



DATE: Monday, September 8, 2008  
TO: Individuals with CF and Families  
FROM: Dr. Elizabeth Tullis, Chair, CCFF Clinic Subcommittee  
Cathleen Morrison, CEO, CCFF  
RE: Pancreatic Enzymes and Phthalates

Pancreatic enzymes are important in ensuring that individuals with cystic fibrosis digest food and absorb nutrients. The vast majority of CF patients in Canada have been on enzymes for a number of decades with good results. The Canadian Cystic Fibrosis Foundation (CCFF) is writing to let you know about an incidental finding of a recent study. A team of Canadian researchers has found unexpected levels of phthalates (pronounced “THA-lates”) in the urine of children with CF who were taking pancreatic enzymes. Phthalates are used in the coating of some pancreatic enzymes and are found in the FDA’s list of inactive ingredients for FDA-approved drugs.

We want to bring this recent finding to everyone’s attention because of the general public concern about the presence of some particular phthalates in our environment. Phthalates are a group of chemicals used in many products, such as drugs, medical supplies, toys, vinyl flooring, wall covering, detergents, lubricating oils, food packaging, cosmetics and personal care products. In CF care, phthalates are used to allow the medicine to pass through the stomach and be released in the intestine, where nutrients are absorbed. Little is known about the effect of these chemicals on humans. Some research on animals suggests toxic effects from certain phthalates.

We are not aware of any evidence that phthalates contained in the coating of enzymes are harmful to people with CF. In fact, Canadians with CF taking enzymes have experienced improved nutritional status, and despite long term usage of these enzymes, there have been no reports of toxicity. Enzymes are one of the key reasons for the increased median age of survival of individuals with CF, which has doubled in the past 25 years.

### ***Recommendation of the CCFF Clinic Subcommittee***

*The CCFF’s Clinic Subcommittee advises that people with CF **continue** taking their pancreatic enzymes as prescribed by their CF doctor.*

The FDA also supports this because the benefits of better nutrition outweigh any potential risk from phthalates.

Your Foundation is working closely with Health Canada, the Food and Drug Administration (FDA), and the U.S. CF Foundation, and is continuing to monitor this issue. We will keep the CF community informed of any significant findings, in a timely way. To learn more, please read the attached “Frequently Asked Questions about Phthalates and Pancreatic Enzyme Products” adapted from materials provided by the U.S. CF Foundation. You can also find this document at <http://www.cysticfibrosis.ca/home.asp>. If you have more questions, please talk with your CF doctor.