January 9, 2023

Gail Bormel, RPh, JD
Director, Office of Compounding Quality and Compliance
Office of Compliance
10903 New Hampshire Avenue
Bldg. 51, Room 5271
Silver Spring, MD 20993-0002

Re: Acetaminophen and Ibuprofen Oral Suspension Shortages

Dear Gail:

On behalf of the American Pharmacists Association (APhA), the National Community Pharmacists Association (NCPA) and the Alliance for Pharmacy Compounding (APC), we are writing to ask FDA to take immediate steps to increase the supply of ibuprofen and acetaminophen oral suspensions by utilizing enforcement discretion to permit pharmacies to compound these medications to alleviate the demand for these products that exceeds the available supply.

Section 503A of the Food, Drug, and Cosmetic Act (FDCA) does not allow 503A facilities to compound regularly, or in inordinate amounts, any drug products that are essentially copies of a commercially available drug product. FDA's Guidance for Industry, "*Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*," notes that FDA does not consider a drug product to be commercially available if "the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act[1]." As of today, the FDA has not placed acetaminophen or ibuprofen oral suspensions on the FDA drug shortage list. As you know, there is wide-spread patient need for these products as described in recent media reports and experienced by our nation's pharmacists and our patients.

Caregivers of ill children are frustrated and concerned about having to go from pharmacy to pharmacy in hopes of finding available product. Many parents are asking compounding pharmacists to prepare these medications. However, without clear regulatory flexibility, compounding pharmacists are unable to adequately meet our patients' needs—most importantly the needs of our pediatric populations.

[1] https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf Accessed 01-04-2023.

Caregivers of these children and pharmacists wanting to help their pediatric patients are also faced with needing to obtain a prescription in order to dispense these compounded medications under the provisions of section 503A of the FD&C Act despite these being OTC products. FDA's additional requirement for a prescription delays patient access to care for this vulnerable population.

We recognize that it is critical for pharmacist compounders to take precautions to ensure proper dosing. FDA could ensure compounders are well-informed on risks, such as dosing errors, as a part of the background information provided in a temporary guidance.

We urge FDA take immediate steps to increase the supply of ibuprofen and acetaminophen oral suspensions, by:

1. Adding ibuprofen and acetaminophen pediatric oral suspensions to the FDA drug shortage list.
2. Issuing temporary guidance for the compounding of acetaminophen and ibuprofen pediatric oral suspensions that provides enforcement discretion regarding the essential copies and prescription requirement provisions for these products until such time that sufficient supply is available across the country.

Thank you for the opportunity to bring these patient access concerns to your attention. We look forward to working together with you to ensure that patients have all available treatment options. Please, contact Michael Baxter, APhA's Acting Head of Government Affairs, at mbaxter@aphanet.org on the steps FDA intends to take to assist our nation's pharmacists meet our patients' needs.

Respectfully,

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American Pharmacists Association (APhA)

Doug Hoey, RPh, MBA
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cc: Jill Furman, JD, Acting Director, Office of Compliance, CDER
Patrizia Cavazzoni, MD, Director, CDER