



Shook, Hardy & Bacon Deepens Regulatory & Compliance Strengths with Addition of Former FDA Attorney

WASHINGTON (April 11, 2018) Citing her decade of experience at the Food and Drug Administration (FDA), Shook welcomes attorney Sonali P. Gunawardhana to the firm's renowned life science team. She will counsel drug and device, food and beverage, and dietary supplement companies on regulatory and compliance matters from Shook's Washington, D.C., office.

"Providing health, life science and consumer product companies with a forward-looking approach to the FDA is critical to meet their business objectives," said Shook Chair Madeleine McDonough. "Sonali brings a wealth of practical guidance and a refined understanding of evolving regulatory challenges. Her FDA knowledge combined with her legal and industry acumen will make her a powerful advocate for our clients."

Gunawardhana moves to Shook from Wiley Rein LLP. Her scope of experience includes assisting pharmaceutical, medical device, and food and beverage manufacturers, suppliers and importers with resolving FDA regulatory challenges. In addition to serving on several Food and Drug Law Institute committees and *Bloomberg/BNA's Medical Devices Law & Industry Report Advisory Committee*, Gunawardhana has been singled out by *LMG Life Sciences* as a Life Science Star for her regulatory and FDA work.

Shook advises global companies on the various stages of the product lifecycle. The firm's product liability litigation attorneys have accumulated multiple victories in courtrooms across the country. In 2017, *Who's Who Legal* named Shook International Product Liability Defense Law Firm of the Year for the 13th consecutive year. Shook Partners Walt Cofer and Alicia Donohue co-lead the firm's Product Liability Litigation Practice.

"Shook has demonstrated prowess in the representation of pharmaceutical and medical device companies," said Gunawardhana. "This move provides me with a unique opportunity to partner with premier trial attorneys and strategists to avoid and resolve FDA challenges for the world's leading health, science and technology companies. I look forward to my next chapter."

Gunawardhana earned her law degree with a focus on health law from the University of New Hampshire School of Law and an LL.M. from the American University Washington College of Law, along with a Certificate in Business Administration from Georgetown University. She also holds a master's degree in public health from Boston University as well as a graduate degree from Webster University and an undergraduate degree from Syracuse University.

For more than seven years, Gunawardhana worked as the Integrity Officer for the Division of Bioresearch Monitoring at the Center for Devices and Radiological Health (CDRH).

She speaks and writes frequently in her area of law and has been interviewed by *Bloomberg*, *Washington Lawyer*, *The Food and Drug Law Institute* and others. She is a resource for reporters writing about these non-client topics:

- How regulators are likely to approach certain matters;
- FDA regulatory changes;
- Clinical trial compliance requirements for drug and medical device studies.

To speak to Shook Chair Madeleine McDonough about the addition of Sonali P. Gunawardhana or to speak to Sonali, contact Media Relations Manager Heather McMichael, 816.389.0419, hcmichael@shb.com.

About Shook, Hardy & Bacon

Founded in 1889, Shook, Hardy & Bacon L.L.P. has 12 offices in the United States and London, with attorneys and professional staff serving clients in the health, science and technology sectors in areas ranging from product liability defense and commercial litigation to intellectual property prosecution and litigation, environmental and toxic tort, privacy and data security, and regulatory counseling.