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Oral Pharmaceuticals, Inc.

September 5, 2014

This letter responds to your question regarding Colgate Prevident® Varnish (5% sodium fluoride) and potential allergic reactions when used in patients with nut allergies. Prevident® Varnish, which is indicated for the treatment of hypersensitive teeth and is intended for application by the dentist, contains synthetic hydrogenated rosins derived from colophony.

Because colophony is derived from pine trees, there has been speculation that patients with allergies to pine nuts may react to Prevident® Varnish, or that patients with allergies to other tree nuts (e.g. almonds, cashews, hazelnuts, pecans, etc.) or peanuts may cross react to Prevident® Varnish.

We have reviewed the scientific literature to ascertain if such an association has been reported, and we have found little credible evidence to support this concern. Prevident® Varnish with colophony-based rosins has a long history of clinical usage in patients with very few reports of allergic reaction. We have reviewed this history and found no cases where people reported a reaction to Prevident® Varnish and had a history of nut allergies.

As with any prescription product, a thorough health history to determine known allergies is recommended before dental varnish use. Prevident® Varnish should not be used in patients with known sensitivity to colophony (pine tree rosin), and for any other known allergies, the patient should consult with the physician to determine if use of Prevident® Varnish is appropriate.

Sincerely,

A handwritten signature in blue ink, appearing to read "Su-yan L. Barrow", written over a light blue horizontal line.

Su-yan L. Barrow RDH, MA, MPH, PhD
Scientific Affairs Manager
Colgate Oral Pharmaceuticals