

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY AND DEPARTMENT OF HEALTH
PROFESSIONS (DHP)
MINUTES OF MEDICATION LABELING WORK GROUP**

Monday, September 14, 2026

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: At the request of the Virginia General Assembly Speaker of the House, a meeting of a work group created to discuss and review ingredient labeling of medication, drugs, vaccines sold and administered in Virginia as referenced in House Bill 831 was called to order at 2:00 PM.

PRESIDING: **David E. Brown, DC**, Director, DHP

MEMBERS PRESENT: **Brian Baird, PharmD**, Virginia Society of Health-System Pharmacists
Shannon Dowdy, PharmD, Vice-Chairman, Virginia Board of Pharmacy
Sharon Gatewood, PharmD, Virginia Pharmacy Association
Kelly Hasty Kale, RPh, Member, Virginia Board of Pharmacy
Jeenu Philip, RPh, Virginia Association of Chain Drug Stores (virtual)

STAFF PRESENT: **Erin Barrett, JD**, Director of Legislative and Regulatory Affairs, DHP
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy

QUORUM: With all members of the work group present, a quorum was established.

APPROVAL OF AGENDA: Agenda was approved as presented.

PUBLIC COMMENTS: PhRMA provided written public comment which was provided as a handout.

DISCUSSION: Ms. Juran provided an overview of the information contained in the agenda packet which included FDA's position on the matter in response to a 2015 citizen petition. Highlights included:

- FDA is aware of no oral drug products currently marketed in the United States that contain wheat gluten or wheat flour intentionally added as an inactive ingredient. FDA would expect any such product, if it existed, to include wheat gluten or wheat flour in the list of

ingredients in its labeling.

- Per FDA, most oral drugs contain no or minimal gluten; wheat gluten is rarely added intentionally.
- FDA considers low-level gluten in drugs as unlikely to harm most celiac patients, except in rare cases of wheat gluten addition.
- Daily gluten intake below 10 mg is unlikely to cause damage; most individuals with celiac generally tolerate less than 50 mg daily.
- When present in drugs, gluten levels are estimated below 0.5 mg per dose, less than in gluten-free foods.
- Nonprescription drug labels must list inactive ingredients' established names under "Inactive ingredients" on the Drug Facts label which appears on the "outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper. This information is visible to consumers at the time of purchase.
- Although not currently mandated by FDA's regulations, manufacturers of prescription oral drug products generally provide a list of inactive ingredients in the DESCRIPTION section of the prescribing information.
- For biologics, FDA interprets the requirement that inactive ingredients be identified in the labeling of biological products "when a safety factor" as meaning that wheat gluten and wheat flour must be identified by those names if they are present in orally administered biological products.
- If the labeling fails to disclose wheat gluten as an inactive ingredient, FDA would consider whether the product is misbranded under section 502(f) or other authorities (e.g., 21 CFR 201.66(c)(8)) in the case of a nonprescription oral drug product).

Work group members acknowledged FDA's position and raised additional points including:

- Members questioned if the federal law pre-empts the state from requiring additional medication labeling requirements.
- Requiring a drug label to indicate if it contains gluten may deter patients from using the drug and therefore, receiving the medical benefits of the drug, without realizing that the concentration of gluten

is believed to be harmless.

- Manufacturers may be reluctant to continue to produce a drug if testing and labeling for minor amounts of gluten are burdensome or cannot be scientifically completed due to insufficient testing methods which could lead to potential drug shortages.
- Because a hospital may stock a drug from multiple manufacturers within the various dispensing cabinets throughout the building, it may be difficult for a pharmacy to label a drug with gluten information or ensure that only a particular manufacturer of drug is administered since patients are routinely transferred to different units within the building. Concern was expressed that this challenge could create a liability for pharmacists.

Having completed all business on the agenda, the work group adjourned at 2:45 PM.

Caroline D. Juran, RPh
Executive Director

DATE: