

Docket Number: 2017-26828  
Gluten in Drug Products and Associated Labeling Recommendations  
*Guidance for Industry*

US Department of Health and Human Services  
Food and Drug Administration

Commissioner Gottlieb:

As someone who must follow a medically prescribed gluten-free diet, being able to identify that a drug is gluten-free is critical to my health. For me, even a minute amount of gluten in a drug can cause debilitating symptoms and/or intestinal damage with long-term complications.

While I am glad the FDA has issued draft guidance for labeling of gluten in medications, the proposal falls far short of meeting my needs.

The fact that labeling of gluten from wheat, barely and rye would be voluntary dilutes the good it is intended to do. Although medications often don't contain gluten, the uncertainty created by the unknown few that do cannot be erased.

As long as gluten is not clearly labeled, I will continue to worry about whether a medication I am taking to treat a condition or illness is compromising the gluten-free diet that currently is the only treatment for celiac disease and other gluten-related disorders.

Drug companies are often uncooperative when it comes to giving gluten-free consumers accurate information about the gluten-free status of their products. The completely voluntary nature of this draft guidance does nothing to change that.

I join with others in the celiac disease and gluten sensitive communities in asking for meaningful change in the form of mandatory labeling of gluten from wheat, barley and rye when it is contained in a drug. Additionally, the FDA should allow voluntary use of a gluten-free label when a medication meets the standard established for food, less than 20 parts per million, including gluten from processing or cross-contact.

All labeling information should be directly accessible by consumers. That way, if my pharmacist changes the brand or generic version of a drug that I take, I would instantly know if it is safe on my gluten-free diet.

Those who have celiac disease, a serious autoimmune condition, and other gluten-related disorders should be able to eat without fear. And, we have a right to take medications without fear, as well.

I want to thank the FDA for recognizing this need and beginning the work to address it.

Sincerely,