

What's Different About Celiac Support Group's

Drug Makers Online Gluten Free Resource List?

Introduction

As of 7/24/16, the FDA continues its research into the issues raised in the 2015 Citizen Petition to Label Gluten in Medications. This petition, on the docket at FDA-2015-P-5081-0001, remains open for comment at 7/24/16.*

If the FDA eventually adopts the Petition's request, this resource will become unnecessary.

In the meantime, Celiac Support Group offers this resource to share whatever clear and current gluten status information manufacturers and/or distributors are providing that's available to consumers.

At 8/22/16, the companies listed in this resource are the only companies that Celiac Support Group has located which meet the requirements for being included. The requirements are:

- The source is a drug manufacturer and/or distributor that lists current gluten status information for its company's products on its company website, and
- The information can be accessed by consumers directly, without cost, and without having to contact the company by phone or email.

Celiac Support Group hopes that the number of drug manufacturers and/or distributors that meet these requirements will grow.

Please notify Celiac Support Group at info@CeliacSupportGroup.org with any suggested additions or corrections for subsequent updates to this resource.

The information contained in the following pages has been accessed only on the dates indicated.

NEXT: **Listings for "All Gluten Free" and "Some Gluten Free" Drug products** (page 2)
 Store Brand and Third Party Information Reporting, Complexities and Risks (pages 3 - 7)
 Frequently Asked Questions (page 8)
 Disclaimers (page 9)

* The petition's exact request is for "A regulation in the form of a mandatory rule: that medications disclose when gluten is present in excess of 20 ppm gluten and/or when medications do not meet the conditions of the finalized (currently proposed) FDA rule 'Gluten-Free Labeling of Fermented or Hydrolyzed Foods.'" (A separate resource, "Citizen Petition - Label Gluten in Drugs", also is available for download from Celiac Support Group's website, <http://www.celiacsupportgroup.org>.)

All Gluten Free

Lannett Company, Inc. <http://www.lannett.com>

On its product FAQs page (here: <http://www.lannett.com/products-FAQ.php>), Lannett Company, Inc. states: “Yes, all of Lannett's products are gluten free.”

There are 192 products in its catalog, which consumers can download directly from the Lannett website. Commonly prescribed medications (such as certain Lipitor, Prilosec, and Synthroid products), and common over-the-counter medications (such as certain Robitussin and Claritin products) are among them.

Camber Pharmaceuticals <http://camberpharma.com>

On its home page and products page, Camber states, “All Camber Products are Gluten Free.”

There are 138 products in its online listing of products. These include Methylphenidate, Simvastatin, and Valganciclovir.

Some Gluten Free

Solco Healthcare US <http://www.solcohealthcare.com>

Solco Healthcare markets and distributes generic prescription products, some of which are gluten-free. For each of the 75 products listed on its Products page, consumers can click “Read more” to check on the product's gluten status. If the item is gluten-free (like Lotensin or Wellbutrin), this information will be the last item in a long list of disclosures. For many Solco Healthcare products, no gluten-free disclosure appears, so no gluten-free claim is being made.

Please email info@CeliacSupportGroup.org when you find other manufacturer and/or distributor information about their gluten-containing or gluten-free products that's directly available to consumers on the internet. Thank you!

Drugs Chains' Store Brand Pain Relievers, Reporting, Complexities and Risks

Caution: Because there are no “rules” for labeling (or discontinuing labeling) of store brand products, be sure to ALWAYS read the label on each specific package to look for “gluten free” before you buy.

Some drug chains label their over-the-counter pain relievers gluten free. Celiac Support Group checked the store brands listed at <https://www.verywell.com/gluten-free-pain-relievers-562382> on 7/24/16 and found store website information as follows:

Target

At <http://www.target.com>, its “gluten-free” website list did not include any of its “Up and Up” brand items (some of which may be labeled “gluten free” on the package). Target's website's “gluten-free” list does include several Tylenol brand products (see Tylenol complexities and risks below) and Benefiber. Benefiber's own website declares, in answering “Does wheat dextrin contain gluten?” at <https://www.benefiber.com/fiber-faqs>, “Benefiber^o powder contains less than 20ppm of gluten and is considered gluten-free, based on the FDA definition of less than 20ppm. However, people who experience gluten intolerance should not consume any products, including Benefiber^o, that contain any level of gluten unless otherwise directed by their doctor.”

Walgreens

At <http://www.walgreens.com>, consumers must search for specific Walgreens products and then look for additional detail. Searching the website for “Walgreens gluten-free ibuprofen” yielded “no direct results,” but offered several options, including 2 Walgreens products. The detail for Walgreens Ibuprofen 200 mg Tablets Color Free & Dye Free did not state that this product is gluten-free. However, Walgreens Children's Ibuprofen 100 Oral Suspension 2 Pack Dye-Free Berry detail did state that the product is gluten-free.

CVS

Similarly, at <http://www.cvs.com>, consumers must search for specific CVS products and then look for additional content that discusses gluten. The CVS Ibuprofen 200 Mg Caplets checked on 7/24/16 stated that these caplets “do not contain gluten.”

Walmart

At <http://www.walmart.com>, Celiac Support Group could not locate a gluten-free Walmart brand pain reliever.

Third Party Information Reporting. Complexities and Risks, Part 1

Tylenol products

7/24/16 Tylenol's official statement has not changed since October 2014, when Tylenol's

“Manufacturer McNeil-PPC ...issued this statement: 'Although we don't add gluten or gluten containing grains to our products, we cannot confirm that the product or any ingredients in TYLENOL[®] products are gluten free. Your safety is of great concern to us; therefore, we strongly recommend that you first consult your doctor before using any product if you have a form of gluten intolerance or sensitivity.'” (source: <https://www.verywell.com/gluten-free-pain-relievers-562382>, webpage updated 6/15/16; Celiac Support Group shared this link in a blog post in December 2014 at <http://www.celiacsupportgroup.org/ceciac-support-group-blog/gluten-in-drugs-action-steps-needed>)

However...

7/25/16 additional information #1: Tylenol's customer service representative verbally repeated the above information but added that Tylenol 8 Hour Arthritis Pain has been tested and is gluten free. The words “gluten free” do not appear on this product's label, and this product also is not identified as gluten-free on Tylenol's website.

7/24/16 additional information #2: Lannett Company, Inc. lists Children's Tylenol Elixir Red Cherry as being gluten free (see All Gluten Free information, above).

Unfortunately, different Tylenol product gluten status information still circulates on the internet. Celiac Support Group's google search turned up, among other information, a 2009 McNeil-PPC PDF that listed a number of Tylenol products as gluten-free. A similar 2008 McNeil-PPC PDF plus listings that represented different Tylenol items as gluten-free still were available by links from the home page of <http://www.glutenfreedrugs.com> on 7/28/16. A New List, also linked from the home page at this website, does not include any Tylenol products.

Third Party Information Reporting. Complexities and Risks, Part 2

GlutenFreeDrugs <http://www.glutenfreedrugs.com>

Celiacs everywhere owe a great debt to Steven Plogsted, the pharmacist (with a PhD in pharmacology) who created the GlutenFreeDrugs website many years ago. His site not only has been the only consumer-friendly gathering of information about gluten status for drugs, it has been his independent and all-volunteer effort.

As an independent all-volunteer nonprofit organization, Celiac Support Group appreciates the challenges that come with such independence and reliance on volunteers. In the case of GlutenFreeDrugs, it appears these include difficulty in easily updating the home page to remove older information. At 7/28/16, the home page directly links to older lists and also links and refers to a New List, as a restated version of the older lists that is not yet complete.

Given the number of differences between the New and older lists, it appears that the New List may be better viewed as a replacement list for the others. The New List was updated on 11/6/15. It contains many additional products not found on the older lists, and it does not contain certain other products that were on the older lists.

However, even the New List is no longer altogether accurate, as the example on the following page (Third Party Information Reporting, Complexities and Risks, Part 3) shows.

Pillbox <http://nlm.nih.gov>

At Pillbox, one can enter a drug name or ingredient and even search for products without particular inactive ingredients. Unfortunately, Pillbox does not specify the sources used for ingredients such as pre-gelatinized starch, which is discussed in the example on the following page (Third Party Information Reporting, Complexities and Risks, Part 3).

In addition, Pillbox's information also can be out of date. A consumer discovered this while trying to find a product without a particular excipient. Three such products were listed on Pillbox. However, none of these three products was available as of the search date.

Third Party Information Reporting. Complexities and Risks, Part 3

“Gluten” vs. “Corn Gluten” vs. Third Party Information

GlutenFreeDrugs' New List illustrates the complexities and risks consumers take when they try to determine the gluten-status of drug products via third party information. Here's one example:

The GlutenFreeDrugs older lists classify Pfizer's Zithromax antibiotic as gluten free. The GlutenFreeDrugs New List says Zithromax contains corn and for gluten is a

“2=manufacturer doesn't knowingly add gluten however since they don't do any final testing they won't guarantee it to be GF but it is very unlikely that it is contaminated with gluten”.

In a 12/2/15 letter to the FDA from Michael Weber (who filed the first citizen petition to label gluten in drugs with the FDA in 2008), Mr. Weber wrote:

“As I was writing this letter, my doctor wanted to prescribe to me the antibiotic Zithromax for an upper respiratory infection due to a bad cold. I called Pfizer to ask if Zithromax tablets were gluten free. A company pharmacist told me that an ingredient in Zithromax contains gluten. I researched Zithromax online, using <http://pillbox.nlm.nih.gov/> and did not see wheat or gluten in the inactive ingredients. In fact, Zithromax is listed as gluten free on <http://www.glutenfreedrugs.com/>. I called Pfizer again and its pharmacist restated that Zithromax contains gluten, in the form of pre-gelatinized starch. Even with my years of interest in this topic, access to resources and contacts, and willingness to conduct research, I am unable to reconcile these conflicting sources information to determine whether a common antibiotic is, in fact, gluten free.” (accessed 7/24/16 at <http://celiaccommunity.org/2016/gluten-in-med-weber-letter-fda/>)

The first question that arises from these conflicting third party information sources is: Did Pfizer mean that its pre-gelatinized starch ingredient contained what this resource *and* Mr. Weber *and* the FDA *and* GlutenFreeDrugs mean by the term “gluten”? OR did Pfizer mean something else?

For instance, another pharmaceutical company (Amneal Pharmaceuticals) in its online catalog labels its products “Contains gluten” whenever pre-gelatinized starch is used and its source is “corn gluten” from maize. “Corn gluten” is not harmful to celiacs. It is different from “gluten,” the term commonly used to describe fractions of protein in wheat, rye and barley.

[And because Amneal Pharmaceuticals appears to be silent about whether “gluten from wheat, rye, or barley” is present or absent as defined in the 2015 Citizen Petition, its online catalog is not included in this resource listing.] ...

Third Party Information Reporting. Complexities and Risks, Part 3 (Continued)

On 7/29/16, Diane Craig called the Pfizer's (Consumer) Information Center to ask about Zithromax tablets. The Information Center had no information about Zithromax with regards to gluten and transferred her call to Pfizer's Medical Information Center. There, a nurse confirmed that an inactive ingredient in Zithromax tablets is pre-gelatinized starch. She added that this ingredient is a "potential gluten source," so Pfizer does not say that this product is gluten-free.

Diane asked for clarification as to the meaning of "potential gluten source." Did this mean the ingredient's potential source was "corn gluten," or could it be "gluten from wheat, rye, or barley"? The answer was that the source was not specified, so it could be any of these - corn, wheat, rye or barley.

The Pfizer nurse also stated that Pfizer is not a gluten-free facility and that Pfizer "does not guarantee that no minute or trace amounts of gluten" are present from raw materials that Pfizer obtains from many other companies. (Diane thanks Pfizer for its transparency and courtesy in providing this information.)

[Pfizer, like most pharmaceutical companies, has an online products listing. However, the only Pfizer product mentioned on GlutenFreeDrugs' New List as being unequivocally gluten free is not listed as a gluten free product on Pfizer's own website. Pfizer's online product catalog, like Amneal Pharmaceuticals' online product catalog, is not included in this resource listing.]

This lengthy example underscores why it's always important, in the absence of a regulation, to ask detailed questions of a product manufacturer about the current status of its product, rather than relying on any third party information.

Frequently Asked Questions

Why isn't my favorite gluten-free (vitamin/mineral/herb) product company listed in this resource?

Supplements (vitamins, minerals, herbal products, etc.) and **Drugs** (over-the-counter and prescription medications), are defined differently and are governed by different labeling rules.

Supplements contain ingredients that are “intended to add further nutritional value to (supplement) the diet,” according to the FDA definition at

<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm195635.htm>

Gluten-free supplement labeling is governed by the FDA Final Rule. See

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362880.htm> for more information.

Drugs are “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,” according to the FDA definition at

<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm195635.htm>

There currently are no FDA rules or regulations regarding gluten in drugs.

Only information provided by Drug manufacturers/distributors is included in this resource.

Why are so few companies listed?

As of 7/24/16, the listed companies are the only companies that Celiac Support Group located which meet the requirements for being included here. These are:

- The source is a drug manufacturer and/or distributor that provides current gluten status information for its company's products on its company website.
- The information can be accessed by consumers directly and without cost.

Celiac Support Group hopes that the number of drug manufacturers and/or distributors that meet these requirements will grow.

Please notify Celiac Support Group at info@CeliacSupportGroup.org with any suggested additions or corrections.

How many Drug products are there?

There are more than 10,000 prescription and 300,000 over-the-counter items.

Disclaimers

Because there currently are no rules or regulations governing the use of the term “gluten free” on drug products, this resource does not test nor warrant nor imply that any drug company using the term “gluten free” on its products is doing so in the manner described in the 2015 Citizen Petition to Label Gluten in Medications. It is the user's responsibility to check with the company to determine the company's specific definition for “gluten free.”

The 2015 Citizen Petition to Label Gluten in Medications asked the FDA to require "that medications disclose when gluten is present in excess of 20 ppm gluten and/or when medications do not meet the conditions of the finalized (currently proposed) FDA rule, 'Gluten-Free Labeling of Fermented or Hydrolyzed Foods'."

Celiac Support Group does not guarantee the accuracy of the information in this resource beyond the access dates given for the links. It is the user's responsibility to check all links and information before relying on the content herein.

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