

## TERMS, CONDITIONS & PRICING POLICIES

### **Directions: Sponsors must sign and return this form to Gibraltar Laboratories, Inc.**

Gibraltar Laboratories, Inc. (GBL) is an independent contract-testing laboratory. GBL also provides educational and consulting services. Sponsors of Gibraltar include public and privately held companies, private citizens or others who request GBL to perform a service for a fee. The Sponsor is defined as the person or organization that requests our services and is responsible for payment of the work.

### **The following terms, conditions and pricing policies apply to all Sponsors:**

1. 1 A written request for services must be submitted by way of a Sample Submission Form [SSF] in the same shipment as the test material. GBL provides a Sample Submission Form for this purpose, which must be completed and sent in with every sample shipment. Clients are 100% responsible for accurately submitting all facts and details requested on the SSF. The completed form identifies the test material, the service(s) requested, the purchase order number or authorization for funding, the quotation number, the person to whom the report should be mailed, and appropriate billing information. Revisions to testing requirements must be submitted in writing, preferable by a revised Sample Submission Form. Testing may not initiate unless the SSF is properly completed. Note: The sponsor must use the SSF to record the sample specification and its decision to authorize charges for a formal written OOS investigation.

2 Gibraltar Laboratories Upstream QA™. Upon receipt of a SSF GBL will email the Sponsor a written Acknowledgment Notification. Such Notification will inform the Sponsor of GBL's receipt of the test material, description of the test material, the service(s) requested, and the proposed initiation and completion dates and other information. Note: Tests that are scheduled for same day as arrival may contain errors on the SSF that are not known to GBL and are not corrected prior to initiating testing or processing. Accordingly, Gibraltar Laboratories does not accept any liability for such.

2. The Sponsor must review the Acknowledgment Notification (see 2 above) and return same to GBL within 24 hours if any revisions or changes are necessary. Failure by the sponsor to timely return the Acknowledgment Notification subjects the Sponsor to administrative fees. Clerical errors by GBL are corrected gratis. Errors by the Sponsor, which require correction are subject to an administrative fee of \$100.00 per incident. In addition, extensive changes to written final or draft reports are billed @ \$250.00 per hour. Sponsors may not use GBL reports or correspondence of any kind for advertising or other promotional purposes without the advance written permission of GBL.

3. Sponsors may not use GBL reports or correspondence of any kind for advertising or other promotional purposes without the advance written permission of GBL.

4. Sponsors shall not be entitled to retain or defer payment of any sums due to the Company on account of any dispute, counter claim or set off which it may allege against the Company.

5. In order to protect confidentiality, GBL does not reveal the names of Sponsors. In the event a Confidentiality Agreement is required; Gibraltar may provide an agreement for the Sponsor to review.

6. It is not possible to anticipate all situations that may require further U.S. EPA or US FDA or other regulatory agency analysis. Thus, submitters should be aware that they may be asked, at EPA's/FDA's or other regulatory agency discretion, to submit additional data or to present data in another format or to provide more detailed explanations of the information submitted. These represent new testing costs to the Sponsor and are solely the Sponsor's responsibility.

7. Limitation of Liability: The Company is neither an insurer nor a guarantor and disclaims all liability in such capacity. Sponsors seeking a guarantee against loss or damage should obtain appropriate insurance. Reports of Findings are issued on the basis of information, documents and/or samples provided by, or on behalf of, Sponsor and solely for the benefit of Sponsor who is responsible for acting as it sees fit on the basis of such Reports of Findings. Neither the Company nor any of its officers, employees, agents or subcontractors shall be liable to Sponsor nor any third party for any actions taken or not taken on the basis of such Reports of Findings nor for any incorrect results arising from unclear, erroneous, incomplete, misleading or false information provided to the Company. The Company shall not be liable for any delayed, partial or total non-performance of the services arising directly or indirectly from any event outside the Company's control including failure by Sponsor to comply with any of its obligations. The liability of the Company in respect of any claim for loss, damage or expense of any nature and howsoever arising shall in no circumstances exceed the fee of the service performed by Gibraltar or US \$10,000 whichever is the lesser. The Company shall have no liability for any indirect or consequential loss (including loss of profits). In the event of any claim, Sponsor must give written notice to the Company within 30 days of discovery of the facts alleged to justify such claim and, in any case, the Company shall be discharged from all liability for all claims for loss, damage or expense unless suit is brought within one year from: the date of performance by the Company of the service which gives rise to the claim; or the date when the service should have been completed in the event of any alleged non-performance. GBL's responsibility for all aspects of work product (protocols, results, reviews, audits, submittals, etc.) is limited to

the Sponsor of the study and not necessarily to third parties (consultants, assignees, successors, licenses, etc.). Results reported pertain only to the samples tested and are not intended to extrapolate to the universe of items which may have been manufactured in parallel. GBL results pertain only to the sample submitted. No predictions, guarantees or warranties of any kind are made by GBL that the work will be performed in a manner that will yield favorable results and/or result in approval by a regulatory agency such as United States FDA or EPA or other regulatory agency. Payment for GBL services performed is not contingent upon, or linked in any manner to, review or approval of the results by the Sponsor, its representative, or any regulatory agency. Unanticipated technical issues, which require an excessive effort on Gibraltar's part to overcome, are billable at a rate of approximately \$150.00 per hour.

8. Indemnification: Sponsor shall guarantee, hold harmless and indemnify the Company and its officers, employees, agents or subcontractors against all claims (actual or threatened) by any third party for loss, damage or expense of whatsoever nature including all legal expenses and related costs and howsoever arising relating to the performance, purported performance or non-performance, of any services.

#### 9. Invoice, Payment & Payment Terms

i. A laboratory report is issued upon completion of the study. An invoice containing reference to the sponsor's PO#, GBL report# and sample # will be issued for each report. Our routine practice is to send reports and invoices by email.

ii. Payment Terms: Our payment terms are net thirty (30) days from our invoice date. Balances past due over 60 days must be brought current before new work will be accepted. In addition, the account will be placed on credit hold. A late payment fee of the lesser of 1.5% or the maximum interest rate allowed by law, of the invoice total will be charged for each month (or portion thereof) that an invoice remains unpaid by you. You are also responsible for any costs, including attorney's fees, incurred by GIBALTAR in the collection of any invoice balance not paid within the previously stated time period.

iii. We accept wire transfer, checks drawn on US Banks, or Visa, Master Card and American Express credit cards. We use the purchase express system to process American Express Credit Cards or you may process your credit transaction at <http://www.gibraltarlabsinc.com/CreditCardProcessing.htm>. For questions regarding credit application or wire transfer routing number, please contact our accounting department at (973) 227-6882 X512.

iv. GLP Studies: Reports intended for submission to the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) in support of a marketing request may need to be conducted under the Good Laboratory Practice (GLP) regulations of the specific agency. Sponsors must notify the laboratory prior to initiation of such tests. GLP studies must be pre-approved by both sponsor and laboratory, performed according to a specific protocol, recorded on the GLP study master schedule, and inspected by the quality assurance department. Gibraltar Laboratories, Inc. complies with all phases of the FDA and EPA GLP or other regulatory agency regulations. If you are required to submit final reports in a specific format, please request the format when you submit the samples. If you need additional assistance, please contact us. \*Additional charges for GLP, protocol studies and special projects will be quoted separately.

v. Controlled Substance Handling Fee: A minimum fee of \$250 will be charged for the first lot and \$125 for each subsequent lot received in the same submission for controlled substance samples received for testing.

vi. Quotations: Our fees are established by quotation or contract. Samples which require special handling, extra processing or manipulations, may incur additional charges. Further, charges for materials required in the performance of testing, including but not limited to reference standards, columns and related test materials, will be billed as a pass through cost to the client. Gibraltar Laboratories, Inc. will provide price quotations after evaluation of the samples or protocol, prior to initiation of the work. The sponsor must approve the quote or contract in writing and submit a Purchase Order number. Most prices include submission of a final report by email or US Mail and maintenance of records and raw data for five years. Requests for overnight delivery, extra or additional copies of reports, sample returns, and archiving of samples will be honored. Charges will be invoiced accordingly. Sponsor requests for various administrative services pertaining to final reports are subject to an administrative fee. Discounts are offered to companies who maintain prepaid balances. Discounts for increased volumes of samples are included in this price list. We will be happy to accommodate standing purchase orders to expedite sample handling. Special negotiated volume price quotes will be reviewed and are subject to change on an annual basis. MINIMUM BILLING CHARGE FOR TEST AND REPORT: \$150.00

vii. Consulting Services: Gibraltar Laboratories, Inc. offers consulting services at a minimum of \$150.00 per hour. Our services include GMP and GLP regulations and applications, microbiology, chemistry, sterility, virology,

biocompatibility, validations, clean room procedures, bioburden control, environmental control, filter validations, packaging material validation, product submissions, product development, FDA and EPA regulations, etc. Requests for cancellation of on-site sampling services such as environmental monitoring, compressed air sampling, nitrogen sampling, pick up services, etc., must be made in writing during normal work hours 8:30 AM to 5 PM Monday –Friday, not including holidays. At least 48 hours notice of cancellation must be provided to Gibraltar. The following cancellation fees travel at \$150/hour/technician (including travel time). In addition, the sponsor will be billed for any additional cost incurred that directly relates to the service cancelled. A minimum of 10% of the service fee will be charged when a sponsor cancels a service.

viii. Rush Charges: Sponsors frequently need samples processed urgently rather than the normal turnaround time based on the workload at the time samples are received. These requests will be honored when capabilities permit. Since "RUSH" requests require staff to interrupt scheduled tests and may require overtime, after-hours, weekend, or holiday readings, a minimum "RUSH" charge of 100% is assessed (minimum fee, \$150.00). RUSH testing must be requested in writing on the sample submission form.

ix. Prepayment Policy: GBL reserves the right to request a prepayment of up to 100% in advance of services being performed. In some cases, GBL may require a 50%, etc. prepayment with the remaining balance due upon presentation of a written draft report. Established customers (with a current account) are invoiced after their studies are completed and results are received. Some studies require a 50% prepayment to help cover the initial cost of doing the test or to establish credit. 100% prepayment will be required for protocol preparation, set up fees, and cost of supplies (e.g. columns, standards). Prepayments will be indicated in the quotation and invoiced upon acceptance of the quotation.

x. OOS Charges: \$950 each occurrence plus the cost of any retesting required to conduct an OOS investigation is billed when GBL is instructed by the sponsor to issue an OOS report. There is no fee for an OOS investigation if the assignable cause is due to a laboratory error.

xi. Miscellaneous Charges Documents that are sent at the request of the sponsor by federal express will be charged to the sponsor and will appear on their invoice. Gibraltar reserves the right to charge for Speed Reports. A \$10.00 fee per speed report will be added to the final invoice if a Speed Report is requested/generated prior to final report. In the event any unforeseen problems, additional testing or expenses arise in the course of carrying out the services, the Company shall endeavor to inform Sponsor and shall be entitled to charge additional fees to cover extra time and cost necessarily incurred to complete the services.

xii. Shipping, Special Handling and Sample Retention: At the sponsor's request, samples can be returned after testing. The Sponsor is responsible for the shipping and handling charges, and the disposal of supplies, specialized equipment and unused test materials. All samples will be shipped via UPS Ground unless otherwise specified. A charge of \$35.00 handling fee will be charged for the shipping of all samples. In addition, the sponsor will be invoiced for the shipping price incurred by us to return the samples, unless a provision is made for shipping to be charged to the sponsor's UPS or FED EX account. Minimum charge = \$35.00 handling fee + shipping price. FDA typically requires retention of reports and related documentation for five years. EPA typically requires retention of GLP documents for 10 years, but in many cases they may need to be retained for the market life of the product. We do not store samples for sponsors. Documentation Storage Fee is \$100.00 per month for records over 5 years old.

xiii. Cancellation of Services: In order to cover administrative costs, a charge of \$250.00 is assessed at the time a service is canceled. In addition, the sponsor will be billed for any cost incurred that directly relates to the service canceled. A minimum of 10% of the purchase order or approved quotation will be charged when a sponsor cancels a service. Cancellation of stability storage services will be billed at 50% of the total plus \$195 per hour administrative fee.

xiv. Suspension or Termination of Services: Gibraltar Labs Inc. shall be entitled to immediately and without liability to either suspend or terminate provision of services in the event of: Failure by the Sponsor to comply with any of its obligations and such failure is not remedied within 10 days that notice of such failure has been notified to the Sponsor. Any suspension of payment, bankruptcy, insolvency, receivership or cessation of business by the Sponsor If the Company is unable to perform all or part of the services for any cause whatsoever outside the Company's control including failure by Sponsor to comply with any of its obligations, the Company shall be entitled to payment of the amount of all non-refundable expenses incurred by the Company, and a proportion of the agreed fee equal to the proportion of the services actually carried out.

xv. International Customers: All shipments sent to Gibraltar Laboratories from outside the United States must pass through customs. There will generally be a cost associated with shipping to/from Gibraltar Laboratories that cannot be determined until the shipment arrives. Please note all customs costs will be billed to the final invoice.  
PRICES QUOTED ARE FOR US DOLLARS OR CHECKS DRAWN ON US BANKS.



# GIBRALTAR

Terms, Conditions, and Policies Acceptance Sheet

The above Terms, Conditions and Pricing Policy are accepted by:

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Company Name (Please Print)

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Authorized Signature

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Date

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Print Name

Please return this form to:  
Accounting Manager  
Gibraltar Laboratories, Inc.  
122 Fairfield Road  
Fairfield, New Jersey 07004-2405  
Tel: (973) 227-6882  
Fax: (973) 227-0812