



November 27, 2023

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2019-N-5959; Medication Guides: Patient Medication Information Proposed Rule**

Dear Dockets Management Staff:

On behalf of the food industry and the thousands of supermarket pharmacies operated by our member companies, we at FMI – the Food Industry Association appreciate the opportunity to provide comments to the Food and Drug Administration (FDA) in support of its *Medication Guides: Patient Medication Information* proposed rule. We thank FDA for recognizing the Citizen Petition, entitled “One Document Solution For All Pharmacy-Based Communications,” jointly submitted in 2008 by FMI and other pharmacy and health care stakeholders, urging the agency to develop a “one-document solution” that combines and simplifies the many documents patients currently receive at the pharmacy for prescription drug products. FMI applauds FDA for responding, in part, by pursuing this rulemaking to facilitate this needed policy change.

As the food industry association, FMI works with and on behalf of the entire industry – including supermarkets and their pharmacies – to advance safer and more efficient consumer supply chains for both food and pharmaceuticals. In total, FMI member companies, which range from independent operators to the largest national and international players, operate roughly 33,000 grocery stores and 12,000 pharmacies, ultimately touching the lives of more than 100 million U.S. households on a weekly basis and representing an \$800 billion industry with nearly 6 million employees. [www.fmi.org](http://www.fmi.org)

FMI Strongly Supports the Proposal

The “Patient Medical Information” (PMI) proposal would simplify and consolidate the many lengthy and often redundant documents that patients receive with their dispensed prescription drugs. Currently, there are several documents that pharmacies are required to disseminate to patients with their prescription medications, including Medication Guides (MedGuides), Patient Package Inserts (PPI), Instructions for Use, and other patient labeling materials. These documents include multiple pages that are redundant and frequently include technical content that is beyond the comprehension of many patients. The PMI, as proposed, would reduce

patient confusion by including FDA-approved information about a prescribed medication in a uniform, one-page document that is clear, concise, and delivered in a consistent and easily understood format to help patients use their prescription drug products safely and effectively.

Additionally, the multiple documents that pharmacists and pharmacy staff are currently required to provide to patients with their medications create unnecessary logistical and financial burdens for supermarket pharmacies and can compromise effective patient counseling. The one-page, FDA-approved PMI, as proposed, would reduce the time and expense associated with locating and printing multiple documents that a patient often discards.

FMI also strongly supports allowing pharmacies to provide the PMI to patients electronically unless the patient requests the information in a paper format. Many patients today would appreciate the ability to have this important information delivered electronically to be accessed at their convenience, while electronically delivered PMI is also more likely to be current and can be formatted and enlarged to be more useful. Moreover, embedded hyperlinks in mobile or web applications can allow patients to navigate within the document and can easily direct the patient to more information, such as definitions of unfamiliar terms and adverse event reporting.

By reducing what needs to be printed and providing an electronic option, pharmacy staff time would spend less time on the logistics of finding the correct required information, and overhead costs on the actual printing would be reduced. Importantly, these changes would also significantly reduce paper use and waste, aligning with our industry's steadfast commitment to advancing environmental sustainability. Finally, public health needs would be better served by providing patients with PMI that is clear and concise in the manner they desire to receive it.

Again, FMI thanks the FDA for the opportunity to provide input on this important topic. If you have questions about these comments or would like additional information, please feel free to contact me at [pmatz@fmi.org](mailto:pmatz@fmi.org) or (202) 452-8444.

Sincerely,

A handwritten signature in black ink, appearing to read "P. Matz", is positioned above the typed name and title.

Peter Matz  
Director, Food and Health Policy