

Glycemic Research Laboratories

Board Certified Human In Vivo Clinical Trials



Low Glycemic

Claim Substantiation For:

*Foods • Meals • Prepared Foods
Nutraceuticals • Pharmaceuticals
and Products in Development*

- A Professional Clinical Research Organization Specializing in Glycemic Index Testing
- Serving the Largest Food & Research Companies in the World
- Official Clinical Testing Facility for the Glycemic Research Institute®
- Board Approved Human In Vivo Clinical Trials
- Member of Association of Clinical Research Professionals
- 25 + Years of Glycemic Expertise

**Glycemic Research Laboratories
Glycemic Solutions Corporation**

111 Second Avenue N.E., Suite 512
St. Petersburg Florida 33701 U.S.A.

www.GlycemicResearchLaboratories.com

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Glycemic Research Laboratories

Board Certified Human In Vivo Clinical Trials

INSTRUCTIONS FOR SUBMISSION OF TEST FOODS

REVIEW PROCESS

To submit a product (herein the “**Test Food**”) for clinical studies:

- 1) Fill out and sign Documents **A, B, C, D** and **E** and submit via fax to:
Glycemic Solutions Corporation: FAX (727) 894-6969

Document “ A ”	Product Submission Form	1 Page
Document “ B ”	Label and Ingredient Information	1 Page
Document “ C ”	Standard Terms & Conditions Agreement for Services	2 Pages
Document “ D ”	Agreement & License for Use of Glycemic Research Institute Certification Marks	9 Pages
Document “ E ”	Certification Program	7 Pages

- 2) The Glycemic Solutions/Glycemic Research Laboratories (GS/GRL) Medical Advisory Board will review the application and respond via email or phone. Clients are assigned a Clinical Studies Coordinator who will work one-on-one to answer any questions, and to coordinate the project.
- 3) If the product is accepted by GS/GRL for Board Approved Human In Vivo Clinical Trials, directions on submitting the Test Food (s) will be forthcoming.

CLINICAL TRIAL COSTS

The cost of clinical testing will depend on the Protocol utilized during the trials. The GS/GRL Medical Advisory Board will review the Application form and product label, as well as the client's desired legal label claims. Per this review, the client will be contacted by GS/GRL with specific pricing.

SUBMISSION FEES

Submission fees are due prior to beginning the clinical trials. All fees are based on U.S. dollars. Payment may be in the form of a check, money order, or bank wire. Contact the Clinical Studies Coordinator (CSC) for bank wiring instructions.

SUBMISSION OF TEST FOODS

Approved Test Foods (products submitted for trials) will be sent to GS/GRL per *Test Food Submission Guidelines*. The Clinical Studies Coordinator will direct the client in all phases of the Application process.

TRIAL RESULTS

Following GS/GRL Human In Vivo Clinical Trials, the client will be advised of the results in a comprehensive written report. The final Official report is sent directly to the client. Follow-up conference calls are available to clients who wish to discuss the results of the final report.

GOVERNMENT REGULATION: GLYCEMIC CLAIMS

Per government regulations regarding Claims and label statements, Glycemic Solutions/Glycemic Research Laboratories does *not* quantify the Glycemic Index of any product without Human In Vivo Clinical Trials.

For more information on Legal/Illegal Glycemic Claims, see

***AVOID FDA ACTION
AGAINST ILLEGAL GLYCEMIC LABEL CLAIMS
WWW.GLYCEMIC.COM***

Glycemic Research Laboratories

Board Certified Human In Vivo Clinical Trials

PRODUCT SUBMISSION OVERVIEW

Fill out the appropriate documents provided herein (Documents A, B, C D & E) Submit Documents **A, B, C D & E** to Glycemic Solutions/Glycemic Research Laboratories (GS/GRL) via **FAX** to **(727) 894-6969**.

Products submitted cannot be returned to the client

Any product sample suspected of, or containing a pathogen or substance considered hazardous will be rejected. Glycemic Solutions/Glycemic Research Laboratories reserves the right to refuse any product deemed unfit for human consumption.

Products accepted for submission must arrive in a sanitary condition in appropriate packaging. The product must be packed with a label and ingredient panel (see Doc C).

Products should *not* be physically submitted until the client has been contacted by Glycemic Solutions/Glycemic Research Laboratories. If the GS/GRL Medical Advisory Board has determined that the product(s) are acceptable for clinical trials, the client will be notified via phone by a Clinical Studies Coordinator.

Glycemic Research Laboratories

Board Certified Human In Vivo Clinical Trials

INSTRUCTIONS FOR SHIPPING TEST FOODS FOR CLINICAL TRIALS

ACCEPTANCE: HUMAN IN VIVO CLINICAL TRIALS

Once the Test Food (s) has been approved by the Glycemic Solutions/Glycemic Research Laboratories Medical Advisory Board, a Clinical Studies Coordinator will contact the client to arrange shipping of the Test Food (s).

SHIPPING THE PRODUCT FOR CLINICAL TRIALS

The Test Food (s) are to be shipped to Glycemic Solutions/Glycemic Research Laboratories (see address below). The product may be sent via Fed-Ex, UPS or Postal Service (depending on shelf-life and stability of the Test Food). Overnight shipping is preferred. If the product is heat-sensitive, pack with a dry-ice unit, and ship via Fed-Ex-Overnight.

SHIPPING PERISHABLE FOODS

When shipping fresh foods, frozen foods, perishable foods (foods that need to be refrigerated or frozen), pack the food in dry ice and send via Fed-Ex overnight to be delivered Monday-Friday, 9 AM-5 PM. If the food does not arrive in an acceptable state, human testing cannot proceed. Notify your assigned Glycemic Solutions Clinical Studies Coordinator as to when the product will arrive.

TEST FOODS SHIPPING ADDRESS:

GLYCEMIC RESEARCH LABORATORIES GLYCEMIC SOLUTIONS CORPORATION

111 Second Avenue N.E. Suite 512
St. Petersburg, Florida 33701 U.S.A.
(727) 894-6900 Fax (727) 894-6969

www.GlycemicResearchLaboratories.com

Glycemic Research Laboratories

Board Certified Human In Vivo Clinical Trials

CALCULATING THE AMOUNT OF TEST FOOD TO BE SHIPPED FOR CLINICAL STUDIES

The Medical Advisory Board will determine the amount (gram weight and serving size) of the Test Food required for clinical testing. The guidelines for selecting the amount of the Test Food to be fed to human subjects is determined by FDA guidelines related to appropriate food servings in foods, Nutraceuticals, and Pharmaceuticals and Glycemic Solutions Board Approved Clinical Trials Protocols. The client will be advised as to the amount of servings and total product required.

RIGHT TO REFUSE TEST FOODS

Glycemic Solutions/Glycemic Research Laboratories (GS/GRL) reserves the right to refuse any product (Test Food) submitted to GS/GRL, per the Rules & Regulations as set forth by the GS/GRL Medical Advisory Board.

QUESTIONS

Questions regarding the status of products may be addressed to the Clinical Studies Coordinator at (727) 894-6900. Prior to beginning clinical studies, specific protocols will be discussed with the client.

Detailed information regarding Glycemic Solutions/Glycemic Research Laboratories clinical studies may be viewed at: www.GlycemicResearchLaboratories.com

*Information regarding “Low Glycemic” Certification Marks
may be viewed at: www.Glycemic.com*



Glycemic Research Laboratories

Board Certified Human In Vivo Clinical Trials

PRODUCT SUBMISSION FORM DOCUMENT "A"

Company Name & Address _____

Date _____

PO # _____

Email _____

Web _____

Contact Person _____

Phone _____

Title _____

Fax _____

Name of Product Submitted _____

Description of Product _____

Clinical Testing Applied For:

_____ **Low Glycemic**

_____ **Certified Natural Beverage**

_____ **Low Glycemic for Diabetics**

_____ **Low Glycemic (Latin Market)**

_____ **Low Glycemic Kid Friendly**

_____ **Certified Nanotechnology**

_____ **Low Cephalic Index**

_____ **Low Glycemic Pharmaceuticals**

_____ **Other ***

* Glycemic Solutions/Glycemic Research Laboratories conducts clinical studies on adipose tissue fat-storage (fat-storing properties), FDA and FTC claims, products in development, efficacy, and other studies related to human biochemistry.

Total Number of Products Submitted _____

(For each product submitted, fill out an additional form.)

Glycemic Research Laboratories

Board Certified Human In Vivo Clinical Trials

LABEL AND INGREDIENT INFORMATION: DOCUMENT “B”

LABEL AND INGREDIENT INFORMATION:

Place the product label and ingredients panel on this page

Glycemic Research Laboratories

Board Certified Human In Vivo Clinical Trials

STANDARD TERMS & CONDITIONS AGREEMENT FOR SERVICES DOCUMENT “C”

All services provided by Glycemic Solutions/Glycemic Research Laboratories (GS/GRL) and/or its affiliates are subject to the terms and conditions stated herein.

Client signature on this Document constitutes acceptance of the Terms and Conditions as stated herein.

A. USE OF NAME

The client agrees not to use Glycemic Solutions/Glycemic Research Laboratories and/or its affiliates name or data in any manner which might cause harm to said companies reputation and/or business. Under no circumstances is the name of Glycemic Research Institute (GRI), Glycemic Solutions (GS), Glycemic Research Laboratories, and/or its affiliates to be published, either alone or in association with that of any other party, without prior written approval from the corporate offices of GRI/GS.

B. PAYMENT TERMS

Total payment is due prior to the onset of the clinical studies. This fee is non-refundable.

C. TRIAL RESULTS

Following completion of the Human In Vivo Clinical Trials, the client will be notified of the results. An Official Report will be generated by GS and sent to the client.

INITIAL_____

D. REFORMULATION

If the Test Food (s) submitted does not qualify as “LOW GLYCEMIC” and/or “LOW GLYCEMIC FOR DIABETICS,” the client may elect to reformulate and resubmit the product. Prior to the trial, or post-trial, Low Glycemic product development is available upon request.

F. FORMULA CHANGES

Any change or modifications in the product formula (Test Food) as tested by GS invalidates prior clinical testing results and/or use of any GRI Mark. No claims or statements as related to GS Glycemic Testing may be made in relation to altered Test Foods as previously tested by GS. Any formula or ingredient changes to Test Foods previously approved as “Low Glycemic” by GS requires updated Clinical Trials for validation by GS and/or GRI.

SIGNATORY PAGE

The client agrees to the Terms & Conditions as stated herein.

Client Signature

Date _____

Client Printed Name

Corporation

Glycemic Research Institute®
Glycemic Research Laboratories
Glycemic Solutions Corporation

111 Second Avenue N.E., Suite 512
St. Petersburg, Florida 33701
U.S.A.

Official Clinical Testing Facility
of the Glycemic Research Institute®

DOCUMENT “D”
Document D. 4.5.2010

AGREEMENT & LICENSE
FOR USE OF
GLYCEMIC RESEARCH INSTITUTE®
CERTIFICATION MARKS

This Agreement made this ____ day of _____, 20____, by
and between the GLYCEMIC RESEARCH INSTITUTE®, a Washington,
D.C. corporation hereinafter referred to as the “GRI”), and its Official
Clinical Testing Facility, Glycemic Solutions, Glycemic Research
Laboratories, a Florida corporation located in St. Petersburg, Florida, and
_____,
a corporation (hereinafter referred to as the “Licensee”).

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WITNESSETH:

WHEREAS, the Glycemic Research Institute (“GRI”), in furtherance of its objective to promote and encourage the use of its *Federal Government Certification Marks*, as duly accepted and registered with the United States government, the Canadian government, and the UK government, has developed a legal Certification Program for use of its Marks (the “Marks”, a copy of which is attached hereto on Exhibit A, and as seen at Glycemic.com); and

WHEREAS, GRI has registered and owns Certification Marks for *Low Glycemic*®, *Low Glycemic Pharmaceutical*®, *Diabetic Friendly*®, *Kid Friendly*®, *Natural Beverages*®, *Low Cephalic Index*®, *Safe Nanotechnology*®, etc. to be used in conjunction with GRI approved foods, Nutraceuticals, and Pharmaceuticals; and

WHEREAS, GRI has assigned *Glycemic Solutions, Glycemic Research Laboratories* (GlycemicIndexTesting.com) as the “Official Human Clinical Trial Facility” authorized to conduct clinical trials per GRI Certification Guidelines, per CFR 21, submitted and registered with the federal governments in the U.S., Canada, and UK; and

WHEREAS, the Licensee seeks to have conducted, GRI Board Approved Human In Vivo Clinical Trials, at *Glycemic Solutions, Glycemic Research Laboratories*, an accredited independent testing laboratory, and is desirous of having the right to use the GRI’s Certification Mark (s) as set forth in this Agreement; and

WHEREAS, the parties hereto desire to record their understandings with respect to Licensee’s use of GRI’s Certification Mark (s).

NOW, THEREFORE, in consideration of the mutual promises contained herein and other good and valuable considerations, the receipt and sufficiency of which is acknowledged, the parties agree as follows:

1. Subject to the following terms and conditions of this Agreement, and upon approval by Glycemic Solutions, per the clinical trials conducted on any product duly submitted to Glycemic Solutions (the “Product”) for GRI approved Human In Vivo Clinical Trials, GRI grants to the Licensee a non-exclusive right and license (the “License”) to use one or more of its Certification Mark (s) on Licensee’s food, Nutraceutical, and/or Pharmaceutical product.

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This License is predicated upon the Licensee following and accepting the Terms of this Agreement, and the terms as set forth under the Glycemic Solutions “*Standard Terms & Conditions Agreement for Services*” as signed by the Licensee/Applicant.

2. Licensee shall not use any of the GRI Certification Marks on any product or product packaging, label, website, brochure, nor on any test or research report, nor in any Press Release or article, nor in any other manner which suggests or implies, directly or indirectly, that GRI certifies, endorses or approves any product other than the specific product (s) that have:

- a. Been submitted to Glycemic Solutions for Human In Vivo Clinical Trials
- b. Undergone GRI approved Human In Vivo Clinical Trials
- c. Passed the protocol (s) for one or more of the GRI Certification Marks
- d. Been notified by Glycemic Solutions that the product submitted has passed all clinical testing protocols per the trial conducted
- e. Received the final Official Report from Glycemic Solutions

Further, upon notice from Glycemic Solutions, that the product submitted (the “Product”) has passed all appropriate clinical trials, the Licensee will fill out and submit the “*Submission of Documentation Form*” to GRI and Glycemic Solutions, as found at the Official GRI website Glycemic.com (PDF form), and will, within 30 days affix the appropriate GRI Mark, per the final *Official Clinical Trial Report*, to any and all labels of the Licensee Product manufactured, marketed or sold anywhere in the U.S. or Internationally.

I. GRI Intellectual Property. The Licensee understands and agrees that products which pass all GRI and Glycemic Solutions Protocols as “Low Glycemic” and/or “Low Glycemic for Diabetics” and/or any other GRI Mark, qualify to use the GRI Federal Government Certification Marks and/or Trademarks, as awarded to the Glycemic Research Institute (GRI) (Glycemic.com) (USPTO.gov). Use of these Marks requires applying to GRI and providing clinical documentation that the product (s) has undergone Board Approved, GRI Approved, Human In Vivo Clinical Trials. Following GRI approved, GS Human In Vivo Clinical Trials for any product submitted, and following approval of the said product (s) by GS, the client agrees not to utilize any “Glycemic” and/or “Low Glycemic” and/or “Low Glycemic for Diabetics” and or similar statement or logo or Seal, other than those Marks belonging to the Glycemic Research Institute. Products that Glycemic Solutions qualify as “Low Glycemic” shall not bear any Glycemic-Related Seal or Mark or Logo or Certification other than that of the Glycemic Research Institute.

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II. Use of GRI Marks. Products that are submitted to Glycemic Solutions for Glycemic Clinical Trials will either a) Qualify to use the GRI Seals of Approval or b) Not qualify to use the GRI Seals of Approval. In the case of (a) wherein a product submitted passes all GRI and GS protocols, said product will be required to utilize the GRI Seal (s) on said product (s) within 30 days following receipt of the GS Clinical Trial Official Report on all labels for said product. When the production of new labels is time-sensitive and/or not feasible, GRI will provide to the client, stickers that adhere to labels, which represent the GRI Seal of Approval that the product has qualified for. The stickers will be made available to the client at the printing cost. Temporary stickers displaying the GRI Seal (s) will only be used until new labels are printed by the client. Prices will be quoted to the Licensee by GRI/GS for printed GRI Marks (stickers to be added to labels).

(II. Continued) Said prices will include printing and shipping costs, and will not be unreasonably priced. In the event that the Licensee elects not to use the stick-on GRI Mark, the Licensee will be required to reprint their product labels (as solely related to the product that is the subject of the GS clinical trial) within 30 days of receiving the Official Glycemic Solutions Clinical Trial Report.

III. Privacy. Following the GS Clinical Trial, in the case of (2.a) wherein the product passes all protocols for one or more of the GRI Seals, said product and company name, likeness, and/or official logo may be featured at GRI and/or GS official websites for public viewing. Companies whose products do not pass (2.b) will not be featured on GRI or GS official websites. The privacy of clients and product that *do not pass* the Clinical Trial protocols will be respected, and *not publicly revealed*.

IV. Products in Development. Products in development, that are not currently on the market, will be given an exemption on mandatory use of the GRI Seals, until the product is introduced to the market (under the name selected by the client for said product). Once the product has entered the public market, it will be subject to the Terms of this Agreement. Exemptions to this section of the document (2.e) can be requested by the client. Any breach of these protocols can result in invocation of section (17.) of this Agreement.

3. The GRI Certification Mark (s) may not be used in any manner, which infers or implies that GRI has certified any product, service or practice other than qualification as related to their Certification Marks, and not to the efficacy of, safety of, or any other warranty of the product as submitted by the Licensee.

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4. GRI has the right, from time-to-time to request, orally or in writing, samples of each use of the GRI Marks by the Licensee, to be provided within ten (10) business days of GRI's request, to confirm that the use of GRI Marks are consistent with this Agreement. Glycemic Solutions and/or GRI retains the right to display (on Official GS/GRI websites) the Logo of, and name of, and product picture of, any client product (s) that has passed the GRI approved Clinical Trials.

5. Licensee acknowledges that this License is personal to Licensee. Neither the License, nor any rights under the License, may be transferred, assigned or sublicensed to third parties. Licensee's parents, subsidiaries, or affiliated entities are not authorized to use the Mark (s), except with the prior written permission of GRI.

6. International Labeling Laws. The GRI Certification Mark (s) are registered with the Canadian and UK governments as valid verification for Low Glycemic claims. The GRI Marks have also been utilized on product labels in every country in Asia since 2002, and in Mexico since 1990 (approved by the Assistant District Attorney of Mexico). No incidence has arisen that would prevent any entity from using GRI Marks in any country globally. In the event that a Licensee receives any official notification from any International country regarding the use of any GRI Mark, the Licensee will immediately (within 10 business days) notify GRI and/or Glycemic Solutions (GS), including forwarding any documentation to GRI/GS. In the event that it is determined that the appropriate legal authorities, in a specific country, questions and/or prohibits the use of any GRI Mark on a product label, GRI attorneys will investigate, and advise the Licensee of the resulting legal position.

7. Licensee agrees that it will not alter, delete, or amend the Mark (s), which it shall receive from GRI, except with respect to size. The Licensee's use of the Mark (s) will be of such size as to permit legibility of the wording. Licensee may use the colors set forth in Exhibit A or may use black or shades of gray. Licensee may only use the entire Mark as shown in Exhibit A and in particular may not display or use the design portion of the Mark without the words original to the specific Mark, as seen at Glycemic.com.

8. Licensee's rights hereunder shall continue only so long as Licensee maintains its good standing with GRI and/or Glycemic Solutions, which are separate corporate entities.

9. Licensee acknowledges the ownership of the Mark (s) by GRI, and agrees that it will do nothing inconsistent with such ownership and that all uses of the Mark (s) by Licensee, or permitted parents, subsidiaries, or affiliated companies, shall inure to the benefit of GRI.

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10. Licensee agrees that nothing in this License shall give Licensee any right, title or interest in the Mark (s) other than the right to use the Mark (s) in accordance with this License, and Licensee agrees that it will not attack the ownership or title of GRI to the Mark and will not attack the validity of this License.

11. GRI reserves the right to cancel this Agreement if, in the sole discretion of GRI, the Licensee (a) misuses the Mark, (b) uses it in such a manner as will likely mislead or deceive the public or purchasers, (c) fails to comply with any term of this License, (d) changes the product formula in any manner whatsoever, (d) fails to use the appropriate GRI Mark (s) assigned to the Licensee's product (following approved clinical trials by Glycemic Solutions) on each and every unit label of said product manufactured or sold.

12. GRI shall provide thirty (30) days' written notice of any proposed cancellation under this Paragraph. If reasonable assurances have not been provided to the GRI within five (5) business days after delivery of the notice to Licensee that the activities giving rise to the proposed cancellation have been terminated, GRI may cancel the License immediately.

13. Upon termination or cancellation of this Agreement for any reason, the License shall cease and Licensee and its permitted parents, subsidiaries and affiliates, shall immediately cease the use or distribution of any materials containing the Mark (s).

14. Nothing in this Agreement shall give to Licensee any right, title or interest in or to the Mark (s), except the right of Permitted Uses as specifically set forth in this Agreement.

15. Licensee will indemnify and hold harmless GRI and or Glycemic Solutions, its officers, directors, and staff against any and all claims, judgments, actions, losses, settlements, expenses or costs of any sort (including reasonable attorneys' fees) (collectively "Claims") arising out of the Licensee's use of the Mark (excepting Claims that the Mark infringes another mark). This paragraph shall survive the termination of this Agreement.

16. Unless earlier terminated in accordance with its terms, this Agreement shall be for a period of three (3) years from the date first written above, and may be renewed by GRI upon submission by the Licensee of the request for another term, to be determined by GRI.

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17. Licensee acknowledges and agrees that compliance with the terms of this Agreement is necessary to protect the goodwill and other proprietary interests of GRI/GS and that a breach of this Agreement by Licensee would result in irreparable and continuing harm to GRI/GS for which there would be no adequate remedy at law. Accordingly, Licensee agrees that in the event of any breach of this Agreement GRI/GS shall be entitled to injunctive relief and/or specific performance, and that Licensee shall not oppose such relief on the grounds that there is an adequate remedy at law, and such equitable remedy shall be cumulative and in addition to any other remedies at law or in equity (including monetary damages) which may be available to GRI/GS, including damages for Certification/Trademark infringement. Licensee acknowledges that GRI/GS reserves the right to file a Trademark infringement lawsuit against the Licensee, in case the Licensee refuses to cease & desist utilizing any of GRI's registered Mark (s) per notification from GRI/GS. The provisions of this Section 11 shall survive the termination of this Agreement.

18. This Agreement shall be governed and construed in accordance with the laws of the State of Florida, County of Pinellas, United States of America.

(Signature page below)

Licensee Initial _____

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**Glycemic Research Institute®
Glycemic Research Laboratories
Glycemic Solutions Corporation**

**AGGREEMENT & LICENSE FOR USE OF
GLYCEMIC RESEARCH INSTITUTE®
CERTIFICATION MARKS**

SIGNATURE PAGE

GLYCEMIC RESEARCH INSTITUTE

Authorized Corporate Signature

Printed Name

Title

GLYCEMIC SOLUTIONS

Authorized Corporate Signature

Printed Name

Title

LICENSEE

Company Name

Corporate Website

Authorized Corporate Signature

Printed Name

Title

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Glycemic Research Institute®
Glycemic Research Laboratories
Glycemic Solutions Corporation

AGGREEMENT & LICENSE FOR USE OF
GLYCEMIC RESEARCH INSTITUTE®
CERTIFICATION MARKS

EXHIBIT A

Glycemic Research Institute® Certification Marks



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Document last amended: April 5, 2010
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www.Glycemic.com
www.GlycemicResearchLaboratories.com

Glycemic Research Institute®

**601 Pennsylvania Avenue
Suite 900
Washington, D.C. 20004**

**NATIONALLY ACCREDITED TESTING &
CERTIFICATION ORGANIZATION**

**CERTIFICATION PROGRAM
2009**

DOCUMENT “E”

The *Glycemic Research Institute*® is a Nationally Accredited Testing & Certification Organization approved by the United States government.

The *Glycemic Research Institute* Certification Program and Certification Marks are Registered and Licensed by the United States, Canada, and United Kingdom governments, and accepted Worldwide per World Health Organization (WHO) Guidelines.

The *Glycemic Research Institute*® government-issued Certification Marks represent 25-years of Clinical Research in the fields of the Glycemic Index, Diabetes, Cephalic Response, Obesity, Adipose Tissue Fat-Storage, and Childhood Obesity.

The *Glycemic Research Institute* Certification Marks are legally authorized to make a clinical statement, such as “LOW GLYCEMIC” or “DIABETIC FRIENDLY” or “LOW CEPHALIC INDEX” or “KID FRIENDLY” on an FDA label for a commercial food, Nutraceutical, beverage, or Pharmaceutical product.

Any Certification Mark statement representing a clinical claim must be backed by Human In Vivo Clinical Trials per FDA CFR 21 guidelines and per the Clinical Trials Guidelines submitted by the organization licensed to use said Certification Mark.

A Certification Mark on a commercial product legally enables *bounding* (*being under legal obligation*) under the following guidelines:

- The existence of a Legal Product Certification Agreement between the *manufacturer* of a product and the organization that possesses accreditation by a national government for *both* testing and product certification.
- Legal evidence that the product was successfully tested in accordance with a nationally accredited standards.
- Legal assurance the accredited certification organization has ensured that the item that was successfully tested, and is identical to that which is being offered for sale.
- Legal assurance that the successful test has resulted in a certification listing, which is considered public information, which sets out the tolerances and conditions of use for the certified product, to enable bounding, and thus compliance with the law.
- Legal assurance that the manufacturer is being regularly audited by the Certification Organization, at unannounced intervals, to ensure the maintenance of the original process standard that was employed in the manufacture of the test specimen that passed the test, and that if the manufacturer should fail an audit, all product certification, including labels of stock on hand, on construction sites, with end-user customers and on distributor store shelves, shall be immediately removed, and all stakeholders will be informed that the de-listed product certification is no longer eligible for use in bounding.

QUALITY ASSURANCE

THE LEGAL RELATIONSHIP BETWEEN CERTIFIER & CLIENT

Product certification and product qualification is the cornerstone of all *bounding* for Certification Marks, and the process of certifying that a specific product has passed performance and quality assurance tests or qualification requirements stipulated in regulations and Nationally Accredited Test Standards, and that a product complies with a set of regulations governing quality and/or minimum performance requirements.

On the part of the certifier, in this case, the *Glycemic Research Institute (GRI)*, is certifying that a product has passed all Clinical Protocols established to use the GRI Marks on a label and/or product marketing.

For products that pass the strict Clinical Protocol, the *Glycemic Research Institute* allows the use the GRI Mark on the product label, thus indicating legal eligibility of the product for use in bounding, and certifies the origin, material, mode of manufacture of products, mode of performance of services, quality, and accuracy of other characteristics of the product.

Products, once certified, may be endorsed with the Authorized Certification Mark and may be eligible to display said Certification Mark, under the direction and guidelines of the *Glycemic Research Institute*.

TRADEMARKS VS CERTIFICATION MARKS

Trademarks are vastly different from Certification Marks. Trademarks are issued to individuals and companies and represent a word (s) or logo used by that entity.





Certification Marks are difficult to register, and are *only issued* by the government to companies that are *Nationally Accredited Testing and Certification Organizations*. It is difficult, lengthy, and expensive to obtain a Certification Mark from the government, as the organization applying for said Mark must prove worthiness on many different levels of competence, expertise, and good standing in the community.

Companies that are legally issued a Certification Mark must follow strict government guidelines in order to obtain, maintain and continue to use said Marks.

EXAMPLE OF VALID CERTIFICATION MARKS

The main purpose of government Certification Mark regulations is to protect consumers against misleading practices.

Some of the more commonly seen Certification Marks are:

	<p>Underwriters Laboratories holds a service mark on the phrase "UL Listed," and allows manufacturers of electrical and other safety equipment to use the UL mark only if they are under follow-up agreement by UL. This lets consumers identify products that meet quality criteria set by a company other than the manufacturer.</p>
	<p>The "Champagne" certification mark, used to indicate goods which have an appellation of origin of the Champagne region in France.</p>
	<p>The Bureau Veritas Certification Mark, used to indicate the Sea-Worthiness of Ships.</p>
	<p>(U in a full circle), the hechsher of the Orthodox Union.</p>
	<p>Underwriters' Laboratories of Canada (ULC), is an affiliate of Underwriters Laboratories. ULC is accredited in Canada to conduct testing and to provide certification, and to author National Standards.</p>

LEGAL REQUIREMENTS FOR CERTIFICATION MARKS

Authorized Certification Mark issuers are required and *must observe* the construction of test specimens to avoid any possible cheating on the part of the submitter or parties affiliated with the submitter.

This is mandated to avoid having an unethical submitter attempt to have certified, a product that is not identical to the original product submitted.

As a result of documented abuses in this field, certifiers typically reserve the right to re-test as a cautionary measure to ward off such behavior.

DE-LISTING

De-Listing is the process of recalling a Certification for a specific product. While De-Listing is rare, it has occurred, which has resulted in having strict and mandatory Certification regimes in place. De-Listing can occur as a result of inaccurate data provided by the client deliberately or non-deliberately submitting a product (such as incorrect Ingredient Listings or Label data), or from Incremental Degradation of a product (changing the original product formula/ingredients from the original), or using the Certification Mark in an illegal and/or unauthorized manner.

The *Glycemic Research Institute* holds full authority to De-List and Recall its government Certification Marks as a result of any breach of protocol on behalf of a client and/or product submitted.

Said breaches include using the Certification Mark on a product that has passed the GRI Clinical Trial Protocol, wherein said product has been sub-licensed to another company. In said case, the Mark cannot be utilized by the sub-licensee without the product being re-submitted to GRI for Clinical Trials.

Only "active" Certification Mark listings matter at the point of purchase or use, as products and companies can become "De-Listed" as a result of improprieties.

The active Certification Mark listing is the cornerstone of all *bounding* in actual use. It is a legal document against which the product is compared to approvals by an *Authority Having Jurisdiction* (AHJ).

ACTIVE CERTIFICATION

An *Active Certification* listing indicates three mandates:

- The product is being made under a Certification, or follow-up agreement that exists between the manufacturer and the certification organization. This means that the certifier can conduct up to 4 unannounced factory audits per year, for the purpose of ensuring that the product being made and sold is still identical to that which was tested.
- The product's packaging, literature and the manufacturer's promotional information is authorized to use the Certification Mark.
- The listing is held and is listed in the Certification Listings Directory of the Certification Organization.

Certification Marks are very highly regarded by governments Worldwide, as well as by stockholders and investors of high-quality products. Accredited Testing Organizations, such as the *Glycemic Research Institute*, are relied on to provide accurate and legal reports and data regarding specific products.

In Germany, Accredited Testing Organizations routinely audits manufacturing locations and submits quality control results to the government and to investors and stockholders. De-Listing can occur in the case of non-compliance. Trends in quality are identified very early and brought to the attention of all stakeholders to enable the prevention of problems.

PRESENTATION OF ACTIVE CERTIFICATION MARKS

Certification Marks are easy to see on product labels and enable users to track down the Certification Listings, the tolerances that guide field use, and whether or not the listing is still active.

In certain cases, a Certification Mark can mean the difference between life-and-death. As an example, fire extinguishers, fire alarms, electrical equipment, hospital equipment, emergency room equipment, Paramedic equipment, and surgery-room equipment, must be clearly labeled with appropriate Certifications.

This understates the reasoning for utilizing and maintaining appropriate Certifications, and personifies the illegality of obscuring a Certification label.

The *Glycemic Research Institute* requires the use of its Certification Marks to be presented clearly on the front of a food, beverage, Nutraceutical, or Pharmaceutical label.

CLEAR UNDERSTANDING

As a potential client of the *Glycemic Research Institute*, I have read and understand, and fully intend to comply with the Guidelines as stated herein.

Client Name (printed)

Client Business Address

Client Official Website

Client Signature

Date