

Bio-Medical & Pharmaceutical

Manufacturing Corporation

Helpful Information & General Policies

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* These items were updated on this version.

4311 SOUTH DR., HOUSTON TX 77053-4820

Phone: 281.835.8051 Fax: 281.835.8114

Preface

Commitment To Quality & Service

Since 1974, Bio-Medical & Pharm. Mfg. Corp. has produced the finest quality cosmetics, skin care, hair care, and agricultural products in the Houston area. Everything we produce is done to standards that exceed the expectations of our customers. From research and development to final production, good manufacturing practices can mean the difference between success or failure either in the marketplace or with government agencies responsible for the protection of the public.

Certain procedures are in place to protect our customers from unnecessary or unexpected costs and to provide them with as much data as possible about their particular products. We feel that it is our responsibility to provide objectivity and stability to markets that can be highly competitive. Our laboratory is able to provide improvements to existing products or major breakthroughs in new product formulation.

Intent To Revise Policies

We occasionally revise our policies based on changes in the legal landscape of the manufacturing industry, market trends, changes in government regulation, and other reasons. The purpose of each revision shall be to ensure our commitment to quality and service and to provide for the continued availability of our products and services.

Amending Policies

These policies may be amended by other contracts or agreements already in effect or later documents which may specifically modify or eliminate certain policies or information in this publication. To do this, a document must specify that it is amending or overriding "Bio-Medical & Pharm. Mfg. Corp.'s policies" and be signed by an authorized agent of Bio-Medical & Pharm. Mfg. Corp.. Agreements or contracts (other than general policies) already in force at the time of this version of Bio-Medical & Pharm. Mfg. Corp.'s policies shall remain unchanged and shall not be superceded by this version. All previous versions of Bio-Medical & Pharm. Mfg. Corp.'s policies are superceded by this version.

Author

This version was authored by Tom Loesch III for publication. Many of the policies included were derived from the advice of Jim Stepp, Attorney, Business Law, and Mark A. Oathout, Attorney, Trademark and Copyright Law. Regulatory sources include the United States of America Federal Food & Drug Agency, the Environmental Protection Agency, the Occupational Safety & Health Administration, the Texas Department of Health & Human Services, The Department of Transportation, and the City of Houston Health Department.

Access To Information & Company Locations

Addresses & Whom To Contact

Our address is: Bio-Medical & Pharm. Mfg. Corp., 4311 South Dr., Houston, Texas 77053-4820.

Paula Wedegartner, President of Bio-Medical & Pharm. Mfg. Corp. has run her own business in Rosenberg for many years making t-shirts, trophies and memorabilia for sports teams, schools, and other clients. She brings years of management and administrative skills to the company.

Dr. Loesch, Secretary of Bio-Medical & Pharm. Mfg. Corp. earned a Ph. D. in Bio-Medical Sciences from the University of Texas and performs all government compliance services, testing procedures, and is the final decision-maker for most financial issues.

Tom Loesch III, Vice-President uses his experience with computers to minimize delays when acquiring ingredients and tracking production. He wrote our proprietary software systems and trains our staff to reduce costs by exploiting automation. He also handles most sales issues.

Graciela Handy, Production Manager has almost 30 years of experience managing various production methods and machinery. She maintains the highest level of efficiency during the production process and controls the flow of goods through the physical locations.

Description Of Locations

Bio-Medical & Pharm. Mfg. Corp. is an FDA registered and inspected facility producing liquids, crèmes, gels, masques, and other products for external use. The property consists of a warehouse, a formulation laboratory, production space, and office space.

Loesch Laboratory Consultants, Inc. is a centrally-located combination of fulfillment and warehousing space, production space, an HPLC laboratory, and office space. It distributes all types of products by freight or parcel delivery service.

Proper Attire & Behavior

To tour either of our locations or our overflow facilities, it is important to arrive in appropriate clothing. Any protective gear you might need will be provided by your guide.

Since Bio-Medical & Pharm. Mfg. Corp. is an FDA registered facility, certain types of clothing are prohibited. These include "dangly" earrings, necklaces, pendants, or other ornaments that could come loose. Open-toed shoes, sandals, high heels, or other shoes that could allow liquids to penetrate quickly or which do not lie flat on the floor under the foot are also unacceptable. Cut-offs, high-waters, spandex, and Capri shorts do not offer protection from splashes and are also prohibited in the production, laboratory, and warehouse parts of the building. Hair and hands must be covered in the production and laboratory areas or whenever handling ingredients.

Since Loesch Laboratory Consultants, Inc. manufactures powders, those with breathing difficulties such as emphysema or asthma should exercise caution when entering the production area. Breathing protection must be worn while production is occurring. "Dangly" earrings, necklaces, pendants, or other ornaments that could come loose should not be worn in the production areas. Since most of the powders we manufacture are white, wearing black is probably not a good idea.

Behavior consistent with health and anti-contamination precautions will be expected at all times.

Authorized Personnel

No one gains access to any location without the approval of the management. Please contact our office to arrange a time for a visit. Our offices are often very busy and can not be interrupted with impromptu tours.

While proprietary, secret, or otherwise confidential processes are going on, no visitors will be allowed past the office area with the sole exception of government inspectors performing their duties.

Bio-Medical & Pharm. Mfg. Corp. may grant extended permission to individuals for various reasons. This authorization is not transferable and is not intended to include other individuals unless approved by our personnel in advance.

Bio-Medical & Pharm. Mfg. Corp. reserves the right to revoke anyone's authorization at any time for any reason.

Where access to formulas and procedures of a confidential nature are involved, Bio-Medical & Pharm. Mfg. Corp. will offer Confidentiality Agreements on a case-by-case basis. A Confidentiality Agreement is a legally binding document designed to protect our customers' information. It is standard procedure to assume that all information is confidential unless otherwise demonstrated. Information that is not protected includes information already in the public domain, information available from alternate sources, and information already known at the time of disclosure.

The Website

www.bio-medicalmanufacturing.com provides a lot of general information about what products and services are available. A contact form also provides an easy way to send us an email even if you don't have an email account. Information about the research and development process is also included.

Shipping & Receiving

Dock Hours

At our South Drive location, the dock is open from 9 am to 3 pm Monday through Friday except holidays. An appointment is recommended to avoid delays.

Proper Labeling

We do not accept the delivery of any shipment which is not appropriately and legibly labeled with the shipper's name, the name of the material, the size, lot number, weight, and other information needed to establish its identity. In the event that a package is found to be missing any of the information necessary to identify it under current regulations, it will be refused or returned to the sender.

Fees

Any ingredients, packaging materials, or other goods which are not owned by Bio-Medical & Pharm. Mfg. Corp. will have a receiving charge assessed when they arrive. For some long-time customers, these charges may be included in the price of products or be otherwise amended by written contract or agreement. Shipments that are not related to production or inventory may be exempt from the following fees.

Fee Schedule For Shipping & Receiving

Inbound Parcels	\$10.00 per session
Inbound Freight	\$50.00 per labor hour
Outbound Parcels	\$25.00 per session
Outbound Freight	\$50.00 per labor hour
Rushed Outbound Shipments (Less Than 24 hours)	\$50.00 per session

Warehousing & Storage

Grace Period

A grace period of at least 30 days will be granted for all materials received at one of our locations during which no storage charges will be assessed.

Assessment Date

On the first business day of each month, a storage charge will be assessed for all materials not owned by Bio-Medical & Pharm. Mfg. Corp.. When the assessment date falls before the end of the grace period, no charges will be assessed until the following month.

Fees

Any ingredients, packaging materials, or other goods provided by our clients' for production will have a storage charge assessed based on the square footage required to store them. The charges will apply to all such materials no matter where they are stored. Materials will be stored with narrow access isles between rows. This extra space will be included in the square footage calculation.

Fee Schedule For Storage

Uncontrolled Storage	\$0.56 per ft ²
Climate Controlled Storage	\$0.83 per ft ²
Hazardous/Flammable Materials Storage	\$4.58 per ft ²
Refrigerated Storage	\$6.44 per ft ²

Any finished products that remain in our warehouse(s) for over 30 days past completion will be assessed a finance charge or storage fee at our discretion.

Bonded Warehousing

When Used

Because our locations have limited space, we often use overflow locations to store ingredients, machinery, packaging materials, and other stuff.

Responsibility & Bonding Coverage

Customers of Bio-Medical & Pharm. Mfg. Corp. are required to inform our production manager before arranging shipping of materials to one of our docks. Necessary information includes storage type (uncontrolled, climate controlled, hazmat, or refrigerated), number of containers, number of pallets, value of the shipment, insurance requirements or coverage, and expected arrival date and time. Be sure to make an appointment with the warehouse dock in advance.

Insurance Requirements

Our insurance does not extend to any overflow locations, so materials which are of a significant value must be covered by our customers' insurance. Bio-Medical & Pharm. Mfg. Corp. does offer insurance riders to cover these materials, but only on a case- by-case basis.

Rerouting Of Shipments

Large shipments may sometimes be rerouted if there is insufficient space or if prior arrangements were not made with our production manager. Unfortunately, we can not assume responsibility for any additional charges which might result from such a rerouting. It is very important to communicate as much information as possible before any shipment arrives to prevent these charges. Sometimes we will advise a customer or supplier to send a shipment directly to one of our overflow locations.

Terms Of Sale

Pricing, Quotes, & Market Pricing

Pricing is done with the understanding that the price is dependant on the description of the product and the conditions of the manufacturing process. Quotes are issued by management or an authorized agent and are usually current for 30 days. In the event of a significant market price fluctuation, prices may be re-quoted at any time. Once an order is confirmed, Bio-Medical & Pharm. Mfg. Corp. is bound to either deliver the product at the accepted price or cancel the order.

A setup charge will be assessed for any orders under 1,000 units. Bio-Medical & Pharm. Mfg. Corp. does allow all sizes of a particular product to be combined to reach this goal. There is also an inherent minimum size for various types of products due to the machinery that is used in production. For example, a 25 horsepower mixer in a 55 gallon stainless steel vessel will require at least 35 gallons of volume to form a smooth crème. Pastes are done in 50 pound batches, so a number of units must be ordered to equal some multiple of 50 pounds.

Any changes to formulas, packaging, or other conditions relating to a quote will nullify that quote and a new quote will be issued when new conditions are agreed upon.

Our management can also make arrangements to maintain a price quoted for longer periods of time. This provides additional stability in highly competitive markets or where profit margins are tight.

Repackaging

We can repackage many types of products including creams, lotions, liquids, gels, powders, makeup, and others. Inbound containers must be new, properly labeled with the manufacturer's name and contact information, the identity of the product, and the lot number. It is our standard policy to require a Certificate of Analysis on all products with some exceptions. We may also require an MSDS on some products.

We often send our products in bulk sizes to other facilities for repackaging or remanufacturing. OTC drugs in sizes larger than 1 gallon will only be shipped to the end user or to a registered drug repackaging facility. Some products may be considered too delicate or sensitive to be repackaged. In these rare cases, we will notify the buyer of any restrictions placed on products they wish to purchase. If these restrictions are ignored, we reserve the right to deny future purchases of that product.

Purchase Orders

A purchase order is a customer's commitment/contract to take delivery of and pay for the products described on the form. Of course, a price quote is necessary for the first one; however, if pricing changes in the future, Bio-Medical & Pharm. Mfg. Corp. will notify its customer of the change.

Orders may be placed by calling or faxing forms to 281.835.8114, by emailing them to sales@bio-medicalmanufacturing.com, or by mailing them to Bio-Medical & Pharm. Mfg. Corp., 4311 South Dr., Houston, Texas 77053-4820.

Order Confirmation

When the management of Bio-Medical & Pharm. Mfg. Corp. decides that the order is acceptable and can be delivered approximately when requested, the order is confirmed. We send out order confirmations for most orders, but one may be provided any time after the order is scheduled. An order confirmation cements the price that will be charged for the product. Bio-Medical & Pharm. Mfg. Corp. reserves the right to cancel an order even after it is confirmed. In this event, one of our agents will contact the customer as soon as the cancellation occurs.

Bio-Medical & Pharm. Mfg. Corp. will refuse orders for products which are not covered under the proper liability insurance which must be extended to the manufacturer of the product. Alternately, the product may be covered by an insurance rider for an additional fee. Please be aware that arranging insurance coverage can sometimes take a few weeks.

Production Scheduling & Rush Charges

Due to the high demand for our products and services, our equipment stays very busy. The associated juggling act is performed by our production manager and depends on several factors. When orders are first accepted, they are assigned an estimated ship date. Bio-Medical & Pharm. Mfg. Corp. does not give exact ship dates because the entire schedule is typically based on groups of estimations. This is one of the limitations of dealing directly with a manufacturer.

Lead times are typically 6-8 weeks but vary depending on market conditions, current production scheduling, and seasonal demand. We do not guarantee delivery by a particular date nor by the 8 week typical lead time. Lead times will be extended as we deem necessary to service clients with the available labor and equipment. No credits, claims, or rebates will be offered for such delays. If you require that your order be delivered by a certain date, you must choose one of the following rush options.

Orders required in less than 6 weeks will be assessed a 15% rush charge unless we are unable to deliver within that time.

Orders required in less than 4 weeks will be assessed a 25% rush charge unless we are unable to deliver within that time. If delivered within 6 weeks, a 15% charge would be assessed instead.

7-day rush production is available for a 100% up-charge (double the price of the product and/or services rendered). This charge would guarantee delivery in 7 days; however, certain restrictions apply. Call our office or call 713.446.1446 to reach the Vice-President to get approval rush production.

Continuing Guarantee

Bio-Medical & Pharm. Mfg. Corp. guarantees to manufacture all products according to the appropriate GMP's (Good Manufacturing Processes) for the product, to maintain appropriate records storage, and to store all ingredients, packaging materials, and finished products in a manner consistent with related GMP's, longevity, stability, and salability.

Bio-Medical & Pharm. Mfg. Corp. excludes from warranty any product which is not manufactured by our personnel.

Bio-Medical & Pharm. Mfg. Corp. excludes from warranty any minor adjustments deemed necessary to outside formulas when the adjustment will not change the fundamental structure and/or effectiveness of a product's individual systems (preservation, emulsion, anti-oxidant buffering, etc.).

Temporary Storage

Finished goods will be stored free of charge until 3 days after production is completed. At that time, the goods will be moved into storage with associated fees. Bio-Medical & Pharm. Mfg. Corp. does not provide any insurance coverage and extends no warranty against the loss of materials in Bio-Medical & Pharm. Mfg. Corp.'s care which is owned by other companies. Customers are expected to carry their own liability and/or comprehensive materials insurance appropriate to the value of the materials to be held in Bio-Medical & Pharm. Mfg. Corp.'s care. Customers will be required to periodically provide documentation of this insurance. If proof of insurance is not available for materials held in Bio-Medical & Pharm. Mfg. Corp.'s care, the owner may be required to take delivery of the products and/or materials immediately.

Available Shipping Methods

We can send and receive shipments in several ways. We recommend: Roadway or common carrier for freight, Federal Express, UPS, United States Postal Service for parcels, and SAC Services, or Apple Courier for local shipments. Most shipping charges will be the responsibility of our customers. Exceptions should be arranged in advance.

Shipments which are billed to Bio-Medical & Pharm. Mfg. Corp. and which are then billed to one of our customers will have a processing fee assessed.

Invoices

Invoices are due according to the terms on each invoice. The date printed on the invoice, not the date of receipt, shall be used when calculating due dates, terms adjustments, or penalties.

Credit Terms & Financing

All customers of Bio-Medical & Pharm. Mfg. Corp. shall have 24% APR credit terms after the net due date assigned to their account. Payments received after their due date will be assessed interest charges (terms adjustments) before that payment is processed. Customers may have different net due periods ranging between 10 and 60 days. A financing charge of 2% of the remaining balance on an invoice will be added for each month beginning the day after the net due date. When any account has invoice(s) which are greater than 60 days overdue, that account and its production may be frozen until the overdue status is resolved. A frozen account will continue to accrue financing charges and/or late payment fees indefinitely.

NOTE: A finance charge left as an unpaid balance will continue to be considered "late" and will accrue interest. The original invoice date will continue to be considered during assessments of extended credit terms and account status until they are paid or otherwise modified by Bio-Medical & Pharm. Mfg. Corp.'s management.

Credit Limits

Unless otherwise specified by Bio-Medical & Pharm. Mfg. Corp.'s management in writing, all customers shall receive a credit limit of up to \$10,000. Temporary increases to credit limits may sometimes be needed when large shipments are made. In order to temporarily exceed the assigned credit limit, a customer should make special arrangements with our Vice-President or other authorized agent before any increase is needed.

Recourse, Penalties, & Collection Action

We are very sensitive to market fluctuations and to the unpredictable nature of the industries we serve. Any customer who is having difficulties making payments on time should immediately contact us to arrange for a financing plan which will help them get control of their finances. When our customers are succeeding, we do also. We are here to help you and we can often find ways to keep your credit clear during hard times. Detailed financial information may be required for some financing plans.

Accounts that are 60 days or more overdue and have no alternate financing plan to fall back on shall be frozen and no further production or shipments will take place. This condition shall supercede certain other agreements including order confirmations and estimated ship dates, and could cause the retention of product not yet shipped. A frozen account will continue to accrue interest and a shipment put into storage could result in additional storage charges.

In the absence of some acceptable plan to resolve delinquent accounts, Bio-Medical & Pharm. Mfg. Corp. reserves the right to seek collection by using whatever legal means our management deems appropriate.

Returns

Any returns must be approved by Bio-Medical & Pharm. Mfg. Corp.'s management in advance. Certain restrictions may apply for each customer regarding how much they can return without penalty depending on the reason for the return(s). We will sometimes replace products which are aging with new products. In this case, no credit would be issued. Instead, an order would be entered to replace the product with the price set to \$0.00 per unit. In other cases, a credit invoice could be issued which could be applied to the customer's next payment.

Credits

Credits are issued on a case-by-case basis to provide for returns, pricing adjustments, market pricing fluctuations, and shipping or accounting mistakes. After all, no one's perfect. Credits may not be taken until a credit invoice has been issued by our receivables personnel.

Records Keeping

What Is Stored

Bio-Medical & Pharm. Mfg. Corp. stores nearly all information relating to manufacturing, accounting, and customer relations. This includes all contracts, batch cards, and other correspondence. Materials of a confidential nature are stored along with other information in customer files, so all customer files are considered confidential and are, therefore, restricted.

Duration

We store most of our records indefinitely in an archive. This far exceeds any requirements by any government agency with jurisdiction over our manufacturing. Our computer files are backed up frequently and stored off-site in order to protect our reporting ability. This includes inventory, shipping, order progress, voicemails, and faxes. Except for regulatory requirements, Bio-Medical & Pharm. Mfg. Corp. will not be held responsible for storing information of any kind. If a customer provides information, such as a formula, to Bio-Medical & Pharm. Mfg. Corp., they should keep the original for their own records.

Government Inspection

Bio-Medical & Pharm. Mfg. Corp. is under the jurisdiction of many government agencies. Sometimes the requirements of satisfying regulations can cause unexpected delays, so it's important to begin any regulatory process as soon as possible. Surprise inspections are the norm for most agencies, so when one occurs, unexpected delays may follow; however, most production and shipping is unaffected.

International shipments of ingredients or finished products may also be held and inspected by customs agents on either end of the shipment. Since it is impossible to tell how long this agency might keep a shipment, delivery dates are "to customs" and not "to customer."

Ownership & Confidentiality

When Bio-Medical & Pharm. Mfg. Corp. creates a new formula or manufacturing process, it will remain the ownership of the information unless the information is purchased by a customer. A confidentiality agreement should always precede the purchase of valuable information in order to prohibit the use of that information after the sale. Some information is not available for sale and will not be disclosed – even under confidentiality agreement. Customers may be required to pay for research or laboratory time related to such information. This does not necessarily constitute the sale of the information derived from the charges. The purchase of information must be arranged with Dr. Loesch, our Vice-President.

Bio-Medical & Pharm. Mfg. Corp. assumes that all information is confidential unless otherwise documented. Before the disclosure of sensitive, valuable, or secret information, customers should obtain a confidentiality agreement to protect that secrecy. Our standard confidentiality agreement even keeps Bio-Medical & Pharm. Mfg. Corp.'s personnel from using the information internally for any purpose other than those related to that customer's development and production.

Copies & Backups

Bio-Medical & Pharm. Mfg. Corp. keeps computer records of large amounts of information including formulas, contracts, research data, correspondence, and more. These files help us to process our customers' requests for development and production and allow us to track all activity and paperwork related to our main business functions. We make backups frequently and store them in fire-proof containers. Copies are also stored off-site in a secure environment. These backups are for internal use only and are not available except in cases where information has been lost and must be restored. Confidentiality agreements also extend to this information as does the assumption that it is confidential unless documented otherwise.

Batch Cards, Formulas, & Research Consultations

Bio-Medical & Pharm. Mfg. Corp. stores information such as batch cards and formulas as both computer records and as hard copies in customer files. Information which falls under a confidentiality agreement is marked when received and stored in customer files. Notes about research consultations may also fall under confidentiality agreement, in which case, the notes from such a meeting would be marked as confidential and then be stored in customer files.

Accounting, Contracts, & Shipping Documentation

Most accounting information is stored as software files; however, statements are stored along with other correspondence in customer files. Contracts, orders, and shipping documentation are also stored on-site. If a customer needs any of this information, they should contact Cathy Westmoreland at 281.835.8051.

Fees

Bio-Medical & Pharm. Mfg. Corp. reserves the right to assess additional fees for compiling and/or providing information other than that normally produced by our internal processes. This could include special periodic reports, compilation of research data, copies of regulatory information, or other functions. The rate will be decided on a case-by-case basis and shall be billable at the time the service is provided.

Research, Quality Control, & Sample Retains

Required Stability & Bacteriology Testing

One of our most important goals is to protect our customers from any kind of product failure that can be detected within a reasonable period of time. This includes all new formulas and all formulas provided by our customers. The minimum period for stability testing is 90 days at elevated temperature. Also required shall be bacteriology testing and preservative challenge testing. It is possible to circumvent these requirements with a "hold harmless" agreement which would absolve Bio-Medical & Pharm. Mfg. Corp. of any responsibility and protect Bio-Medical & Pharm. Mfg. Corp. from any prosecution or loss related to the manufacture of products which were allowed to bypass the required tests. These tests are short-term in scope and are not guaranteed to detect all problems. Formulas created by Bio-Medical & Pharm. Mfg. Corp. are guaranteed against loss; however, formulas provided by other sources including research texts will not be guaranteed against failure unless properly tested by Bio-Medical & Pharm. Mfg. Corp.

Some tests may involve putting formulas in contact with samples of printed material, labels, containers, or other packaging materials which must be acquired by our personnel or provided by a customer before testing begins.

3rd Party Testing Of Products

When dealing with products that are classified as drugs, it is standard practice to have a third party do all of the testing. This eliminates any possibility of a conflict of interest since the testing facilities we use have no vested interest in our company.

Advanced bacteriology, RIPT, SPF and other testing is also handled by a third party.

Warranties & Exclusions

Bio-Medical & Pharm. Mfg. Corp. warrants all of its products against defects in manufacturing and guarantees that all products are manufactured to established GMP's (Good Manufacturing Practices) as set forth for various types of products. Bio-Medical & Pharm. Mfg. Corp. excludes from warranty any formula or product which does not pass the minimum mandatory testing described above. Additional testing may also be required as deemed necessary by the management to provide a warranty.

Bio-Medical & Pharm. Mfg. Corp. guarantees that its personnel will address all compliance issues in a timely manner. Bio-Medical & Pharm. Mfg. Corp. is under no obligation to advise its customers about regulatory or other changes concerning products which are not manufactured at one of Bio-Medical & Pharm. Mfg. Corp.'s locations (repackaging is not manufacturing). For all products manufactured at Bio-Medical & Pharm. Mfg. Corp., we will provide due diligence with monitoring and research in order to keep our customers well-informed about required label changes and updates to formulas; however, Bio-Medical & Pharm. Mfg. Corp. will not be held responsible in any way (unless otherwise contracted) for deficiencies or inaccuracies which are not corrected before manufacturing. Any costs such as label replacement, new printed materials, or amended labeling which are incurred as a result of regulations or other requirements of the aforementioned governmental agencies are solely the responsibility of the customer.

Quality Control

Our quality control procedures are designed to protect us and our customers from unnecessary expenses and production delays due to insufficient quality of the finished product. Quality control procedures often require us to wait for the results of 3rd party testing, external paperwork, and/or government agency response before making a production run or shipment of product available for pickup or delivery. This process can not be circumvented once begun and Bio-Medical & Pharm. Mfg. Corp.'s management reserves the right to refuse any request, whether made under "hold harmless" agreement or not, to abandon normal quality control procedures. In such a case, a customer shall not be released from their obligation to take timely delivery and make timely payment for products ordered from and produced by Bio-Medical & Pharm. Mfg. Corp..

We do not guarantee that ingredients of any kind will pass quality control. If an ingredient fails quality control tests and is quarantined, delays can result; therefore, it is very important for customers providing ingredients to label the containers properly. Minimum requirements can be obtained by consultation with Dr. Loesch or Tom Loesch III. In the event that a customer provides a material which is refused by quality control, the shipment may be refused upon delivery, returned after delivery, or held in quarantine. The customer is responsible for any resulting shipping, handling, inventory control, or storage charges.

Quality control data is considered privileged information and will not be released without the consent of our management – regardless of confidentiality status. Research data on some products may be permanently restricted due to proprietary manufacturing processes or the future value of the data. One such product is Pro-Tect™ Sunscreens which use the Pro-Spectrum® process. Information about this product line is restricted to marketing data, graphs, the status of quality control tests, and other general information. Disclosure of research data about this product line is prohibited.

Sample Retains

The term "product stability" is a general term encompassing several types of stability. These include the stability of the package, the stability of the material inside the package (liquid, crème, gel, paste, powder, etc.), the strength of the outer box or carton the packages are stored or shipped in, the concentrations of any active ingredients (which must remain within certain specifications), and other types of stability including but not limited to freezing, high-temperatures, impacts, or shipment to high altitudes or in unpressurized aircraft.

In order to establish the long-term stability of products, to observe how products age over extended periods of time, and to provide evidence in the case of complaint or other issues relating to product stability, Bio-Medical & Pharm. Mfg. Corp. must retain random samples of all products. Over-the-counter drug products will also require periodic testing to establish their efficacy according to FDA GMP's. Customers will be required to pay for these tests, so permission to perform these tests will be obtained by our personnel before the tests are performed.

Customers will be required to pay a surcharge for samples of their products retained from each size and each batch of product. Retained samples are taken for each unique packaging run of each unique package. That is, a 4 oz. Pro-Tect™ SPF 15 sunscreen is not the same as a 4 oz. MediFore™ SPF 15 sunscreen even though they are the same formula inside the bottle. A different label makes it a unique product.

Fees

Consultations and regulatory monitoring contracts are available by request only.

For most packaging runs, a "retained samples" surcharge will be added. This charge will be equal to the wholesale cost of all samples retained for that packaging run – all sizes. The number, sizes, and labels for each of these charges are recorded on the batch cards or repackaging records for that packaging run.

Certain tests will be charged to customers as they are performed for package or product stability. These may include preservative challenge testing, bacteriology, active ingredient assays, HPLC (High-Pressure Liquid Chromatography) tests, USP Identity tests, or others.

For all materials shipped to us from another company intended for repackaging at our facility, a \$50 bacteriology charge will be assessed unless the nature of the material is such that it does not require testing (dry products) or that it is incompatible with our testing procedures (sulphur and other reactive materials).

Labels & Packaging Materials

Types Of Labeling: Drug, Cosmetic, & Agricultural

Different types of products have different labeling requirements. A product whose label does not meet the requirements of all government agencies with jurisdiction are considered "misbranded" and are subject to recalls, penalties, additional shipping costs, and lost sales. We feel it is our responsibility to make sure that our clients' products stand up to the highest scrutiny.

Cosmetic products such as hair care and skin care formulations, masques, vitamin enriched serums, and others usually have the most relaxed requirements, but some things are considered "standard." These include:

- ✓ "Manufactured By...", "Manufactured For...", "Distributed By...", or some other acceptable identifier of the relationship of the product to the contact information;
- ✓ Contact information including company name, city, state, and phone number;
- ✓ List of ingredients in descending order of concentration;
- ✓ A product name which does not violate any existing trademark or copyright on file;
- ✓ Appropriate directions;
- ✓ Appropriate warnings or cautions.

Drug products have all of the same requirements with a few changes and additions:

- ✓ Active ingredients listed in descending order of concentration (showing the concentration percentage is optional);
- ✓ Other ingredients may be listed either in descending order of concentration or alphabetically depending on the claims made;
- ✓ Cautions, warnings, or other regulatory information;
- ✓ An emergency number must be printed on the label or provided by a message or person at the phone number printed on the label.

Agricultural products' requirements for labeling are quite complex and require a significant amount of research because they can involve the greatest number of governmental agencies. There are so many different types of products and so many different regulations that can be involved that there really is no standard. Each product's labeling is unique. Typically, the same requirements usually apply as the ones for cosmetic products, but a company is not always required to list ingredients. Along with the complexity of the agricultural industry's needs, this can often mean that there is more information than can fit on a bottle. There is an option for this.

"Extended labeling" is typically some type of folding booklet or pocket which is affixed directly to the product container. This technique allows a customer to fit large amounts of information, graphics, warnings, directions, and other things on more surface area than the bottle has. A pocket must be sealed to be considered extended labeling.

"Amended labeling" is any printed piece of material that is loosely attached, hung, packaged with, or always sent with a product. This is sometimes an option to extend the marketing appeal of a product, but typically required information must be printed on the bottle. This technique is very versatile, so customers should consult with Dr. Loesch for specific cases.

Approval Of Content

We offer the services of Dr. Loesch who earned a Ph. D. from the University of Texas in Bio-Medical Sciences to all of our customers. For companies which are not customers, he also does consultation work for quality control, labeling compliance, and other services. He is also an expert in researching labeling compliance issues. All customers who have products manufactured or repackaged at Bio-Medical & Pharm. Mfg. Corp. should have their label text and design approved by our management **before** going to print. Labeling which does not comply with all requirements will be rejected. This could cause delays in production or loss of a position on the production schedule altogether, so it's very important to verify compliance before delivering or even printing labels.

Available Guidance

Many of Bio-Medical & Pharm. Mfg. Corp.'s customers do not have any production going on in our facilities. Instead, they use our company as a research and development consultant. We can help your R&D department by providing Ph. D.-level services without employing a full-time Ph. D. or building laboratory space. We also have many relationships with qualified people in various fields. If we can not provide consultant services, we very often know where to find someone who can.

Storage Conditions

Bio-Medical & Pharm. Mfg. Corp. stores all light packaging materials in moderately-controlled environments. That means the environments can get very hot (around 120° F.) or very cold (below freezing). Since plastics, cardboard, and most other packaging materials do well as long as they are dry, that is the standard.

All ingredients are stored in climate-controlled conditions ranging from 20° to 40° C. These areas are heated in the winter and air-conditioned in the summer and often ventilated by powerful exhaust fans. Because all drug products and drug ingredients are stored in these areas, we monitor temperatures for FDA compliance. This ensures product quality and consistency. Customers' ingredients which are stored at one of our facilities must also be stored in compliance with our internal standards. The only exception is underground storage of isopropyl alcohol which is limited to 8,000 gallons per shipment.

Flammable materials are stored in a designated storage area. Most of this type of storage is done at bonded facilities in Houston.

Stability samples are stored in laboratory-controlled conditions which means that they can be protected from light, stored at controlled temperature (from 0° to 45° C.), or held in some other mechanically-controlled way such as artificial sunlight or increased gravity. Some limitations apply to the length of time samples may be held in these conditions.

Cosmetic labeling is stored in cardboard boxes in any available storage that is appropriate for the type of material the label is made of. Typically, this is with our regular inventory.

Drug labeling is stored in designated spaces in storage cabinets near the production area. These labels are signed out, the counts are validated retrospectively, and their use is carefully documented by the Production Manager who is the only person authorized to take them out of storage for production. Some special types of labeling include temperature detectors, radiation detectors, bar codes, UPC codes, tamper-evident seals, and holographic authenticators.

Fees

Bio-Medical & Pharm. Mfg. Corp. will sometimes store a small number of labels between production runs, but this is dependant on the availability of space. When space is tight, customers must take remaining labels with the last shipment of orders in progress or coming up on the schedule. Bio-Medical & Pharm. Mfg. Corp. reserves the right to charge storage fees for labeling stored beyond the scope of order production.

When packaging materials or other materials are not in production or coming up on the schedule within 14 days, Bio-Medical & Pharm. Mfg. Corp. reserves the right to charge storage fees. If materials are already in storage for a customer, any packaging materials received more than 14 days before production will be subject to storage fees on the normal assessment date (the 1st of every month).

Package Design & Printing Services

Types Of Labeling

The choice of labeling materials is very extensive. We have access to everything from raised printing on plastic, glass, and metal to multi-color digital process printed labels with ultra-high resolution. Labels can be varnished, laminated, ultra-violet cured, metallic hot-stamped, or silkscreen-textured to suit almost any marketing executive's desires. Our experienced staff will be happy to help you choose a printing medium for your package. This assistance can be very valuable because it could mean the difference between passing the stability testing or failing it. Samples of most printing methods and labeling materials is available upon request and may also be used in preliminary testing to help narrow the options.

We can design labels to fill almost any order. We use experienced graphic artists and reputable printing companies for all label designs. We can design and arrange printing for amended labeling, hang-tags, boxes, cartons, and lots of other types of materials. In most cases, we will even connect you with our sources if you would rather purchase directly from the printer.

Amended Labeling

"Amended labeling" is any type of printed material that **always** ships with each container of product. This can include the box a jar goes in, a card the product hangs from, or hand-outs given to patients with a product. Consult with us about specific regulations regarding the placement of required information.

Packages Available

We will help connect you with our sources for all types of packages. Bio-Medical & Pharm. Mfg. Corp. maintains an extensive database of suppliers and our relationships with many of them allow us to get great prices on larger quantities. Some packages are so specialized or unique that they must be manufactured to order. This can take up to 16 weeks and the delay should be considered when choosing a package for a new product. Usually, the more popular a package is, the easier it is to find – except in cases where the design is copyrighted or the mold is unavailable.

We even have access to a label adhesive that absorbs bubbles so customers can now put clear labels on clear glass for a flawless look. In turn, that gives us the ability to put multi-color digital process labels on clear glass jars with ultra-high resolution. This has only recently become possible.

Collateral Material

Other types of marketing materials and devices are available. Since we have access to graphic artists and programmers, we can deliver interactive CD's to promote products or CD presentations to display at trade shows. Brochures, business cards, mailers, websites, and many other types of promotional materials are available from our sources.

Printing Methods

Some products may require certain printing methods be used due to their deleterious effect on inks. Bio-Medical & Pharm. Mfg. Corp. reserves the right to refuse any printing material or method if it is deemed "too risky" or "unsafe" or is incompatible with applicable GMP's. Our sources are capable of many printing methods including:

- ✓ Metallic on glass or plastic;
- ✓ Silkscreening on any surface;
- ✓ Ultra-violet cured on any surface except paper;
- ✓ Etching on any surface except paper;
- ✓ Hot stamping on plastics and paper;
- ✓ Digital hybrid lithographic/flexographic process on label mediums;
- ✓ Embossing on plastics and paper;
- ✓ Flexographic printing on some label mediums;
- ✓ Opaque, translucent, opalescent, transparent, smoked, any many other specialty processes.

Graphics File Formats

Since most printers require label or other designs to be sent as computer files, we have the capability to format our graphics in nearly any format needed by a printer. Our most common format is Adobe Illustrator or Adobe Photoshop in PC format but we can also send some files to Macintosh computers.

Outsourcing

Bio-Medical & Pharm. Mfg. Corp. uses a family of companies to offer a wide range of services. We frequently outsource to these companies or refer our customers to those sources in order to hold down pricing. Design is usually done in stages of billable hours until a final design is reached. Stages typically follow this pattern:

1. Mockups – Several designs are done in various styles until a favorite is reached. Since the label design is a very important part of any product, mockups are not the place to skimp. The more extensive the set of choices, the better chance for a successful match with the marketing concept.
2. Writing & Text Approval – The directions, ingredients, and other written materials are compiled and edited to fit within the label dimensions.
3. Artwork Layout – The graphics, the text, and all other images to be printed are laid out in software to create the digital printer file.
4. Ordering of Die – If the label is a die-cut one, as most are, a die must be used. Customers can either choose from die dimensions available from a printer's stock or they can order a die to their own label specifications. This can sometimes take several weeks, so dies should be ordered as soon as a customer is ready to commit to those dimensions.
5. Final Approval – The customer bears the final responsibility for the spelling, content, graphics, artwork, and packaging and must give final approval in writing before artwork is sent to a printer. Abiding by trademark and copyright laws is also the responsibility of the customer.
6. Sending The Printer File – We can send out files on CD, floppy, zip disk, email, or FTP. Sending the file occurs after final approval and final payment are made.
7. Receiving Label Stock – Labels are sent to Bio-Medical & Pharm. Mfg. Corp. before production begins.

Copyright Issues

According to United States laws, the copyright for a piece of art, artwork, or design is held apart from the art itself. The artist or art provider is entitled to require payment for the use of this copyright and to damages in the event of misuse. For guidelines, contact the Graphic Artists' Guild at <http://www.gag.org>.

Fees (Intellectual Property & Example OTC Drugs)

Fees are estimated before a job begins and usually finalized by contract. For very small jobs, a verbal contract will sometimes do. For larger jobs, a series of work periods and payments may be required to manage cash flow and risk and to ensure that we and our customer is comfortable with the way a design job is proceeding. While some deposits are non-refundable, others can be prorated if work on a project is to end. Contact Tom Loesch III for more information on pricing, services, and availability.

Here is an example of the fees required to bring a new OTC drug product to market and the intellectual property rights involved.

Free Exclusivity: For any formula we have developed at our own expense and which is not already in production for any other company, we offer 1 year of free exclusivity to the first/current buyer. After 1 year, you must choose one of the following 2 options or do nothing. If nothing is done, the formula becomes available to everyone just as it was made available to the first/current buyer.

Option 1: Ongoing Exclusivity

If our company is to pay all of the fees associated with keeping the formula compliant with FDA's requirements for ongoing stability studies, we will require two things...a yearly payment plus a minimum yearly production level.

Option 2: Permanent Ownership

If you want to be in complete control of the formula, you must bear all of the expenses involved in keeping the formula compliant with FDA's requirements for ongoing stability studies. At your request, we would assign a price to the formula which you would pay once. Upon payment, you would receive ALL of the research data, development notes, reports, testing results, batch records,

mixing procedures, quality control procedures...everything related to that formula. Your purchase would also bring the formula under our Confidentiality Agreement with your company effectively protecting the information from being used in other development projects under the conditions outlined in the Confidentiality Agreement. The price of the formula will be based on our assessment of the formula's potential to generate revenue...which would we would lose if it were sold to you. Tip: You don't have to purchase a formula right away if you are granted a year of free exclusivity. Use the free time to consider which option is best for you.

R&D FEES

(F) Fixed Cost - A cost which is incurred on a regular schedule and which does not change except when providers change pricing to keep in-line with market pricing.

(V) Variable Cost - A cost which is incurred at least once but which may be incurred again or which is incurred at unknown intervals. These costs are given as a range/timeframe instead of a single number like \$110-\$330/year.

* - applies only to the formula owner.

FDA Label Registration of OTC Drug Labeling (F) - Each manufacturing facility must register each label (each size, each design, each package type counted separately) for all OTC drug products with the FDA. This is a one-time fee unless the label is changed by the client or forced to change by a change in the FDA's regulations. \$400-450 per label.

USP 51 Antimicrobial Effectiveness Test (AKA: Preservative Challenge Test) (V*) - This test is run on a formula to ensure that it is properly preserved. It is repeated as many times as is necessary to ensure a stable and safe product. \$450/test.


90-Day Accelerated Stability Study (V*) - 4 assays for each active ingredient done at T=0, 30 days, 60 days, and 90 days yielding a theoretical 2-year expiration date. Samples are held at high temperature during the study to simulate the rapid passage of time. If an assay fails, it must be repeated to determine the problem with the formula. For a 2-active formula this costs a total of \$880-\$1400 over 3 months. This study is performed only once until the formula is significantly changed.

3-Year Real-Time Stability Study (F*) - 4 assays for each active ingredient done at T=0, 1 year, 2 years, and 3 years yielding a 3 year expiration date or the option to drop the expiration date. Samples are held at room temperature during the study. Assays do not usually fail during this study because failures usually appear in the accelerated study. For a 2-active formula this costs a total of \$880-\$1400 over 3 years.

Batch Assays (F*) - Each active ingredient listed on the label must be tested for to verify proper specifications in each and every batch made. \$110-\$175 per ingredient. Some tests are more expensive than others. For example, the assay for Titanium Dioxide (a sunscreen active) costs \$110 while the assay for Oxybenzone (a sunscreen active) costs \$170.

Ongoing Stability (V*) - At least one randomly-chosen batch per year must be put through its own stability study to establish the ongoing viability of the formula, the research data, and the stability data obtained at the start of production for a drug product. These tests are billed as they are performed at 1 year intervals from the manufacturing date of each batch in ongoing stability. For a product with 2 actives, this would cost \$220-\$350 per batch per year. For a product that is made at least every year, there will be up to 3 ongoing stability studies running concurrently costing \$660-\$1050 per year.

W. T. Loesch III, VP, QCU Signed to: Pages 1 - 11



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