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Shipman & Goodwin offers a broad range of legal services to companies doing business or desiring to do business in the United States. We offer high quality, cost-effective services in a personalized manner. This proposal outlines some of the services that are available from Shipman & Goodwin for Chinese life sciences, biotechnology, pharmaceutical, medical device, biologic, traditional Chinese medicine and other medical products companies that desire to do business in the United States. We can provide a range of fees for each type of project listed below. The legal fees for our services will depend largely on the scope of the project. We can often provide a flat fee or a good estimate once we understand the services that you desire to receive. Thank you for the opportunity to provide you with this proposal.

Doing Business in the United States

There are many ways that you can do business and market your product in the United States. You could own and operate a manufacturing facility and/or a distribution network, or could use one of the following methods for manufacturing and distributing a product.

DOING BUSINESS IN THE U.S.

TYPE OF PROJECT
<p>Distribution Agreement You could distribute your product through a U.S. sales representative under a Distribution Agreement. We can draft and negotiate a Distribution Agreement.</p>
<p>License Agreement and Technology Transfer You could license your technology to a U.S. company so that the U.S. company can manufacture and market the products using the technology in the U.S. We can draft and negotiate a License Agreement.</p>
<p>Manufacturing and Supply Agreement You could engage a U.S. manufacturer to produce a product for distribution by the U.S. manufacturer or a third party distributor. We can draft and negotiate a Manufacturing and Supply Agreement.</p>
<p>Joint Venture with a U.S. Company You could enter into a joint venture with a U.S. company and the joint venture could manufacture and/or distribute the product. We can structure the joint venture and draft and negotiate the joint venture documents.</p>
<p>Collaboration or Development Agreement You could collaborate with a U.S. company to develop a product or an improvement to an existing product. We can draft and negotiate a Collaboration or Development Agreement.</p>
<p>Sales, Supply & Wholesale Agreements Often products are sold to resellers or wholesalers who then supply the product to the final seller. We can negotiate a sales, supply or wholesale agreement.</p>



FDA Regulation

Marketing a product in the U.S. that is regulated by the FDA can be a complicated process and generally requires approvals. The U.S. FDA¹ is a very well established agency with vast enforcement capabilities. We can assist a Chinese company that desires to bring their regulated product to market in the U.S. We can assist with the following FDA-related projects:

FDA PROJECTS
Determination of FDA Regulation We can work with independent counsel to determine how a product will be regulated by the U.S. FDA. We can research and report to you on relevant FDA regulations.
FDA Approval We can assist with FDA approvals working with a consultant (e.g. a contract research organization) who specializes in filing such approvals. We can provide legal services related to FDA approval submissions.
Education and Training We can educate and train workforce members on applicable FDA rules and regulations. We can provide training specific to your product, working with independent opinion counsel where necessary.
Compliance Plan We can provide a set of internal controls that effectively reduces the risk of noncompliance with U.S. laws and regulations relating to the manufacture and sale of products. We can draft and provide guidance on implementation of a Compliance Plan, working with independent opinion counsel where necessary.
Research We can provide advice on contracting for or performing clinical trials to obtain approvals in the U.S. We can provide advice and draft and negotiate research agreements, working with independent counsel where necessary. We often work with sponsors and contract research organizations in their negotiations with study sites.

Intellectual Property Considerations

Protecting the intellectual property associated with a product is very important in the U.S. The U.S. has well established patent laws that can protect a product or prevent a product from being sold in the U.S. Our attorneys design and implement strategies to maximize, retain and safeguard the value of the goodwill and innovation, trade secrets and proprietary information represented in your intellectual property portfolios. We can assist with the following intellectual property-related projects:

INTELLECTUAL PROPERTY PROJECTS
Education We can provide advice, education and training on intellectual property rights in the U.S. We can provide education and training based on your portfolio.
Policy Development We can provide policies and procedures to follow when developing and commercializing products to improve IP protection and viability of product commercialization. We can draft and provide implementation guidance on intellectual property policies.

1. There are also other regulators who may be involved depending on the type of product and how the product is reimbursed, including the Centers for Medicare and Medicaid Services (CMS), the Department of Justice (DOJ), the Office of Inspector General (OIG), the Office of Civil Rights (OCR), and other state and federal agencies.



INTELLECTUAL PROPERTY PROJECTS (cont.)

Freedom to Operate

We can work with independent patent counsel on a freedom to operate evaluation and possible opinion. We can provide advice on the patent landscape for your product and work with opinion counsel if necessary.

Patent Liability & Prosecution

We can work with specialty patent prosecution counsel to obtain a patent.

Intellectual Property Defense

We can provide intellectual property defense if a person is alleging that you are infringing their intellectual property. We can provide counseling related to possible infringement.

Product Reimbursement

The success of many products depends on third party reimbursement for the product. In the U.S., medical products can be paid for by the patient, but more often reimbursement is paid by the government or a commercial payor. We can assist with the following reimbursement-related projects:

PRODUCT REIMBURSEMENT PROJECTS

Obtaining Reimbursement

We can provide advice on a strategy for obtaining reimbursement. We can assist in preparing a strategic plan for reimbursement.

Government Reimbursement

We can assist with government contracting to obtain government reimbursement. We can negotiate and manage government contracting.

Commercial Contracting

We can assist with commercial contracting to obtain commercial payor reimbursement. We can negotiate and manage commercial contracting.

This brochure outlines many of the services that are available from Shipman & Goodwin for Chinese life sciences, biotechnology, pharmaceutical, medical device, biologic, traditional Chinese medicine and other medical products companies seeking to do business in the United States. Should the need arise for other services, we would be able to provide you with similar information in those areas of law.

About Our Firm

Shipman & Goodwin is a full-service law firm recognized for its depth of knowledge and experience in a number of industry sectors, including clean energy, export compliance, financial services, real estate development, information technology, government, petroleum, telecommunications, emerging and middle market companies, franchising, health care, life sciences, education and retail. With more than 175 attorneys and offices throughout Connecticut and in New York and Washington, D.C., the firm represents many businesses, institutions, individuals and government entities from a variety of countries worldwide.



J. DORMER STEPHEN, PARTNER

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Dormer is Co-Chair of the Firm's Business and Finance practice group, and handles venture capital and private equity and debt transactions, mergers and acquisitions and general corporate matters. His practice involves the representation of Fortune 500 companies, private equity funds, emerging growth companies and investment banks in structuring, negotiating and documenting seed through later stage equity and debt investments, mezzanine financings, syndicated credit facilities, mergers and acquisitions, buyouts, rollup strategies, joint ventures, intellectual property transactions, work-outs and financial restructurings and general corporate matters. Constituent companies are in a broad range of industries including biologics, biotechnology, financial services, health care services, insurance, life sciences, media, medical devices, pharmaceuticals, software and telecommunications. He also represents public and private clients in an "outside general counsel" capacity. Roles include counseling on strategic initiatives (such as joint ventures, joint development projects and intellectual property licensing and collaboration), commercial contract matters (such as distribution and supply agreements, license agreements and employment agreements) and other general corporate matters (such as employment and severance matters, equity incentive plans, corporate governance, real estate matters and insurance matters).



DONNA L. BROOKS, PARTNER

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As outside general counsel, Donna Brooks advises clients in diverse industries, including healthcare, life sciences, agri-business, technology, services and manufacturing. Her clients include emerging growth companies and middle market companies, including cooperatives and public companies. Donna assists her clients "in the business of doing business." She provides practical advice with respect to business organization, business operations and contracting, corporate governance, asset management, finance, capital raising, private and public securities offerings, equity compensation, joint ventures, and mergers and acquisitions. Donna also counsels development stage companies with research and development agreements, including sponsored research and consulting agreements with universities and their faculty and technology transfer offices. Donna also advises companies regarding both federal and state securities laws compliance and with the preparation and filing of SEC periodic reports, registration statements, Section 16 stock ownership reports and proxy materials.



JAMES C. SCHULWOLF, PARTNER

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Jim Schulwolf represents senior and mezzanine lenders, venture capital investors (including SBIC's), private equity funds, hedge funds, emerging growth companies and private companies in financing, investment, leasing, acquisition, corporate, licensing and restructuring transactions. Jim regularly advises these clients with respect to structuring, negotiating, and closing complex transactions. Jim also regularly advises clients with respect to distressed investments and the restructuring of existing investments and loans. In addition, Jim advises clients, including municipalities, universities, and non-profit entities with regard to interest-rate swaps and hedging transactions. Jim is the Chair of the Commercial Finance Committee of the American Bar Association's Business Law Section and is a member of the Connecticut Law Revision Commission Advisory Committee on 2010 Amendments to Revised Article 9. Jim's experience also includes the representation of senior lenders in complex commercial, asset-based, and acquisition financings; mezzanine lenders and hedge funds; SBIC's and venture capital funds; emerging growth companies; hedge fund, buyers, sellers and sponsors; and nanotechnology companies in corporate, licensing, joint venture, and capital raising activities.



WILLIAM J. ROBERTS, ASSOCIATE

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As a member of the Life Science and Medical Products client team, Bill represents medical device companies, pharmaceutical companies, clinical laboratories, tissue banks and organ procurement agencies. Bill advises clients on contracting matters, employment and independent contractor agreements, accreditation, product reimbursement (including Federal Supply Schedule, Medicare, Medicaid and other public payors) and regulatory compliance, including FDA, marketing, and data security requirements. In both the health care and life science contexts, Bill works extensively with clients on the development and implementation of compliance programs and responding to compliance incidents. Bill is often asked to conduct employee trainings, review and prepare compliance policies and procedures, and represent clients during privacy breaches and government inquiries.



MATTHEW J. MONTEITH, ASSOCIATE

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Matthew Monteith practices primarily in the areas of business and finance. Matthew represents commercial banks, venture capital investors, private equity funds, tax credit financiers and other senior and junior lending institutions, as well as emerging growth companies and other corporate borrowers, in connection with a variety of commercial transactions including term and revolving credit facilities, mezzanine financings, acquisitions and dispositions, preferred equity investments, entity formation, and general corporate and contracting matters.