Submitted electronically via www.regulations.gov

July 31, 2026

Kyle Diamantas, J.D.
Acting Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medication Guides for Prescription Drug Products [Docket No. FDA–2025–N–6869]

Acting Commissioner Diamantas,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback on FDA's *Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medication Guides for Prescription Drug Products.*

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 235,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

NCPA thanks FDA for recognizing the Citizen Petition, entitled "One Document Solution For All Pharmacy-Based Communications," submitted by Catalina Health (now part of Adheris), National Association of Chain Drug Stores, National Community Pharmacists Association, Food Marketing Institute, Healthcare Distribution Alliance, and the National Consumers League, in its Medication Guides: Patient Medication Information Proposed Rule from May 2023:

> 4. Citizen Petition
>
> In June 2008, we received a citizen petition (the 2008 citizen petition) from a large group of stakeholders representing pharmacy practice, medical consumers, and medical communications companies (Docket No. FDA–2008–P–0380). The 2008 citizen petition asked us to adopt an FDA-approved, concise, plain language, single-page patient information document for prescription drugs. The 2008 citizen petition requested that the one-page "single patient document" combine and simplify the many documents that patients currently receive at the pharmacy for prescription drug products (Ref. 15). In 2010, the petitioners voluntarily withdrew the 2008 citizen petition, citing FDA's significant work

and strides toward achieving the goals of the 2008 citizen petition with the ongoing development of PMI (Ref. 16).[1]

Estimated Burden

FDA estimates that dispensers will spend approximately 1.25 hours to prepare and distribute the Medication Guides. Under 21 CFR 201.24(e), authorized dispensers are required to provide a Medication Guide directly to the patient (or the patient's agent) upon dispensing a product for which a Medication Guide is required. As shown in Table 2, FDA estimates that, in the next three years, 88,736 authorized dispensers will provide Medication Guides to approximately 5,705 patients, annually.[2] FDA estimates that authorized dispensers will spend approximately 10 seconds to provide the Medication Guide to a patient. In Table 2, FDA also estimates that the estimated 88,736 authorized dispensers providing Medication guides to approximately 5,705 patients annually will result in over 506 million annual disclosures, totaling over 1.3 million hours of work.

NCPA has the following concerns:

Accuracy of the 10-Second Estimate

FDA is revising its estimate that authorized dispensers will spend approximately 3 minutes to provide the Medication Guide to a patient, to 10 seconds. In both instances, FDA does not substantiate this claim with evidence or research. **NCPA believes that the 10-second estimate may be a significant underestimation, and questions whether this estimate accurately reflects: counseling time when questions arise; workflow interruptions; printing, paper, toner, and maintenance costs; and reprints when guides are lost or damaged. NCPA believes that FDA is unclear on the precise administrative burden to pharmacies.**

NCPA recommends that FDA allow maximum flexibility in how patient medication information (PMI) is provided to patients by pharmacies. Downloading PMI may not be necessary, and therefore some administrative burden relieved, if any online central repository of PMI uses a permalink concept which is adopted by drug compendia in a manner such that pharmacies can provide it to patients in a manner acceptable to the patients (e.g. hyperlink in patient profile, 2D matrix barcode on the receipt, link delivered by SMS).

FDA's current medication guides[3] do not fit the above standards as a central repository of PMI because it hyperlinks to a position in the Package Information, which is not intended to be given to patients, rather than a page formatted to be printed and given to patients. If pharmacists hit Ctrl+p on any of those entries, they would get 10s of pages printed out, i.e., the full PI.

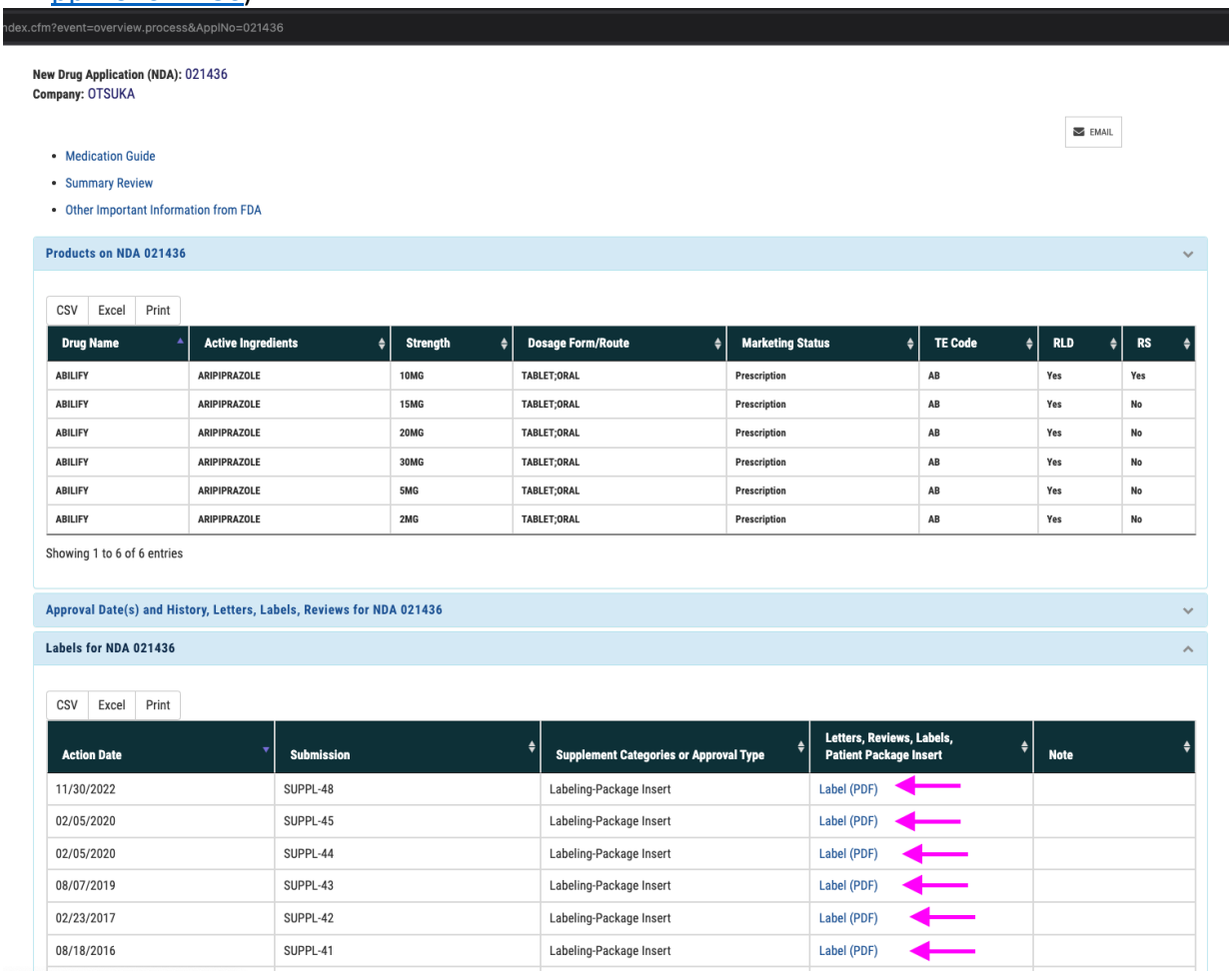
We suggest FDA consider and provide detail on whether FDA provides updates via a "pull" method (i.e., pharmacies need to upload updates) or a "push" method (i.e., FDA automatically pushes out updates to pharmacies). Further, we believe the agency should explain how it would exercise enforcement discretion

[1] FDA, *Medication Guides: Patient Medication Information,* 88 Fed. Reg., 35718, (May 31, 2023), at 35700.
[2] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medication Guides for Prescription Drug Products, Fed Reg Vol 91 No 125 (July 1, 2026), at 40001.
[3] See Medication Guides.

if an authorized dispenser provided outdated PMI to a patient due to FDA not making a timely update to its repository. As above, implementation flexibility could relieve the pharmacy of needing to pull or accept push updates.

Given the increased administrative burden, NCPA argues that FDA should:

- Title any online central repository something like "Patient Medication Information Guides" and model it after existing databases;
- Host a PDF for every single current and future PMI, as they currently do for every product label (example: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf)
    - EXAMPLE: FDA currently keeps a running list of every version and a link to each product label. This product page shows how the Drugs@FDA database keeps product label version history and link to PDF for each: (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021436)



ndex.cfm?event=overview.process&ApplNo=021436

New Drug Application (NDA): 021436
Company: OTSUKA

EMAIL

- Medication Guide
- Summary Review
- Other Important Information from FDA

Products on NDA 021436

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
ABILIFY	ARIPIPRAZOLE	10MG	TABLET;ORAL	Prescription	AB	Yes	Yes
ABILIFY	ARIPIPRAZOLE	15MG	TABLET;ORAL	Prescription	AB	Yes	No
ABILIFY	ARIPIPRAZOLE	20MG	TABLET;ORAL	Prescription	AB	Yes	No
ABILIFY	ARIPIPRAZOLE	30MG	TABLET;ORAL	Prescription	AB	Yes	No
ABILIFY	ARIPIPRAZOLE	5MG	TABLET;ORAL	Prescription	AB	Yes	No
ABILIFY	ARIPIPRAZOLE	2MG	TABLET;ORAL	Prescription	AB	Yes	No

Showing 1 to 6 of 6 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 021436

Labels for NDA 021436

CSV | Excel | Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
11/30/2022	SUPPL-48	Labeling-Package Insert	Label (PDF)	
02/05/2020	SUPPL-45	Labeling-Package Insert	Label (PDF)	
02/05/2020	SUPPL-44	Labeling-Package Insert	Label (PDF)	
08/07/2019	SUPPL-43	Labeling-Package Insert	Label (PDF)	
02/23/2017	SUPPL-42	Labeling-Package Insert	Label (PDF)	
08/18/2016	SUPPL-41	Labeling-Package Insert	Label (PDF)	

- FDA should make any online central repository database queriable on openFDA API (https://open.fda.gov/apis/drug/), just like how the Drugs@FDA and NDC directory are currently. The API should be able to return the link to where the latest PDF version is hosted (e.g., a link like this to PMI PDFs): https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf)

- The pharmacy information system should incorporate patient preference for a printout, printed link (e.g., QR code on purchase receipt) or electronic delivery (SMS, portal). It could provide a hyperlink or generate a QR code if a permalink is incorporated in the drug compendia files to the latest PDF from the API. API could also have XML or JSON of the PMI content to be injected into the pharmacy management system (PMS) or other product if desired.

- A QR code fundamentally would resolve to a link (e.g., https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf).

FDA should allow for maximum implementation flexibility. Therefore, **NCPA recommends that FDA says that QR codes, SMS, and portal access are an acceptable means to present patients with PMI, and that FDA allow the details to be worked out by the pharmacy and its technology vendor.**

FDA API should also provide a permanent link for each product in any PMI database which is set in their server to automatically redirect to the latest PMI PDF label. This would enable pharmacists to be able to print a QR code that resolves to the current version of a PMI PDF.

Pharmacies can then distribute the PMI either as a one-page insert (upon request of the patient, or as preferred by the pharmacy) or in an electronic manner acceptable to the patient. Pharmacies should not bear any financial costs associated with accessing PMI in any online central repository. The decrease in paper would save pharmacies additional burden folding inserts.

NCPA believes that any final rule regarding PMI should require PMI that: 1) has demonstrated optimum understanding for patients; 2) is provided electronically at no additional cost to pharmacies; and 3) minimizes the administrative burden to community pharmacies.

As stated above, NCPA believes that the 10-second estimate for pharmacies to provide the Medication Guide to a patient may be a significant underestimation, and questions whether this estimate accurately reflects: counseling time when questions arise; workflow interruptions; printing, paper, toner, and maintenance costs; and reprints when guides are lost or damaged. NCPA believes that FDA is unclear on the precise administrative burden to pharmacies. To date, pharmacists have borne the lion's share of the patient labeling burden, an unfunded mandate for pharmacists. The FDA must consider the direct and hidden costs to community pharmacists.

NCPA thanks FDA for the opportunity to provide feedback, and we stand ready to work with FDA to offer possible solutions and ideas. Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association