immediate, specific concerns and requests:

1. We are grateful for FDA's March 14 "Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency," providing enforcement discretion for pharmacy compounders who prepare alcohol-based hand sanitizers for consumer use during the COVID-19 public health emergency. However, under that guidance, pharmacists are required to utilize USP-grade alcohol, which many compounders are unable to source at present, thereby undermining the effect of the FDA

action and the ability of compounders to meet consumer need. At the same time, FDA has issued additional guidance, “Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19),” allowing certain “manufacturing firms” to prepare hand sanitizers using food-grade alcohol. The result is a double standard, a situation in which, because of materials shortages, those with technical training and expertise are unable to meet the current need for hand sanitizers, while others who may have limited expertise are allowed to prepare them using materials prohibited to pharmacists. Accordingly, **we ask FDA to immediately amend the “Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency,” guidance to allow licensed pharmacists to utilize the same materials (i.e., food-grade alcohol) in preparing hand sanitizers as those allowed by FDA for non-pharmacy manufacturing firms during this public health emergency.**

2. We anticipate potential shortages of critical OTC products used by COVID-19 patients. Some of these products, such as pain relievers, zinc and vitamin C supplements, cough medications, and saline solutions for nebulizers, can be safely compounded by pharmacists. We also anticipate potential shortages of critical FDA-approved prescription drugs, including drugs dispensed pursuant to a patient-specific prescription, as well as those distributed to hospitals, clinics and doctors to administer to patients in a clinical setting. 503A compounding pharmacies can help meet the increased demands for these products to prevent and mitigate shortages. **We ask FDA to immediately issue guidance providing enforcement discretion for pharmacists to compound products that are “essentially a copy” of an FDA-approved drug that FDA identifies may be or is anticipated to be, in shortage during this public health emergency.**
 - a. We recommend that FDA identify classes of drug products or specific drug products that patients rely on for treatment and prevention of symptoms related to COVID-19, influenza, strep, and other related conditions for compounding under this guidance.
 - b. We recommend that the guidance clarify that pharmacists may compound them immediately or for office use, pursuant to a drug order from a licensed prescriber.
 - c. On March 23, 2020, FDA added hydroxychloroquine sulfate to category 1 under the “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” The FDA stated that it does not intend to object to registered outsourcing facilities using hydroxychloroquine (or chloroquine phosphate, which was already on category 1), to compound human drugs provided the drugs meet other conditions and requirements in the Federal Food, Drug, and Cosmetic Act. (FD&C Act). Compounding pharmacies that compound pursuant to section 503A of the FD&C Act are fully capable to compound these products from bulk as well to meet the market demand to prevent and mitigate a shortage. The enforcement discretion we seek would enable 503A compounding pharmacies to fill the urgent public health need along with 503B outsourcing facilities and other sources.

Again, we thank you for considering our suggestions and concerns during this public health crisis. To reiterate, we stand ready to work with the FDA at this critical time – to be a resource

on how compounding pharmacies can safely provide critical OTC and prescription drug products in shortage. *Our clinical and practical expertise and marketplace knowledge can be a helpful and potent resource to FDA and can improve the effectiveness and clarity of FDA guidance on matters related to compounding during this public health emergency.*

We know the entire FDA team is doing important work for our nation's patients at this critical time, and we thank you for your prompt attention to our concerns.

Please contact Scott Brunner, CAE, of the Alliance for Pharmacy Compounding at 404-844-8607 or scott@a4pc.org if you wish to consult with the compounding experts at our organizations.

Sincerely,

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