PreserVision® Eye Vitamin AREDS2 Formula Soft Gels and Peanut Oil

PBM has been made aware that the PreserVision AREDS2 Formula vitamin lists “soybean oil with peanut oil” and “soybean lecithin with peanut oil” in the inactive ingredient list.

The manufacturer, Bausch & Lomb, indicated that peanut oil is not an intentionally added ingredient.  The product contains refined soybean oil that may contain minimal traces of refined peanut oil due to being processed on equipment (by their raw material supplier) that was also used to process peanut oil.  Refined peanut oil is purified, refined, bleached and deodorized, which removes the allergenic proteins from the oil. Studies show that most allergic individuals can safely eat refined peanut oil, but not cold pressed, expelled or extruded peanut oils – often referred to as “gourmet oils”.  The FDA does not consider highly refined peanut oil as a food allergen. [1, 2]

Although Bausch & Lomb states that the contact is with refined peanut oil and the FDA exempts this as being labeled an allergen, they also state that “if you are allergic to peanuts, please speak to your physician regarding whether or not you should avoid peanut oil”. [3]

It is estimated that 0.6% of the U.S. population has peanut allergies. [4] Although it appears that the risk of an allergic reaction is very low, mass conversions to the AREDS2 Formula at the facility level should not occur. Conversions can take place if the pharmacy is able to confirm with the patient that they do not have a peanut allergy – either through verbal communication or documentation in the medical record. Conversions to the AREDS2 Formula, in patients with peanut allergy, should be done under the care of their provider.

The eye vitamin product, PreserVision + Lutein, lists soy lecithin and soybean oil in their Other Ingredients – but makes no mention of peanut oil. Although peanut oil is not listed among the ingredients, PBM cannot assure that PreserVision + Lutein is not at risk of contact with peanut oil during the manufacturing process as it is manufactured in the same facility as the AREDS2 Formula. [3]

As an aside, there are other prescription items that contain peanut oil. [5] The antidote for toxic metal poisoning, dimercaprol, lists peanut allergy as a Precaution in its Prescribing Information, while the photosensitizing agent, methyl aminolevulinate, and progesterone (Prometrium) capsules list this as a Contraindication. Fluocinolone topical and otic preparations list peanut allergy as both a Contraindication and Precaution.

1. Peanut Allergy White Paper. The Peanut Institute, Albany, Georgia. Retrieved February 27, 2014. <http://www.peanut-institute.org/eating-well/allergy/peanut-oil-no-allergens.asp>
2. Food Allergen Labeling and Consumer Protection Act of 2004, Section 203 (c)(1) Accessed on February 28, 2014 at <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106187.htm>
3. Personal communication with Valeant Pharmaceuticals North America/Bausch + Lomb. Medical Information Department. Emeryville, CA.
4. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. The Journal of Allergy and Clinical Immunology [Volume 126, Issue 6, Supplement](http://www.jacionline.org/issues?issue_key=S0091-6749(10)X0014-8) , Pages S1-S58, December 2010
5. Drug Therapy Considerations in Patients with Peanut Allergy. Pharmacist’s Letter/Prescriber Letter 2009; 25(6): 250608.