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NFCA Comments to the Food and Drug Administration

Docket No. FDA-2009-N-0295

Providing Effective Information to Consumers About

Prescription Drug Risks and Benefits

On behalf of the three million Americans who have been diagnosed or are awaiting diagnosis of Celiac Disease, as well as others who are gluten intolerant, the National Foundation for Celiac Awareness respectfully requests that all consumer medication information (CMI) lists gluten (wheat, barley or rye) as an ingredient when used as an excipient. This will promote more effective use of medication and will improve the quality of care of the consumer.

One of every 133 Americans has celiac disease, and the only treatment for this life-long disease is the implementation of a strict, gluten-free diet. Since gluten, e.g. modified starch, may be used as an excipient in medications, accurate and complete labeling is critical in the treatment and management of this disorder.

Due to the lack of adequate labeling of medication, patients endure physical and psychological stress. This labeling limitation also impacts the quality of US healthcare and creates a financial burden on an already taxed healthcare system resulting from unnecessary treatments.

In 2007, Linda G., a diagnosed celiac living in Cherry Hill, NJ, required a visit to the Emergency Department of her local hospital. Oral medication was ordered for her treatment, but the gluten-free status of the drug was unknown. Because Linda was reluctant to take the medication, the nurse documented that she refused the prescribed treatment; this created additional anxiety for the patient. Fortunately the drug was able to be administered by injection, thus avoiding the gastrointestinal system, and Linda was stabilized. Since it was unknown if the required medication was gluten-free, Linda was discharged without pharmaceutical follow-up. Within a week she was back in the ER for the same medical problem; this could have been avoided if the required medication was effectively labeled.

Canadians are able to rely upon the Canadian Pharmacists Association's (CPhA) online Compendium *Pharmaceuticals and Specialties* (CPS) list of pharmaceutical manufacturers that do not use gluten as an excipient. In the United States, the quality of medical care for consumers who follow a gluten-free diet is frequently compromised when they are forced to choose between taking a prescribed medication that may contain gluten (and will make them ill,) and delaying that pharmaceutical treatment to determine the medication's gluten-free status.

Adequately labeling medication with both the active and inactive ingredients will allow more effective use of the product not only for those with celiac disease, but for others with a variety of food allergies. To further assist pharmacists, including this information in a common database as well as the package insert will result in a more informed and healthier consumer.

Background:

Celiac disease is a genetic, autoimmune disease that damages the small intestines and interferes with the absorption of nutrients from food. When people with celiac disease ingest gluten, the protein in wheat, barley and rye, the entire body is affected causing a myriad of symptoms. This common disease affects approximately one percent of the population, though ninety-five percent are undiagnosed! Due to increased awareness, the number of people identified with celiac disease is rising rapidly. Another segment of the population is gluten-sensitive, further increasing the number of people needing to follow the gluten-free diet.

NFCA is a non-profit organization with the mission to raise awareness about celiac disease and gluten intolerance and to improve the quality of life for children and adults affected by this autoimmune disease. NFCA is a proven leader in the country and its educational programs have been recognized internationally. Among its programs, NFCA partnered with the American Society of Healthcare Pharmacists (ASHP) and developed *Gluten in Medications* – a course that helps pharmacists identify when there is the possibility of gluten in medications.

Relatively few medications actually contain gluten. Despite this, the lack of adequate labeling of gluten in medication is a pervasive problem that impacts pharmacists, in addition to the millions of affected US consumers. It has become a public health crisis. This is demonstrated in several ways:

1. In 2008, NFCA conducted a survey to ascertain the experiences people with celiac disease had in Philadelphia area hospitals. 79% of the respondents reported that the pharmacists and physicians were unable to verify the gluten-free status of needed medications during their hospital stay.
2. *Gluten-Free Living* magazine, the most widely-read, printed publication catering to the gluten-free population, recently ran a two-part feature about gluten in medications. Ann Whelan, the Editor/Publisher, said to NFCA, "One of the most common questions received at *Gluten-free Living* is about gluten in medications. People are confused and frightened."
3. Dr. Dennis Cada, the editor of *Hospital Pharmacy*, a medical journal for pharmacists, reported to NFCA that its February, 2009, editorial about gluten in medications received the most feedback, letters and comments compared to any other topic – ever!
4. Registration in ASHP and NFCA's *Gluten in Medications* webinars, mentioned above, exceeded expectations and the system's capacity due to the large number of pharmacists who were hungry for information about how to meet their patients' needs.

5. Craig Massaro, the owner of Lupe's Drug Store, a community pharmacy in Fairfield, Connecticut, reports a common concern of pharmacists: because excipients are not listed in a central database, he and his staff must manually research each medication for their gluten-free patients.
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