

## *Food and Drug Regulation*

AVH has an active litigation and counseling practice involving FDA law, focusing primarily on drug and tobacco products. The firm actively represents clients before the Food and Drug Administration – both informally and formally through the Citizen Petition process and in litigation. By coupling the firm’s knowledge of the regulatory landscape with the firm’s in-house scientific capability and patent litigation expertise, the firm offers a comprehensive team to enable companies to bring drug products to market in the most efficient, competitive and profitable manner.

The firm specializes in navigating the intricacies of the Hatch-Waxman Act. Areas of particular focus include:

- ANDA requirements;
- Patent listing and certification issues;
- 180-day generic marketing exclusivity;
- Forfeiture of the exclusivity period under the 2003 Medicare Modernization Act;
- Bioequivalence;
- Pediatric exclusivity;
- New Chemical Entity and New Dosage Form exclusivity;
- Patent term extensions; and
- Labeling carve-outs and requirements.

AVH regularly interacts with FDA on behalf of its clients, including responding to inquiries from FDA on compliance and marketing issues.