

Preparing a Successful Contract

by Justin J. Prochnow

“Handshake agreements” were the way many business relationships were historically cemented. While some companies still operate through an arcane combination of purchase orders, emails and other communications, the increase of critical events such as inspections, recalls and class actions make the uncertainty of this archaic system problematic. A well-written and detailed manufacturing, distribution or supply agreement can alleviate some of the uncertainties and clarify the respective obligations of the parties. Following are nine considerations to keep in mind when negotiating an agreement with business partners.

1 Define Key Terms

It is important to ensure everyone is on the same page when negotiating contract terms. The only way to do that is to make sure it is easily understood, and all of the terms are clearly defined. Identification of key terms such as “products,” “territory” and “net profits” is crucial so no ambiguities can lead to discord and potential disputes. Parties should avoid using “legalese” (yes, a lawyer said that!) and use simple terms that everyone understands.

2 Rights and Responsibilities/ Indemnification

A day doesn’t go by without another potential class action lawsuit being filed for alleged false marketing and advertising, or product liability claims. The division and declaration of the rights and responsibilities of the contracting parties to comply with applicable laws and regulations, as well as any indemnifications between the parties, have become one of the most important aspects of any agreement. The initial responsibilities may be clear due to the nature of the services provided, but the onus of those responsibilities can be shifted. Often, the modified golden rule—“he who has the gold makes the rules”—controls which party has the clout

to get indemnification or place the burden of responsibilities on the other party. Of course, the time to negotiate and obtain any indemnifications is up front when the contract is being negotiated and prepared. That will not happen when things have fallen apart.

3 Intellectual Property and Related Rights

Protection of intellectual property (IP) rights is another important reason for a written agreement. It is critical to establish who owns the rights to the IP, such as a product formula. It is also important to consider whether the contract manufacturer, if it does not own the rights, can produce substantially similar products for competitors of the customer. If so, the specific parameters of that right must be defined. Additionally, provisions governing the confidential nature and nondisclosure obligations tied to IP or trade secrets are always critical to clarify between parties. Issues such as the use of trademarked names or copyrighted materials are often covered in separate licensing agreements.

4 Regulatory Responsibilities

A topic often overlooked when contracting, but one that has obtained increasing importance in recent years, is the clear identification of the regulatory responsibilities of the parties. As FDA conducts inspections with increasing frequency, especially with respect to dietary supplement companies, identification of the respective responsibilities of each company in the manufacturing, supply and distribution chain can make such an inspection go as smooth as possible. Companies can’t “contract away” their responsibilities from a regulatory standpoint. However, if a contract clearly identifies the obligations a company may have and a representation that the company will fulfill those obligations, such a contract may be helpful in convincing FDA that a company has done its due diligence

in complying with the cGMPs (current good manufacturing practices) or other regulatory requirements.

5 Venue and Forum

If the relationship breaks down, and the parties can’t work out their differences, the location and forum for settling differences could be important, especially if one of the parties is from outside the United States. Many agreements contain arbitration clauses that compel resolution of all agreement-related disputes by arbitration, whether in front of one arbitrator or an arbitration panel. Arbitration is often less expensive, faster and, importantly, private. Parties can also agree to confine any dispute resolutions to a particular city or state.

6 Entitlement to Attorneys’ Fees

The general rule regarding the apportionment of attorneys’ fees is called the “American Rule,” which provides that each party is responsible for its own attorneys’ fees and costs unless provided for by statute, rule or agreement. Thus, parties may want to include an attorneys’ fee provision to specify who will be responsible for fees if a dispute arises between the parties. Such clauses often award attorneys’ fees and costs to the “prevailing party.” Of course, the definition of “prevailing party” becomes important (a call back to defining key terms clearly!). For example, if a lawsuit includes 10 claims by the plaintiff and a demand of \$1 million, and the plaintiff wins on four of the claims and is awarded \$100,000, who is the prevailing party? Arguments over who the prevailing party is in a lawsuit can put such a clause that is intended to resolve disputed matters more quickly, due to the possibility of a large award of fees, at the center of a new and expensive dispute.

7 Assignment of Rights

In many situations, contracts are entered into because one or both parties have specifically chosen to work together. Maybe a company likes a

particular form of an ingredient supplied by a partner or a company may have audited facilities of a manufacturer before entering into an agreement. If the specific relationship is important, companies should make sure obligations and rights under the contract cannot be assigned to another party without approval. Otherwise, a company may find itself handcuffed to another company it doesn't want to work with.

8 Termination and Expiration

Most companies enter into an agreement with the intent of maintaining a long and fruitful relationship. But eventually, all good things must come to an end, and contracts are no exception. It is wise to put an exit strategy in place for the expiration or termination of an agreement. Most agreements have an initial term—some agreements will automatically renew, while others may expire at the end of the term if there is no renewal. Sometimes, however,

circumstances arise that spur parties to desire to terminate agreements before the term expires. Provisions should be included that allow parties to terminate for cause after providing reasonable notice of any alleged breach to the breaching party and a reasonable amount of time to correct the breach. Contracts should specify who takes ownership of inventory upon termination, and what obligations and responsibilities might come with the termination of an agreement.

9 Know What You Are Agreeing To

Agreements are one of the most important aspects of a business—they set forth the parameters and terms for how companies are going to operate together. Accordingly, they must be entered into with the requisite level of attention and care. A lawyer seasoned in dealing with business agreements for food, beverage and supplement companies should prepare or, at the very least, review the agreement before

it is signed. Don't assume because the other party is a friend that the agreement will be fair to both sides. And don't assume because the agreement was previously used that it has been properly drafted. Once again, it is much harder to modify an agreement once it has been signed and business has been conducted between the parties. The little extra amount of focus directed to the agreement during its formation is likely to pay big dividends down the road. ■



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