

August 2, 2010

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Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

**Citizen Petition**

The undersigned submits this petition under Section 402 (a)(5) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to enforce existing law with pet foods and treats.

**A. Action requested**

Per Section 201 (f) of the Federal Food, Drug, and Cosmetic Act, "The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Thus, pet food and treats are included in the definition of food within the Act.

Section 402, Adulterated food, states "A food shall be deemed to be adulterated - (a) Poisonous, insanitary, or deleterious ingredients." "(a)(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter;"

Section 301 of the Act, states Prohibited Acts and Penalties: (a) "The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." (c) "The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise."

Presently, FDA compliance policy states "POLICY:

Pet food consisting of material from diseased animals or animals which have died otherwise than by slaughter, which is in violation of 402(a)(5) will not ordinarily be actionable, if it is not otherwise in violation of the law. It will be considered fit for animal consumption."

FDA compliance policy acknowledges violations of the Act in pet food. This Citizen Petition requests the Commissioner to enforce the Federal Food, Drug, and Cosmetic Act as it is written with respect to pet foods and treats.

Further, FDA allows pet foods that contain illegal ingredients sourced from diseased animals or animals that have died otherwise than by slaughter (labeled by FDA as "suitable for use in animal feed") to be marketed/sold to unknowing pet owning consumers as 'premium', 'choice', and a long list of pleasing terms. Section 403 of the Act states "A food shall be deemed to be misbranded- (a) False or misleading label. If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2)." Pet foods and treats that include ingredients sourced from diseased animals or animals that have died other than by slaughter, unless labeled as such (which of course there is none) would be a violation of labeling laws.

Petitioner(s) as well requests Commissioner to enforce all Food, Drug, and Cosmetic Act labeling laws for the safety and health of all pets.

**B. Statement of grounds**

The grounds of this request are Federal law; the Food, Drug, and Cosmetic Act. The Act clearly includes pet food/treats within the definition of food. The Act clearly deems a food to be adulterated and thus prohibited if it contains in whole or in part a diseased animal or an animal

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which has died other than by slaughter. FDA Compliance Policy states pet foods consisting of diseased animals or animals which have died other than by slaughter will not be actionable. This in itself is sufficient grounds to prove Federal laws are violated with some pet foods and treats.

Further, FDA report 'Risk of Pentobarbital in Dog Food' confirms some pet foods violate Federal Food, Drug, and Cosmetic Act. FDA testing found pentobarbital in dog food purchased off store shelves. Pentobarbital is used to euthanize dogs, cats, horses, and rarely cows. FDA testing confirming a euthanizing drug in dog food would/should deem those products adulterated; a violation of the Food, Drug, and Cosmetic Act.

Further, follow up FDA investigation determined that the common pet food ingredients "Meat and Bone Meal (MBM), Beef and Bone Meal (BBM), Animal Fat (AF), and Animal Digest (AD) are rendered or hydrolyzed from animal sources that could include euthanized animals." Based on this FDA research, any pet food or treat that contains meat and bone meal, beef and bone meal, animal fat, and/or animal digest could be adulterated according to the Act.

FDA commonly uses the term "suitable for use in Animal Feed". Until the recent ban on BSE Specified Risk Material (SRM) in animal feed, even these risk and illegal materials were deemed 'suitable for use in animal feed' by FDA. Federal Food, Drug, and Cosmetic Act does not separate definition and regulation of suitable for use of human food and suitable for use in animal food. Definitions of food, adulterated food, and prohibited food within the Act covers all food, human and animal.

Petitioner(s) believes FDA does not have authority to override Federal law. Various FDA/CVM documents make statement to CVM being unaware of any adverse health effects due to animals consuming pet foods/treats containing disease animals or animals that have died other than by slaughter. Regardless of such statements by CVM, Federal law states these type of pet food ingredients are illegal. Petitioner(s) requests FDA to enforce all Federal Food, Drug, and Cosmetic Act laws with respect to pet foods and treats. Petitioner requests that all pet foods and treats containing FDA's determined pentobarbital risk ingredients (meat and bone meal, beef and bone meal, animal fat, and animal digest) to be removed from store shelves until manufacturer can provide complete and concise evidence ingredients are within the guidelines of the Food, Drug, and Cosmetic Act. Petitioner requests that any pet food/treat manufacturer sourcing ingredients from 'dead stock' renderers and/or USDA rejected meat or meat products or 4D animals (rendered or otherwise) be considered adulteration high risk; requiring frequent FDA inspection and burden of evidence of compliance from the manufacturer.

#### C. Environmental impact

Petitioner(s) has no knowledge of environmental impact by FDA enforcing Federal Food, Drug, and Cosmetic Act. It is assumed however, that detailed environmental impact studies have previously shown no dramatic environmental impact when FDA enforces the Act. It is assumed that Congress would not have written and passed the Food, Drug, and Cosmetic Act - including the protection of pet food and treats - should a dangerous environmental impact be the outcome.

#### D. Economic impact

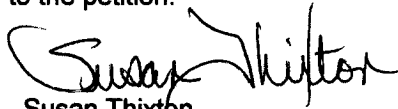
Petitioner(s) acknowledges the possibility of economic impact of industry. Petitioner(s) acknowledges the possibility of economic impact of pet owners.

The pet food ingredients meat and bone meal, beef and bone meal, animal fat, and/or animal digest (deemed by FDA testing to be most likely pet food ingredients to contain a euthanized animal) are used in many pet foods and treats in a variety of price categories. Various documents from related pet food industry businesses found on the FDA website discuss the economic impact to their industry when BSE Specified Risk Materials were banned from animal feed. Petitioner(s) would suspect that Rendering Industry, without the pet food/treat market as a sales outlet for ingredients sourced from diseased animals and animals that have died other than by slaughter, would suffer the greatest economic impact.

However, the economic impact to pet owners that unknowingly feed their dog or cat a food with ingredients sourced from diseased animals or animals that have died other than by slaughter must be considered as well. If meat or meat ingredients sourced from diseased animals or animals that have died other than by slaughter were considered nutritious and/or beneficial to the health of those that consume them, they would not be considered an adulterant by Federal Food, Drug, and Cosmetic Act. While there is no scientific evidence to prove pet foods/treats that contain an ingredient sourced from diseased animals or animals that have died other than by slaughter would have an adverse effect on the health of the pets that consume them, the Petitioner(s) takes a common sense approach. Common sense tells us because this type of meat ingredient is illegal according to Federal Food, Drug, and Cosmetic Act, Petitioner(s) believes these ingredients to be a risk to the health and longevity of pets. The long term health effects of a pet consuming such inferior and illegal ingredients could be quite costly in veterinarian care.

E. Certification

The undersigned list of concerned pet owners certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Susan Thixton

[Redacted] 5  
exemption 6

Sandy Duke

[Redacted] 3

Elizabeth A. Peters

[Redacted] 3

Robert Brian Vohs

[Redacted] 3

Cooper Thomas

[Redacted] 1

Kate DePaul

[Redacted] 9

Cynthia Tobias

[Redacted] 3

Brenda Robertson

[Redacted] 3

Michael Farkas

Jo Anne Rando-Moon

[Redacted] 1

[Redacted] 1

Maria Nilsson

[Redacted] 2

Tamara Kirschner

[Redacted] 3

Charles Willis

[Redacted] 1

Troy Bloxsom

[Redacted] 1

Kim Willis

[Redacted] 2

Charles Willis

[Redacted] 2

Adrienne Simpkins

[REDACTED] 3  
exemption 6

Judy Morgan  
[REDACTED] 4

Karryn Hart  
[REDACTED] 3

Margaret Payne  
[REDACTED] 2

Margo Baldrige  
[REDACTED] 5

Jill Boyle  
[REDACTED] 3

Robert Schwartz  
[REDACTED] 4

Dr. David Oliver  
[REDACTED] 7

Lorena Saxe  
[REDACTED] 3

Darleen Wood  
[REDACTED] 5

Edith Lee  
[REDACTED] 2

Kim Thomas  
[REDACTED] 9

Gloria J. Cestero-Hurd  
[REDACTED] 7

Karen Baratta  
[REDACTED] 5

[REDACTED] 2

Frances Takacs  
[REDACTED] 3

Kendyle Woodard  
[REDACTED] 3

Joan Beard  
[REDACTED] 7

KAREN OLSON  
[REDACTED] 5

MerveBeth Albert  
[REDACTED] 4

Kristine Jensen-Van Heste  
[REDACTED] 5

Carol Minkus  
[REDACTED] 5

Sherrill Meeker  
[REDACTED] 4

Denise Garrett  
[REDACTED] 4

Sharron Nuckols  
[REDACTED] 3

Rita Eccles  
[REDACTED] 4

Amy Thomson  
[REDACTED] 2

Patti Long  
[REDACTED] 4

Sallie Riley

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Barbara Woodcox

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Lindsey Anrette

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Sue Blanton

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Gary Woodcox

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Carrie Coulter

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[Redacted]

Victor Birdsong

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Tessa Gumm

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Tim Seagren

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behija mehremic

[Redacted] 3  
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Tyler Philp

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Donna LaLuzerne

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Linda J Pruitt

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Susan Woods

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Jacqueline Cameron

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Patricia Sweet

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Gwen Cleary

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Lorri Ketterman

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Christina LaHaie

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Viviane Lerner

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Michelle Leonard

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Stephen Baker

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Julie Piontkowski

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Gail Whitesmith

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Curtis Skurka

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Shanna Howard

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[Redacted]

Christine Wagner

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Sandra Short

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Carol Lobmeier

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Frances Osborn

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Sarah Smith

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Robert Welborn

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Diane Jurek

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Stephanie Kemper

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Ginny Marriott

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Linda Meyer

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Delisa Cook

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Lynette Lauer

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Kerri Wagner

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Joyce Miller

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adriana buttner

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Melissa Maston

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Nancy Harwood

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Valerie Smith

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Richard L. Weavil

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Jean Scime

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Pamela White

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Nancy Lancaster

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Kim Reagan

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Troy Reagan

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Holly Collins

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Ruth Brocklehurst

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cheryl kassed

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David Goldsmith

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Judith Boitt

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Audra Johnson  
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Gretchen Cox  
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heidi wollum  
[redacted] 9  
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Tammy McConnell  
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exemption 6

Marvalice Ammons  
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Linda Clark  
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Kellie Tatem  
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Mary E. Ricker  
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Holly L Price  
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Kathy Straedev  
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Margaret Stafford  
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Ellen O'Cibbir  
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Darryl Young  
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Iori marceau  
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Georgia Llewellyn  
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Thomas Lyons

Donna Metlin  
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Wendy Forster  
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Frank Feist  
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BARB MATHEWS  
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Pamela Johnson  
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Olivia Schlowwer  
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[Redacted] 3

Victoria Butler  
[Redacted] 4  
[Redacted]

Angel Rosell

exemption 6

Sandeleh Francis

Danita Condrav

Joan Rochford

J.B. Johnson-Allen

Emilie M Bottiagi

christal couturier

Rhonda Magnotti

Leah Weeks

Darlene Roy

Lisa Wesley

Patricia M. Smock

ronald r kowalski

Mickey Meincke

joni futterer

Kristen Campbell

Melissa Ellis

Elinor Lee

Rich Chambers

Dorine Getty

Pauline Pellack

Sandy Giannetti

LISA WIDENHOFFER

christina skaggs

Jane Ries

Sharon White

Jana Benitez

Melissa Spreda

Magdalena Mazurek

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Andrea Kelly  
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Patricia Chelton  
[Redacted] 0  
[Redacted] 1

Judith M. Meek  
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Lori Coleman  
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Susan M Weatherford  
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Arlene Aquino  
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Susan Weyrauch  
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Michelle Profant  
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Karin Wallin  
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Vicki Fitzgerald  
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Lynne Fowler  
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Diane Cail  
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Marlene Rossman  
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Anna Williams Lavoie

[Redacted] 5  
Barbara Morrissette  
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Alan Thompson  
[Redacted] 3  
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Liliana Ruano  
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Susan Smith  
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Lisa Delano  
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Julie Papay  
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Lien Muir  
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Patricia Fiscella  
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Kathy Chadwell  
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Michael Cecere  
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Stephen Cecere  
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Alison Roth  
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Sandy Arora  
[Redacted] 1  
[Redacted] 1

Connie J. Bickerton  
[Redacted]

exemption 6 [redacted] 3

Deborah Fritzier [redacted] 1

F. Peter Hall [redacted] 2

Rhea Elliott [redacted] 4

Darryl F. Littlepage [redacted] 3

Linda Kelly [redacted] 4

Nancy Passage [redacted] 0

Lynda Miller [redacted] 4

Ethel Quinn [redacted] 1

Marianne Castiglia [redacted] 7

Leslie Machado [redacted] 2

Dale Reindl [redacted] 1

Christian Bruce [redacted] 1

Dana Radell [redacted] 3

Stefanie Bohannon [redacted]

[redacted] 3

Shirley A. Xistras [redacted] 7

Linda Dominguez [redacted] 5

Kim Hammon [redacted] 5

Brenda Donovan [redacted] 3

Robin Dorey [redacted] 1

Catherine Houston [redacted] 2

Alice Bowron [redacted] 2

Lauren Tourville [redacted] 3

Eric Lee [redacted] 4

Debby Bradford [redacted] 4

Adrienne Tucker [redacted] 3

Diane Lauer [redacted] 2

Karen Sue Tucker [redacted] 3

Theresa Clark [redacted]

Mary K Chelton  
[REDACTED] 2

exemption 6

Tim Nyce  
[REDACTED] 0

Kathleen Murray  
[REDACTED] 4

Dr. Vickie West  
[REDACTED] 4

Patricia Lauer  
[REDACTED] 3

Michael S Wilson  
[REDACTED] 2

Donna Hoaglin  
[REDACTED] 7

Alena Mammana  
[REDACTED] 0

Molly Needleman  
[REDACTED] 1

Diana Dunigan  
[REDACTED] 3

Vicki Anderson  
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Catherine Cox  
[REDACTED] 3

Jody Newman  
[REDACTED] 1

annmarie taylor  
[REDACTED] 7

[REDACTED] 9  
Shevl Culley  
[REDACTED] 2

Debbie Culley  
[REDACTED] 2

Ed Culley  
[REDACTED] 2

Devon Melanie Dougall  
[REDACTED] 7

Linda Sergio  
[REDACTED] 5

Pamela Bryan  
[REDACTED] 4

Andrea James  
[REDACTED] 3

BEN GRAVELY  
[REDACTED] 2

Tracy Haramia  
[REDACTED] 7

Amy Blomquist  
[REDACTED] 1

Debra Ciarletta  
[REDACTED] 2

F.J McCabe  
[REDACTED] 3

Tammy Henost  
[REDACTED] 5

Merilee Kelley  
[REDACTED]

Shona Bailey Powers

[REDACTED] 3

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Stephen Legg

[REDACTED] 9

[REDACTED] 4

Vicki Graves

[REDACTED] 2

[REDACTED]

Barbara Gunvaldsen

[REDACTED] 7

[REDACTED] 3

Jeanne Hensley

[REDACTED] 6

[REDACTED] 2

Susie Gillam

[REDACTED] 5

[REDACTED] 9

Cynthia Lewis

[REDACTED] 4

[REDACTED] 1

Carol Jordan

[REDACTED] 1

[REDACTED] 6

Betzi Bateman

[REDACTED] 3

[REDACTED] 6

Pat Bourret

[REDACTED] 2

[REDACTED] 4

Carol Kerr

[REDACTED] 4

[REDACTED] 0

[REDACTED] 0

Toby Levy-Preston

[REDACTED] 0

[REDACTED] 2

CAROLINE BROMM

[REDACTED] 5

[REDACTED] 3

Nancy Champion

[REDACTED] 2

[REDACTED]

[REDACTED] 1

Owen Kelley

[REDACTED] 1

[REDACTED] 1

Diane Orado

[REDACTED] 3

[REDACTED] 4

Sharon Collette

[REDACTED] 5

[REDACTED] 1

Debbi Cole

[REDACTED] 0

[REDACTED] 3

Sharon Bolton

[REDACTED] 4

[REDACTED] 2

nelly valla

[REDACTED] 3

[REDACTED] 3

Karen Cannon

[REDACTED] 2

[REDACTED] 1

Catherine Leece

[REDACTED] 1

[REDACTED] 4

cory paul

[REDACTED] 1

[REDACTED] 3

[REDACTED] 3

ellen richter

[REDACTED] 7

[REDACTED] 9

Catherine Houston

[REDACTED] 2

[REDACTED] 9

Shawn Chelf

[REDACTED] 2

[REDACTED] 1

Janet Seeley

[REDACTED] 5

[REDACTED] 2

Karen Niemczura



Samuel Luke Oglesby

exemption 6

Aida Marina

Pamela Miller

Melissa Adams

Kathy Burgess

Valerie Roberts

Chuck Gruver

Faye Bishop

Kathleen Mahoney

Karen Murray

Elizabeth Witt

Rebecca Homan

Debbie Hoblitzell

Lynn Curtis

Carrie Ouradnik

Susan Ann Kelley

Diane Richards

Anne Williams

MICHAEL DONOVAN

Alex Irinvi

Louise E. Quinlan

Peggy Wunder

Tamy Sullivan

JEAN JAKUSZ

Jeanne Nash

pamela hobby

Alexis Van Kerkhove

Bonnie Escobar

exemption 6

Joni W. Lowther

[REDACTED] 7

Melanie Burian

[REDACTED] 2

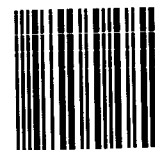
[REDACTED] 5

Nancy Burke

[REDACTED] 7



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