



Life Sciences

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**STRADLEY
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RONON**

Our Practice

Stradley Ronon's Life Sciences Practice Group employs a comprehensive and collaborative interdisciplinary approach to tackle the wide-ranging business and legal needs of our life sciences clients. Our life sciences attorneys advise companies in Food and Drug Administration (FDA) regulation and compliance matters, corporate law, investment transactions, intellectual property law and specialized litigation matters. Our clients range from Fortune 500 public companies with multiple commercial brands to emerging companies developing nascent technologies. Our clients are active in the full spectrum of life sciences industries, including pharmaceutical, medical device, biotechnology and other FDA-regulated companies.

Quantity	per 26g serve	Average quantity per serving	Average quantity per 100g
	446kJ (107cal)	Energy	502.42 kJ
	20.1g	Protein	1g
Total	1.8g	Fat Total	2g
Saturated	1.3g	Fat Saturated	2g
Total	2.1g	Fat Trans	0g
Sugars	1.5g	Carbohydrate	23g
	47mg	Sugar	15g
	194mg	Dietary Fibre	0g
	103mg	Sodium	45mg
	11223mg	Recommended Daily Allowances (United States)	
Acids	4943mg	Vitamin A	0%
		Calcium	15%
		Vitamin C	0%
		Iron	2%

Nutrition Facts	
Serving Size 1 Rounded Scoop (32g)	
Servings Per Container 71	
Amount Per Serving	
Calories 130	Calories from Fat 0
Total Fat 1g	2%
Saturated Fat 0.5g	1%
Trans Fat 0g	0%
Cholesterol 30mg	6%
Sodium 60mg	12%
Total Carbohydrate 5g	10%
Sugars 3g	6%
Protein 24g	48%

Our Experience

Our attorneys handle a broad array of life sciences matters in areas such as:

FDA Regulation and Compliance

We work with clients to resolve conventional and unique regulatory and compliance challenges of product development, approval and marketing. Our attorneys regularly advise pharmaceutical companies on commercialization strategies, achieving

and maintaining compliance for marketed products, and advising on the regulatory aspects of products liability. We also have significant experience counseling cosmetic, food, beverage and dietary supplement product companies on their regulatory challenges. Our broad range of regulatory and compliance services includes:

- representing clients in citizen petitions to the FDA

SUCCESS

Stradley Ronon's recent successes for our life sciences clients include serving as counsel to:

An international contract research organization (CRO) in its acquisition of a venture capital-backed CRO focused on later-stage clinical trials.

A CRO in a private placement of \$2 million in convertible preferred securities to angel investors.

A venture capital fund in a Series A preferred stock investment in a drug discovery and development company focusing on small molecule therapeutics for central nervous system disorders.

A pharmaceutical marketing services company in the development of a specialized services agreement that was accepted by various pharmaceutical companies in lieu of the typical master services agreement.

A pharmaceutical services company in various rounds of institutional investment.

- advising on legal standards and regulatory requirements for day-to-day core business operations during product development and commercialization
- providing legal regulatory support and risk management for Office of Prescription Drug Promotion (OPDP) labeling issues to meet promotional strategies and minimize product liability risk
- providing legal support for promotional review and medical/scientific review
- assisting clients in performing self-evaluative audits in cross-functional areas and designing corrective action plans
- extensive planning and implementation of Risk Evaluation and Mitigation Strategies (REMS) and legal support in preparation for FDA advisory committee meetings, with a focus on benefit risk, safety and risk management analysis, and counseling
- responding to government inquiries and document production
- assisting clients in developing cosmetic, food, beverage and dietary supplement product labeling and advertising practices in conformance



with the law and FDA requirements

Risk Management and Litigation

Our seasoned trial team works closely with clients to identify and analyze risks associated with clinical trials, informed consent documents, labeling, advertising and post-marketing activities. We have significant experience in defending life sciences companies in commercial, intellectual property and products liability cases, as well as serving as national defense counsel in high-profile mass tort and products liability litigation throughout the United States.

Life Sciences Transactions

Our corporate attorneys advise life sciences companies at all stages of the growth cycle – from incubator to product, from product to commercialization, and from emerging to profitable. We have deep experience in handling all forms of corporate and commercial transactions, including early stage financings, mergers and acquisitions, divestitures, and collaboration and licensing agreements. We are known for combining technical know-how in structuring and negotiating important business transactions with broad industry knowledge to close deals in a manner that maximizes value for our clients.

Intellectual Property

Our attorneys represent various life sciences organizations – ranging from traditional pharmaceutical companies to start-up biotechnology ventures and teaching hospitals, universities and other nonprofit entities. We have comprehensive experience in developing and managing intellectual property portfolios, and counseling clients regarding due diligence and freedom to operate studies, enforcing intellectual property rights.

Having worked with a variety of medical device and biotech companies, as well as universities and hospitals, our attorneys are adept at handling the unique intellectual property challenges of corporations in the life sciences industry. Our dedicated practitioners are client-focused, constantly looking for ways to make the most of our clients' intellectual property by:

- identifying new opportunities and gaps in intellectual property protection

Our People

Our life sciences lawyers are leaders in the profession and have received numerous industry awards and recognitions. Our group is comprised of attorneys who are educated in pharmaceutical and bio-pharmaceutical sciences; have scientific knowledge in antibody structure and genetics; teach pharmaceutical regulation at local universities; and have working experience in regulated companies. Our attorneys also speak at industry conferences and are published and quoted in life sciences publications and trade journals such as *Update Magazine*, *imPACT Times* and *The National Law Review*.

intellectual property strategies that correlate with business objectives

- forming strategic alliances, licenses and other collaborations for research and development, funding and commercialization of products

Some of our recent intellectual property matters include:

- preparing and prosecuting patent applications for universities and companies in the pharmaceutical and biotechnology fields
- defending medical device companies in patent litigation
- creating patent strategies for medical device, pharmaceutical and biotechnology companies
- negotiating license, manufacturing and supply agreements with U.S. and foreign biotechnology corporations
- performing due diligence for venture capital companies investing in drug delivery developers

For more information on our Life Sciences practice, visit www.stradley.com/lifesciences.



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ABOUT STRADLEY RONON

For more than 95 years, Stradley Ronon has helped private and public companies – from small businesses to Fortune 500 corporations – achieve their goals. With nine offices and more than 200 attorneys, Stradley Ronon is proud to help companies manage their legal challenges and grow their businesses.

www.stradley.com

LOCATIONS

Pennsylvania
Washington, D.C.
New York
California
New Jersey
Illinois
Delaware



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