

May 1, 2017

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned hereby submits this Citizen Petition pursuant to 21 CFR 10.30, and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of Food and Drugs to require a new warning concerning the risk of esophageal cancer for all over-the-counter (“OTC”) drug products that are labeled to relieve or prevent heartburn associated with reflux disease, acid indigestion and sour stomach.

A. Action Requested

The Petitioner hereby requests that the Commissioner of Food and Drugs immediately require a new warning concerning the risk of esophageal cancer for all over-the-counter (“OTC”) drug products that are labeled to relieve or prevent heartburn associated with reflux disease, acid indigestion and sour stomach. The warnings should note that these OTC drug products do not eliminate the risk of esophageal cancer and a person should see their physician if they experience persistent heartburn associated with reflux disease, acid indigestion or sour stomach due to the risk of esophageal cancer.

B. Statement of Grounds

As many as 15 million Americans experience heartburn every day. Persistent heartburn (two or more times per week) can be a symptom of gastroesophageal reflux disease (“GERD”), a condition where stomach contents, including acid, splash into the esophagus, producing cellular changes that can ultimately result in cancer. For some patients with esophageal cancer, heartburn symptoms are the only warning they are at risk. Yet most patients are unaware that heartburn could be the sign of deadly esophageal cancer.

A recent public market research survey of more than 1,000 American adults found that only 14% were aware that reflux disease, a condition that causes heartburn, could cause esophageal cancer.

About three million Americans currently have a condition known as Barrett’s Esophagus, a precancerous condition that results in as much as a 125-fold increase in an individual’s chance to develop esophageal cancer. More than half of those with Barrett’s Esophagus are unaware

they have the condition because it presents no symptoms. That is why esophageal cancer is often only discovered when it has reached advanced stages when treatment outcomes are very poor.

There are a significant number of OTC drug products that are available to relieve or prevent heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages.

Such products include, among others, antacid products such as magnesium hydroxide, aluminum hydroxide, and calcium carbonate, ranitidine, famotidine, cimetidine, esomeprazole, omeprazole, lansoprazole, pantoprazole and nizatidine. Many of these products were formerly available by prescription and are very effective in relieving the symptoms associated with heartburn. As noted above, persistent heartburn is often the result of stomach acid splashing into the esophagus. This constant exposure to stomach contents can produce cellular changes in the esophagus that lead to cancer.

Because these products are effective in providing symptomatic relief, many patients will not seek medical intervention for persistent heartburn that can lead to Barrett's Esophagus and esophageal cancer.

The warnings on current products are not sufficient to alert patients to the risk of esophageal cancer associated with persistent heartburn resulting from reflux disease, acid indigestion or sour stomach.

The current warnings instruct patients to:

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- If you need to take more than 1 course of treatment every 4 months.

The Petitioner firmly believes that given the prevalence of Barrett's Esophagus, a stronger warning is warranted on these OTC products that are indicated to relieve or prevent heartburn associated with reflux disease, acid indigestion and sour stomach

The warnings should include a stronger, bold and prominent statement that persistent heartburn can be a sign of increased risk of esophageal cancer and explain that drug products do not eliminate that risk.

The warnings should be bold and prominent. The Petitioner proposes the following language for such a warning.

**PERSISTENT HEARTBURN CAN INDICATE INCREASED RISK OF DEVELOPING
ESOPHAGEAL CANCER.**

THIS MEDICATION WILL NOT ELIMINATE THAT RISK.

ASK A DOCTOR BEFORE USE IF YOU HAVE

- **HAD HEARTBURN OVER 3 MONTHS.**

THIS MAY BE A SIGN OF A MORE SERIOUS CONDITION

STOP USE OF THE PRODUCT AND SEE YOUR PHYSICIAN

- **IF YOUR HEARTBURN CONTINUES OR WORSENS; OR**
- **IF YOU NEED TO TAKE THIS PRODUCT FOR MORE THAN 14 DAYS; OR**
- **IF YOU NEED TO TAKE MORE THAN 1 COURSE OF TREATMENT EVERY 4 MONTHS.**

In our view, the inclusion of a bold, prominent and strong warning will serve to better inform patients of the risks associated with persistent heartburn and the need to see their physician due to the risk of esophageal cancer that can go undetected if the patient is getting symptomatic relief from the OTC drug products.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact Statement

The Petitioner will, upon request by the Commissioner, submit economic impact information in accordance with 21 CFR 10.30(b).

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner that are unfavorable to the Petition.

Respectfully Submitted,



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