

Email from FDA: Alpha Gal and Medicine

Forwarded Message -----

From: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>

To: "julie-mayberry@att.net" <julie-mayberry@att.net>

Sent: Wednesday, February 19, 2014 7:51 AM

Subject: FW: Alpha Gal Allergy

Dear Ms. Julie Mayberry,

Thank you for writing to the Food and Drug Administration (FDA). Your email was forwarded to the Division of Drug Information in the Center for Drug Evaluation and Research (CDER) for response. We greatly appreciate you taking the time to inform us of your situation. We share your concern about the importance of educating the medical community of lesser known conditions and welcome your desire to raise awareness regarding Alpha-Gal allergy.

When any new drug is submitted for approval, the company seeking approval must assure the FDA of the safety and effectiveness of the entire product, including the inactive ingredients, taking into consideration the derived source of the ingredients used. The FDA then has the responsibility to review whether the ingredient(s) pose(s) any safety hazard or adversely affect a product's efficacy. As information becomes available to FDA indicating a relationship between a particular ingredient and a potential hazard to consumers, pertinent steps may be taken either to require appropriate labeling or to prohibit the use of those ingredients in drugs. To assist with our efforts, we urge the public to report any problems they experience with drugs or their ingredients to our MedWatch program. This program is a voluntary system of reporting to FDA the problems that patients experience with products we regulate. We view this reporting system as a source for signaling trends. Should a trend emerge, the FDA will work with the sponsor of the product to address the problem. Consumers and healthcare professionals are encouraged to report any problem directly to our MedWatch program via the Internet by visiting the MedWatch homepage at <http://www.fda.gov/Safety/MedWatch/default.htm>, then clicking on "Submit a Serious Medical Product Report Online" and "Reporting by Health Professionals" or "Reporting by Consumers", respectively. Consumers can also report directly to the MedWatch Program by calling 1-800-FDA-1088 or the MedWatch form can be downloaded and either faxed or mailed to us.

Active ingredients are required to be listed on the label of both prescription and over-the-counter (OTC) drugs. However, inactive ingredients are only required to be listed on the label of OTC drug products. Although most manufacturers of prescription products do choose to list the inactive ingredients in their drugs' FDA approved labeling, the Federal Food, Drug, and Cosmetic Act (referred to as the Act) generally does not require them to do so. The FDA generally recommends that consumers read the labels of OTC drugs for the list of inactive ingredients. For prescription drugs, we recommend that patients contact the manufacturers of their prescription medicines to ascertain the ingredients if the patient's prescribing healthcare professional or pharmacist does not have this information available. Patients and healthcare professionals can obtain the labeling for most drugs, including generics and over-the-counter products, on the DailyMed web site (<http://dailymed.nlm.nih.gov/dailymed/about.cfm>). Labeling

for drugs that have been approved by the FDA can also be obtained from our Drugs@FDA web site (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>). For prescription drugs, this labeling will allow you to view the active and inactive ingredients contained in the product under the "Description" section of the labeling.

We are aware that patients and healthcare providers do not have readily accessible information to easily determine whether drug products contain an ingredient that was derived from a mammal source, as the Act also does not require manufacturers to list the derived source of their ingredients. If this information is not found in the product labeling, it may be obtained directly from the manufacturer by healthcare professionals and patients.

We appreciate your interest in educating the medical community of this important issue. To extend this effort, the Centers for Disease Control and Prevention (CDC) may also be able to provide assistance in reaching this goal.

We thank you again for your efforts and please do not hesitate to contact us again with questions about your medications.

Best regards,

KDe

Drug Information Specialist | Division of Drug Information
Center for Drug Evaluation and Research | Food and Drug Administration