601 Pennsylvania Avenue Suite 900 Washington, D.C 20004

#### PET FOOD DIVISION

# Independent Clinical & Analytical Ratings on Pet Foods

PET FOOD RATINGS
PET FOOD AWARDS
PET FOOD TREATS
PET FOOD OF THE YEAR

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601 Pennsylvania Avenue Suite 900 Washington, D.C 20004

## FOUNDED IN 1983 25 + YEARS OF CLINICAL EXPERTISE

#### **BOARD CERTIFIFED HUMAN IN VIVO CLINICAL TRIALS**

U.S. GOVERNMENT CERTIFICATION PROGRAM
UNITED KINGDOM GOVERNMENT CERTIFICATION PROGRAM
CANADIAN GOVERNMENT CERTIFICATION PROGRAM

**CLINICAL STUDIES: INVESTIGATIONAL TRIALS** 

FDA & FTC CLAIM SUBSTANTIATION

<u>CLINICAL ASSESSMENT</u>
Foods, Beverages, Nutraceuticals & Pharmacueticals

www.Glycemic.com

www.GlycemicResearchLaboratories.com

www.GRIKidFriendly.com

www.NaturalBev.com

www.GRIPetFoods.com

Glycemic Research Laboratories GRI Official Trials Laboratory Glycemic Solutions St. Petersburg, Florida (727) 894-6900

#### GLYCEMIC RESEARCH INSTITUTE GLYCEMIC RESEARCH LABORATORIES GLYCEMIC SOLUTIONS

Official Clinical Trials Laboratory St. Petersburg, Florida (727) 894-6900

## CLINICAL TRIALS & CERTIFICATION PROGRAMS

Human Foods & Products that are accepted for *In Vivo Clinical Trials* are limited to orally ingested foods, beverages, Nutraceutical, and Pharmaceuticals.

Human Foods & Products that are accepted into the *Clinical Testing Program* will undergo *Board Approved Human In Vivo Clinical Trials*.

Testing of Kid Friendly® foods and beverages is under the direction of the Glycemic Research Institute® Human Nutrition & Biochemistry Division, Childhood Obesity Unit, Clinical Trials Laboratory.

Testing of animal foods is under the direction of *Glycemic Research Institute*® *Pet Foods Division*.

Test Foods (products submitted) that pass the clinical protocols qualify to display the *Glycemic Research Institute*® Government Certification Marks on products labels and brochures, and to make specific claims. All Clinical Trials are based on FDA CFR21 Guidelines.

Companies may submit products that are in development, in the R & D stage, and/or products that are already on the market.

A Clinical Studies Coordinator will be assigned to work one-on-one with the client.

#### **INVESTIGATIONAL TRIALS**

Products-in-development can be analyzed for their glycemic, diabetic, fatstoring, and/or Kid-Friendly properties, depending on the client needs. These trials are "Investigational" and help assist companies develop Low Glycemic products that address specific health issues, such as obesity, diabetes, and the current childhood obesity epidemic. Following the *Investigational Trials*, the client will receive a full report on the results of the trial, and may request a phone conference with the Medical Advisory Board to discuss results of the trials and directional advice on options for reformulating the Test Food.

#### PROGRAMS, SERVICES & CLIENT OPTIONS

The *Glycemic Research Institute*® offers the following Programs:

#### **BOARD CERTIFIFED HUMAN IN VIVO CLINICAL TRIALS**

#### **GOVERNMENT CERTIFICATION PROGRAMS:**

UNITED STATES GOVERNMENT CERTIFICATION PROGRAM
UNITED KINGDOM GOVERNMENT CERTIFICATION PROGRAM
CANADIAN GOVERNMENT CERTIFICATION PROGRAM

**CLINICAL STUDIES: INVESTIGATIONAL TRIALS** 

FDA & FTC CLAIM SUBSTANTIATION

**CLINICAL ASSESSMENT** 

INSTRUCTIONS & APPLICATION FORMS ARE AVAILABLE AT THE FOLLOWING OFFICIAL GLYCEMIC RESEARCH INSTITUTE WEBSITES

• Foods: <u>www.GlycemicResearchLaboratories.com</u>

www.GlycemicIndexTesting.com

• Products-In-Development: www.GlycemicResearchLaboratories.com

www.GlycemicIndexTesting.com

• Beverages: www.GlycemicIndexTesting.com

www.NaturalBev.com

• Sports Products: www.GRIProSports.com

• Natural Beverages: <u>www.NaturalBev.com</u>

• Nutraceuticals: www.GlycemicResearchLaboratories.com

www.GlycemicIndexTesting.com

• Pharmaceuticals: www.GlycemicResearchLaboratories.com

www.GlycemicIndexTesting.com

• Pet Foods: www.GRIPetFoods.comGlycemic

Glycemic Research Institute® Pet Foods Division

#### **PRESS RELEASE**

Upon completion of the *Glycemic Research Institute*® *Board Approved Human In Vivo Clinical Trials*, the client may request an Official Press Release. Samples of actual Press Releases may be seen at Official Glycemic Research Institute® websites.

#### **ASSISTANCE**

To learn more about the Programs offered by the *Glycemic Research Institute*®, call (727) 894-6900 or email csc@GlycemicIndexTesting.com

#### **OFFICIAL WEBSITES**

www.Glycemic.com

www.GlycemicResearchLaboratories.com

www.GlycemicIndextesting.com

www.GRIKidFriendly.com

www.NaturalBev.com

www.GRIPetFoods.com

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#### PET FOOD DIVISION

# Independent Clinical & Analytical Ratings on Pet Foods

PET FOOD RATINGS
PET FOOD AWARDS
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PET FOOD OF THE YEAR

#### PET FOOD AWARDS PROGRAM

The Glycemic Research Institute® (GRI) conducts Independent Clinical and Analytical research on Pet Foods and Pet Treats.

The Glycemic Research Institute® has been conducting Human In Vivo Clinical Trials since 1983, and began their Pet Food Division in 2004.

GRI has examined hundreds of pet foods from 2004 to the present in order to determine the healthiest overall products, focusing on anti-aging, diabetes, arthritis, glycemic, blood glucose and insulin response, in the canine and feline.

As a Non-Profit independent research organization, GRI has no ties to the pet food industry, and does not accept monies from any company for the *Pet Food of the Year* Award or any other GRI Pet Food Award.

## CRITERIA FOR SELECTING "PET FOOD OF THE YEAR" AWARD

As a species, dogs are cats are evolutionarily designed to utilize animal proteins and fat as their primary fuel, with Low Glycemic fruits and vegetables as a secondary fuel. It is important to include Low Glycemic species-friendly fruits and vegetables in canine and feline pet foods.

Dogs and cats require biologically appropriate diets in order to thrive and stay healthy. Though the food supply in both humans and pet diets has changed over the last hundred years, they both have resulted in weight gain, diabetes, arthritis, joint disorders, and a plethora of health issues, including mild-to-severe skin problems in the canine and feline.

Currently, dog and cat foods commonly contain ingredients that are totally inappropriate for the species.

An acceptable pet food should be designed to meet the biological needs of the species. An *outstanding* pet food will reflect appropriate ratios of protein-to-carbs-to-fats, and will only contain ingredients that are acceptable to that species.

Pet foods that contain significant levels of High Glycemic ingredients and/or ingredients not deemed acceptable for the species will be excluded from being considered for the "Pet Food of the Year" award.

Pet foods that contain sweeteners that are known to be contraindicated, such as Xylitol, Stevia, Agave, and Acesulfame K, will be excluded for consideration as "Pet Food of the Year."

Pet foods that meet the guidelines for "Pet Food of the Year" will reflect the strict criteria set by the Glycemic Research Institute® for a healthy, appropriately formulated food, and will reflect the current science in the field of nutritional animal biochemistry.

Products selected as "Pet Food of the Year" will have demonstrated an *above average* commitment to an animal's total health and an approach to formulating a pet food that is as exemplary as advanced science allows.

## DEFINING LOW GLYCEMIC & DIABETIC FRIENDLY PET FOOD

The Glycemic Impact<sup>TM</sup> of a canine and/or feline food is extremely important in their lifespan and health status. This includes the Diabetic-Risk-Factors related to ingestion of pet foods.

Determination of the glycemic status of a pet food is both complicated and convoluted. Looking at the label does not reveal the glycemic status of a pet food, or a human food. Many ingredients that are included in both human and pet foods are impossible to identify and impossible to tag as either High Glycemic or Low Glycemic without benefit of analytical and clinical trials.

For example, Maltodextrins are found commonly in many foods. A label, both pet foods and human foods, can declare "No Sugars" and still contain a huge amount of sugar. The legal loophole is in the definition of "Sugars."

Maltodextrins are the highest glycemic sugar on this planet, and yet, the FDA allows them to be called "Carbohydrates" and not "Sugars." So foods and beverages, including pet foods, can claim "No Sugars" and "Sugar Free" while containing any amount of Maltodextrin-Sugars.

Thus, labels are deceptive in analyzing their actual metabolic response.

In the canine and feline, High Glycemic pet foods, and High Glycemic diets high in sugars and carbohydrates accelerate the aging process, reduce lifespan, exacerbate cancer, diabetes, and other disease states.

One symptom of improper diet is skin diseases, which range from mild to severe, and are manifested by itching and scratching, rashes, and dull and dry coat.

Specific Protocols for analyzing pet foods are described below in the document:

#### PROTOCOLS FOR ANALYZING & TESTING PET FOODS

#### **HIGH-QUALITY INGREDIENTS**

Glycemic Research Institute's pet food recommendations mandate highquality proteins as the primary ingredient in any per food.

#### According to *PetEducation.com*:

"High-quality ingredients are essential for a healthy pet. Some economy brands of dog food are made from inexpensive ingredients that are not easily digested, and therefore, do not provide the best nutrition. While they may technically meet the legal specifications for percentages of protein, fat, carbohydrates, etc., these foods have lower energy values and lower-grade proteins.

Because of this, many health-building nutrients may pass right through your dog's system without being absorbed.

It also means that you have to feed larger amounts of that lower quality food to provide your pet with the same nutrition as a smaller amount of premium food. When you compare the cost of these foods on a per-serving basis, and realize how quickly you go through a bag, economy foods may actually cost more in the long run.

When you are looking for a healthy food for your dog, reviewing the list of ingredients on the back of the bag is a good place to start. By law, pet food labels must list their ingredients by weight.

Look for meat, fish, egg, or some type of meat meal or fish meal as the first or second ingredient.

Meat, fish, and eggs all have a high biological value, which means they have a high percentage of protein in the form of digestible, usable amino acids."

#### **CORN IS CONTRAINDICATED**

Corn is typically found in dog foods, and is a prime example of inappropriate pet food ingredients. When is the last time you saw a dog grazing in a corn field?

Corn is the worst possible product to feed a dog, even in small amounts, as their metabolism reacts to corn extremely negatively. Corn elevated blood glucose levels in the canine and feline, which causes skin problems, diabetes, and a plethora of other physical problems.

#### **HIGH GLYCEMIC INGREDIENTS**

Ingestion of corn and grains directly affect blood sugar levels in humans, as well as dogs and cats. The canine biochemistry is hard-wired to produce glucose from amino acids (proteins), which balances blood sugar levels.

Dogs can detect the smell of amino acids more distinctly than any other odor, as they have evolved into an efficient meat-detecting machine.

High Glycemic ingredients are contraindicated in canine and/or feline pet foods and treats.

High Glycemic ingredients over-elevate blood glucose levels, and increase risk of epilepsy, hypothyroidism, allergies, yeast infections, cancer and diabetes.

- Primary (high) levels of High Glycemic grains in canine and feline pet foods are not acceptable. These include wheat, corn, rice, and brown rice.
- Primary (high) levels of High Glycemic carbohydrates include potatoes (at high levels), potato starch, beets, and cooked carrots.

Many pet food manufacturers have recently begun to add potato starch to dog and cat food. This practice is unfortunate, because most consumers are not aware that potato starch is High Glycemic and contraindicated in pet foods of any type.

The Glycemic Research Institute® does not accept canine/feline foods or treats that contain high levels of potato starch. It is added to pet food because it is a very inexpensive raw material that adds bulk to the formula. This is also the case with corn.

Unlike regular potatoes and potato starch, sweet potatoes do not have the same negative effect on the canine, and are an acceptable ingredient in pet foods, as long as the ratios of proteins-to-carbs are in alignment.

#### **CANINE ARTHRITIS**

Pain management in the arthritic canine requires reducing inflammation, and reducing excess adipose tissue body fat. Sore and inflamed joints are a common side effect of arthritis in dogs.

In the lean, muscular canine, arthritic-soreness is reduced as compared to the overweight dog. Excess adipose tissue fat is exacerbated in the canine and feline via ingestion of grains and starches, which can be fattening.

#### **TOXIC INGREDIENTS**

Many foods and plants are safe for humans to consume, but are quite toxic to dogs and cats. Xylitol and chocolate can cause death in the canine. The following foods and plants are contraindicated in dogs/cats. Foods that can cause death, even in small doses, are tagged as *LETHAL*.

**XYLITOL** (Lethal): The Animal Poison Control Center of the American Society for the Prevention of Cruelty to Animals reports a substantially increased number of cases involving xylitol poisoning in dogs. Found in sugar-free chewing gum, candy, and baked goods, xylitol is a sweetener that can cause serious and sometimes life-threatening problems for pets.

<u>CHOCOLATE</u> (Lethal): Includes milk chocolate, dark chocolate, Cocoa powder, baking chocolate, dry cocoa powder, chocolate milk, chocolate candy, coca nut, chocolate ice cream, chocolate chip cookies, chocolate cake.

#### **OTHER TOXIC INGREDIENTS**

- THEOBROMINE (Lethal)
- CAFFEINE (Lethal)
- DRINKS THAT CONTAIN CAFFEINE & ENERGY DRINKS
- COFFEE & COFFEE GROUNDS (Lethal)
- GRAPES, RAISINS
- YEAST DOUGH, BREADS MADE WITH YEAST
- ONIONS & GARLIC
- SOY (endocrine disruptions)
- TEA
- AVOCADO
- ALCOHOL
- MACADAMIA NUTS
- VEGETABLES: Vegetables in the nightshade family, such as tomatoes, potatoes, eggplant and peppers should be avoided in canine/feline foods, as these foods can aggravate arthritic-inflammation and weight gain.

#### **TOXIC PLANTS**

Many household and yard plants can sicken and/or kill your pet.

- Lilies, Lily of the Valley, oleander, azalea, yew, foxglove, rhododendron and kalanchoe (heart problems if ingested).
- Rhubarb leaves and shamrock contain substances that can produce kidney failure. Certain types of lilies (*Lilium* and *Hemerocallis* species) are highly toxic to cats, resulting in kidney failure, even if small amounts are ingested.
- Sago palms (*Cycad* species) can cause liver damage, especially if the nut portion of the plant is consumed.
- Fungi: certain varieties of mushrooms can cause liver damage and other medical problems.
- Philodendron, castor bean, corn plant, mother-in-law's tongue, Hibiscus and hydrangea.

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#### **PET FOOD DIVISION**

# PROTOCOLS FOR ANALYZING & TESTING PET FOODS

The following methodologies are utilized in determining the Glycemic and Diabetic properties of pet foods.

#### **HPLC ANALYSIS**

Following HPLC/U-HPLC analysis, the data is cross-analyzed with *Glycemic Research Institute* (GRI) records of known glycemic indices of raw materials, and assigned a glycemic and diabetic index. Per GRI Certification Protocols, pet foods that meet the criteria are legally (FDA/FTC) allowed to display the GRI Certification Mark (s) on labels and attendant marketing material, which signify specific claims.

#### **High Speed Liquid Chromatography HPLC and U-HPLC**

- Conventional and ultra-high pressure modes
- Optimized performance for sub two micron particle columns
- Isothermal injection and separation enhances reproducibility
- Innovative LightPipe<sup>TM</sup> technology for increased sensitivity
- Rapid peptide identification and quantitation
- Fast efficient separations of metabolic profiles
- Ballistic gradient small molecule identification
- New columns geometries and particle sizes for improved speed, resolution and/or sensitivity

#### **QUATERNARY PUMP/ISOTHERMAL INJECTION**

A quaternary pump with only 65 microliters of delay volume, assuring rapid transfer of even the most complex gradients from the pump to the column. Isothermal injection and separation provide superior reproducibility by eliminating all external environmental influences to the chromatography.

#### HPLC ANALYTICAL ANALYSIS

Food compounds in pet foods analyzable by HPLC include amino acids, peptides, proteins, lipids, carbohydrates, sugars, sweeteners, alcohols, vitamins, organic acids, organic bases, mycotoxins, additives, preservatives, colorants, antimicrobial residues, pesticide residues, bittering substances, phenolic compounds, pigments, nitrosamines, growth promoters, anions, and cations.

#### **ASSAY PRINCIPLES: PROTEINS**

Protein interactions are analyzed using a label-free detection method. Sample in solution is injected over a sensor surface on which potential interacting partners are immobilized.

As the injected sample interacts with the immobilized partners, the refractive index at the interface between the sensor surface and the solution alters to a degree proportional to the change in mass at the surface.

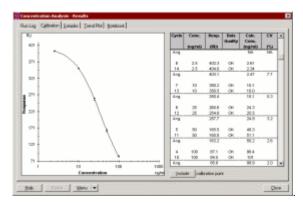
Surface plasmon resonance (SPR) is exploited to detect these changes in real time and data are presented in a "sensorgram" (SPR response plotted against time).

Concentration test assays are designed as indirect (inhibition) assays. A known concentration of a relevant binding protein is mixed with the sample and injected over a sensor surface on which a corresponding derivative is immobilized.

Any target molecules present in the sample bind to the binding protein and so inhibit it from binding to the sensor surface. The higher the concentration of the target molecule in the sample, the higher the level of inhibition, and hence the lower the SPR (see below) response.

Concentrations are calculated by interpolation of the binding responses on a calibration curve.

Page 3 of 3. Glycemic Research Institute/Pet Food Analysis



#### **CALIBRATION CURVE**

#### **DATA SYSTEMS**

- Method transfer calculators for isocratic method and gradient method transfer
- Xcalibur MS data system
- ChromQuest Chromatography Data System (CD)

#### **GLYCEMIC IMPACT**

The metabolic goal of designing Low Glycemic, Diabetic Friendly canine and feline pet foods is to improve glucose and insulin metabolism in companion animals by controlling the postprandial glycemic and/or insulin response in those animals.

Measurement and quantification of postprandial glucose and insulin levels in the canine involve oral non-forced feeding of the Test Food. Changes in serum glucose and insulin concentration are calculated post-meal period by using the plasma concentration before the meal as a baseline.

Postprandial responses are compared for maximum increase, time to peak increase, and incremental area under the glucose (AUCG) and insulin (AUCI) curves for each food. The integrated area under the postprandial glucose and insulin response curves is calculated by the trapezoidal method. Area increments under the curves for a given food are determined for a 3-4 hour period after the meal.

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#### GRI PET FOODS PROGRAM GLYCEMIC RESEARCH INSTITUTE

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#### **COMMONLY ASKED QUESTIONS**

## Q. HOW CAN PET FOOD THAT CONTAINS POTATOES BE CONSIDERED LOW GLYCEMIC?

**A.** The mere inclusion of potatoes in a pet food, or human food, does not determine the resulting glycemic index and load, as that is determined by the protein-carb-fat ratios, with particular emphasis on the type of proteins utilized.

Pet foods that contain a sufficiency of high quality proteins, with lower levels of potatoes (not potato starch), blunt the glycemic response from inclusion of potatoes in the food.

The glycemic response to oral ingestion of corn in the canine and feline is very negative, exhibiting high glycemic perimeters, and corn is never acceptable in a dog or cat pet food. Corn, however is beneficial to certain animals, such as horses, squirrel's, ducks, chickens, and other birds.

## Q. WHAT IS THE CRITERIA FOR SELECTING "PET FOOD OF THE YEAR"?

**A.** The criteria for the Glycemic Research Institute's (GRI) "Pet Food of the Year" is described in the GRI document:

Independent Clinical & Analytical Ratings on Pet Foods

#### O. WHAT ARE THE PROTOCOLS FOR TESTING PET FOODS?

**A.** The Protocols and Methods for the Glycemic Research Institute's (GRI) "Low Glycemic" Seal of Approval and/or the "Diabetic Friendly" Seal of Approval and/or the "Pet Food of the Year" award is described in the GRI document:

#### PROTOCOLS FOR ANALYZING & TESTING PET FOODS

## Q. IS THERE A COST FOR THE GLYCEMIC RESEARCH INSTITUTE® "PET FOOD OF THE YEAR"?

**A.** No. All Pet Food Awards are Pro Bono (free of charge).

## Q. IS THERE A COST FOR LOW GLYCEMIC TESTING, SUCH AS MANUFACTURERS WHO WANT TO TEST THEIR PET FOOD?

**A.** The Glycemic Research Institute® does not charge for the Certification Marks or Pet Food Awards. The Clinical Laboratory (Glycemic Research Laboratories/Glycemic Solutions) does charge a fee for clinical trials and/or analytical studies that are not related to GRI Pet Food Awards. The *Clinical Studies Coordinator* can provide information to clients that are seeking analytical and/or clinical trials.

#### **Clinical Studies Coordinator**

Glycemic Research Laboratories 727.894.6900 CSC@GlycemicIndexTesting.com

## Q. WHY DID ORIJEN CANINE FOOD WIN THE AWARD FOR "PET FOOD OF THE YEAR"?

**A.** Orijen Canine Food exemplifies a pet food that is based on the evolutionary and biological needs of the canine. Orijin did not apply for this award, they were selected by the Glycemic Research Institute® (GRI) after a study was undertaken by GRI scientists, comparing *Orijen* to hundreds of other canine pet foods on the market.

The Glycemic Research Institute's (GRI) "Pet Food of the Year" award is Pro Bono and no pet food company knows which pet foods are being tested by GRI until the award is announced to the public.

For complete information on *Orijen's* formulas, their website contains a *White Paper*, which has explicit details on how their food is designed, formulated, and researched:

ORIJEN CANINE FOOD - www.orijen.ca - Champion Pet Foods

#### Q. ARE ANY ANIMALS HARMED DURING TESTING?

**A.** Absolutely not. Everyone at the Glycemic Research Institute's (GRI) *Pet Food Division* is a devout animal lover. GRI's moto regarding animals is:

"The greatness of a nation and its moral progress can be judged by the way its animals are treated" Gandhi

#### **ANIMAL RIGHTS**

The Glycemic Research Institute's official position on the rights and dignity of all animals is found in the GRI document published at our website:

#### ANIMAL RIGHTS STATEMENT

#### PET FRIENDLY ENVIRONMENT

Glycemic Research Institute® scientists, researchers, and staff frequently bring their own pets to the office. Two frisky German Shepherd pups belonging to our Chief of Biomedical Research are often found romping around the office, trying to tempt the staff to *play ball*.

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# ANIMAL RIGHTS STATEMENT

"The greatness of a nation and its moral progress can be judged by the way its animals are treated"

#### Gandhi

The Glycemic Research Institute (GRI) is an *Animal Rights Activist Organization* and is against inhumane treatment and/or inhumane laboratory testing involving *any animal whatsoever*.

The Glycemic Research Institute® is passionate about animals and their rights to dignity and loving care throughout their lives.

No animals are harmed or sacrificed or treated inhumanly in any Glycemic Research Institute® trial.

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## SIERRA FOUNDATION SPECIAL SERVICE DOG AWARD

The Glycemic Research Institute's® philanthropic branch, the *Sierra Foundation*, is dedicated to providing pet food, medical treatment, bedding, and other pet needs, as a gift to special pets.

The *Sierra Foundation* has selected this year's recipient of the *2009 Special Service Dog Award*, which was awarded to Doberman canine companion *Maggie*, who faithfully dedicates her life to her owner, Pamela Wier.

Maggie is a Seeing-Eye-Companion to Pamela, and is always by her side, providing love, companionship, and guidance. Pamela and Maggie have been together for the past seven years.

Despite their daily challenges, Maggie and Pamela remain outgoing and cheerful. In their hometown of Colorado Springs, Pamela is known for her infectious laugh and great sense of humor, which Maggie seems to thoroughly enjoy. Maggie and Pamela's friends, Carl and Patti Grall, nominated Maggie for the 2009 Special Service Dog Award.

The *Sierra Foundation* will supply all of Maggie's nutritional needs for her entire life, including a complete supply of *Merrick Low Glycemic Pet Foods*, funded entirely by the *Glycemic Research Institute*®.

Congratulations to Maggie for a job well done!

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