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BEFORE THE UNITED STATES DISTRICT COURT  
 DISTRICT OF NEW JERSEY

IN RE PET FOOD PRODUCTS : Civil Action No. 07-2867  
 LIABILITY LITIGATION :  
 : MDL Docket No. 1850 (ALL  
 : CASES)  
 :  
 : **DEL MONTE'S NOTICE OF**  
 : **EMERGENCY MOTION TO LIMIT**  
 : **ITS RETENTION OF RECALLED**  
 : **PET TREATS, FOOD, RAW WHEAT**  
 : **GLUTEN AND MIXTURES**  
 : **CONTAINING RECALLED WHEAT**  
 : **GLUTEN**

**ORAL ARGUMENT REQUESTED**

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**PLEASE TAKE NOTICE** that pursuant to Fed. R. Civ. P. 26(b)(2)(C)(iii), 26(c)(2) and 26(c)(4), and upon an expedited briefing schedule to be determined by this Court, Defendant Del Monte Foods Company ("Del Monte"), shall move in the United States District Court, for the District of New Jersey, Mitchell H. Cohen Building & U.S. Courthouse, 4th Street & Cooper Streets, Room 1050, Camden, New Jersey 08101, before the Honorable Noel L. Hillman, U.S.D.J., for an Order limiting the amount of pet food, treats, raw wheat gluten and mixtures

containing recalled wheat gluten (cumulatively referred to as "Product" or "Products") that Del Monte is currently storing. Del Monte seeks to retain only a statistically representative amount of Product, as set forth in the accompanying sampling plan of Dr. George P. McCabe.

Del Monte moves to limit its retention of Product because: (1) the FDA has directed that Del Monte destroy all Product in its possession; (2) there exist public health and safety concerns associated with the continued storage of large quantities of Product, including but not limited to cross-infestation and inadvertent re-entry into the stream of commerce; (3) there are significant costs associated with storing the Product which is comprised of over 51,000 pounds of recalled ChemNutra, Inc. wheat gluten; 42,000 pounds of mixtures containing recalled wheat gluten; 1,028,306 million units<sup>1</sup> of organized recalled pet treats and food; and, 83,526 containers of unorganized inventory; and, (4) the substantial financial burden and the actual and potential health and safety issues associated with storing these large quantities of Product are unnecessary because retention of a statistically representative subset of these Products will satisfy the future research needs of Plaintiffs and any other interested persons or entities.

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<sup>1</sup> A unit is a can, bag or pouch of pet treats or food that is packaged for individual retail sale.

Thus, Del Monte seeks an Order directing that Del Monte: (1) need only retain up to 500 units of pet treats or food per SKU date from its Organized Recalled Product in accordance with Dr. McCabe's sampling plan; (2) need only retain 500 samples per batch number of raw wheat gluten and recipe of mixtures containing recalled wheat gluten, respectively, in accordance with Dr. McCabe's sampling plan; and (3) permitting Del Monte to destroy the Unorganized Material as well as all other Product in its possession that is not needed to execute Dr. McCabe's sampling plan.

PLEASE TAKE FURTHER NOTICE that in support of its Motion, Del Monte Foods Company will rely upon the accompanying Memorandum of Points and Authorities; the Affidavit of Richard Fama; the Affidavit of Good Faith of Richard Fama; The Declaration of Michael Hayes; the Declaration of George P. McCabe; and all other papers filed with this Court in this litigation. A proposed form of Order is also submitted herewith.

Dated: November 16, 2007

Respectfully submitted,

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: **MEMORANDUM OF POINTS AND**  
: **AUTHORITIES IN SUPPORT OF**  
: **DEL MONTE'S EMERGENCY**  
: **MOTION TO LIMIT ITS**  
: **RETENTION OF RECALLED PET**  
: **TREATS, FOOD, RAW WHEAT**  
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I. INTRODUCTION AND SUMMARY

On April 1, 2007 and April 6, 2007, Del Monte issued recalls of certain pet treats and food it manufactured with wheat gluten purchased from ChemNutra, Inc., due to possible contamination.<sup>1</sup> These recalls serve as the basis for Del Monte's

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<sup>1</sup> ChemNutra, Inc. recalled 18 "batch numbers" of wheat gluten on April 2, 2007 imported from one Chinese supplier due to possible contamination.

inclusion in this litigation. As a result, Del Monte has continued to store over 51,000 pounds of recalled ChemNutra, Inc. wheat gluten; 42,000 pounds of mixtures containing recalled wheat gluten; 1,028,306 million units<sup>2</sup> of organized recalled pet treats and food; and, 83,526 containers of unorganized inventory (collectively, "Product" or "Products").

A. Product Currently Stored by Del Monte

There are four categories of Product currently stored by Del Monte that are the subject of this Motion: Organized Recalled Product, Unorganized Inventory, raw wheat gluten and Work-In-Progress.

The majority of product currently being stored by Del Monte is "Organized Recalled Product." See ¶ 4 of the Declaration of Michael Hayes, Director of Quality Assurance at Del Monte Foods Company accompanying this Memorandum, ("Hayes Decl."). Organized Recalled Product for purposes of this motion means units of recalled pet food treats and food that are presently organized in a manner similar or identical to that in which they were packaged by Del Monte at its manufacturing facilities. See Hayes Decl., ¶ 4. Organized Recalled Product is

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<sup>2</sup> A unit is a can, bag or pouch of pet treats or food that is packaged for individual retail sale.

comprised of pet treats and food manufactured by Del Monte that never left Del Monte's possession, as well as pet treats and food that were returned to Del Monte in a manner similar or identical to the way Del Monte shipped the goods. Hayes Decl., ¶ 4. Typically, the Organized Recalled Product is packaged with individual units contained within cardboard cases. The cases are stacked and placed on top of full or partial pallets. Hayes Decl., ¶ 4. Because Organized Recalled Product exists in a manner similar or identical to that in which it was packaged by Del Monte, it can be easily inventoried and accounted for by Del Monte. Hayes Decl., ¶ 4. The Organized Recalled Product can be identified by brand and product type (also referred to as "SKU")<sup>3</sup> and by date of production (collectively, the "SKU date"). Hayes Dec. ¶ 4.

A complete inventory of Del Monte's Organized Recalled Product can be found in Attachment 1 to Hayes Decl. The cost to Del Monte of storing the 1,028,306 units of Organized Recalled Product is over \$29,000 per month and \$348,000 per year. Hayes Decl., ¶ 6.

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<sup>3</sup> SKU is an acronym for Stock Keeping Unit, and it is the identifier used by the retailer and supplier to locate an individual product as it appears on the retailer's shelf.

The second type of product currently stored by Del Monte is "Unorganized Inventory." Unorganized Inventory refers to containers of varying types that are predominantly re-used banana boxes. Hayes Decl., ¶ 7. The contents of these containers are haphazardly organized and may contain recalled Del Monte pet food products, but often also contain pet food products that were not subject to Del Monte's recalls and other manufacturers' product. Hayes Decl., ¶ 8. Many of these containers also contain such items as car parts, household cleaners, and other non pet food products. Hayes Decl., ¶ 8. Because of the unorganized nature of these containers and the amount of handling that they have been subjected to prior to Del Monte's receipt of them, the items contained therein frequently break open, causing their contents to spill or leak, resulting in the single greatest cause of infestation at Del Monte's facilities. Hayes Decl., ¶ 8. Del Monte has estimated that it is currently storing 83,526 containers of Unorganized Inventory. Hayes Decl., ¶ 7. The cost to Del Monte to create an inventory of this Unorganized Material, if required, is estimated to be \$167,052. Hayes Decl., ¶ 9.

The third category of product stored by Del Monte is recalled raw wheat gluten that was purchased from ChemNutra, Inc. Hayes Decl., ¶ 10. The raw ingredient is stored by Del

Monte in 55-pound bags, which are the same bags they were shipped in by ChemNutra, Inc. Hayes Decl., ¶ 10. A complete accounting of Del Monte's inventory of raw wheat gluten can be found at paragraph 10 of the Hayes' Decl., which accompanies this Memorandum.

The fourth category of product currently stored by Del Monte is "Work-In-Progress." Hayes Decl., ¶ 11. Work-In-Progress is a dry mixture of ingredients that was pulled off the production line by Del Monte at the time of its recall. Hayes Decl., ¶ 3. This dry mixture contains, in part, recalled wheat gluten purchased from ChemNutra, Inc. Hayes Decl., ¶ 3. Del Monte is storing over 42,000 pounds of Work-In-Progress in large tote bags. Hayes Decl., ¶ 11.

All four categories of Product are infested with various insects and maggots. Hayes Decl., ¶ 13. Del Monte has been forced to repeatedly fumigate this Product and will be required to continue doing so. Hayes Decl., ¶ 13.

Attached to the Hayes Declaration as Attachment 3 are photographs that depict the storage and condition of the Products central to this motion.<sup>4</sup> In these photographs, the

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<sup>4</sup> These photographs are annexed to Michael Hayes' Declaration as Attachment 3.



Unorganized Inventory is discernable from the Organized Recalled Product without explanation. The infestation and content leakage from the canned goods is also clear. The infestation and leakage as depicted will only worsen over time.

B. The Burdens on Del Monte Due to Continued Storage Of Infested Product

In addition to identifying the categories of infested Products held by Del Monte, Michael Hayes' Declaration also describes the impact the infestation has had on Del Monte's business. Del Monte was forced to move infested pet treats and food from a distribution center in Fort Worth, Texas to an Independence, Missouri warehouse due to fears that the Fort Worth location would fail a safety and health audit by the American Institute of Baking ("AIB"), which inspects distribution centers for food safety risks. Passing an AIB audit is a condition precedent for many of Del Monte's customers, including Wal-Mart. Therefore, failing an AIB audit would significantly affect Del Monte's business practices.

Most importantly, on November 13, 2007, The Food and Drug Administration ("FDA") confirmed previous communications with Del Monte and recommended the complete destruction of all four categories of Product due to health and safety concerns. The FDA has acknowledged that the current health and safety hazards concerning the retention of these Products are not due

to Del Monte's handling or management of the Products, but are the result of the lengthy duration of time the Products have been stored. Specifically, the FDA has advised Del Monte that destruction is recommended because, historically, the longer recalled products are retained, the greater the likelihood they will be accidentally introduced into the stream of commerce, even when the utmost care is taken. The FDA's correspondence to Del Monte can be found as Attachment 2 to the Hayes Declaration.

Because of these burdens, Del Monte, in conjunction with other Defendants, has been working with two Plaintiff groups to reach an agreement on the retention and sampling of the Products subject to this motion. However, after over two months of negotiation with very little evidence that the Plaintiffs groups are willing or able to reach a timely agreement, the continued infestation, and the FDA's recommendation to destroy all of the stored Products, Del Monte has been forced to move this Court for relief.

Also accompanying this Memorandum is an Affidavit of Good Faith of Richard Fama that chronicles Del Monte's efforts to resolve this discovery dispute in good faith prior to making this motion. The contents of that Affidavit are incorporated by reference herein.

C. The Sampling Recommendation by Del Monte's Expert

Although the FDA has recommended the complete destruction of Product, Del Monte, realizing its duty to preserve potential evidence, instead seeks to retain only a statistically representative sample of the Product in question. To establish the amount of Product that is sufficient to satisfy the future testing requirements of Plaintiffs and all other interested parties, Dr. George P. McCabe, Professor of Statistics, and Associate Dean for Academic Affairs, College of Science, at Purdue University, has been retained by the Defendants, including Del Monte, to conduct an analysis and offer his opinion as to the quantity of Product needed to be retained, as well as a method of collecting a representative sampling of the Product. The Declaration of Dr. George P. McCabe accompanies this Memorandum, ("McCabe Decl.").

Dr. McCabe opines that Del Monte need only retain samples from each SKU date of Organized Recalled Product, batch of raw wheat gluten, and recipe of Work-In-Progress to determine the mean percent of contamination, plus or minus two standard deviations, for each population. McCabe Decl., ¶ 4. His Declaration demonstrates that Del Monte should be relieved of the extreme burden and expense of storing and maintaining all of the Product presently in its possession, and also demonstrates

that Del Monte can reconcile the FDA's recommendation to destroy all of the Product to ensure Public Health and Safety with its duty to preserve potential evidence in this litigation.

According to Dr. McCabe, Del Monte's retention of up to 500 units of Organized Recalled Pet Food Product per SKU date would satisfy Plaintiffs' and others' future needs to identify the range of the percentage of contamination, if any, on any particular SKU date. McCabe Decl., ¶ 10.

As Dr. McCabe describes in his Declaration, taking samples of up to 500 units of pet treats or food for each SKU date will result in a 95% statistical confidence that testing on the sample population will be statistically equivalent to the results that would be obtained by sampling every unit from that SKU date. If Del Monte is currently storing less than 500 units for a given SKU date, Dr. McCabe's sampling plan calls for 500 samples for the total number of units available. McCabe Decl., ¶ 16.

In addition, Dr. McCabe describes the manner in which the Product should be collected by Del Monte to assure that the units retained are randomly selected and are therefore an adequate representative sample of each SKU date. McCabe Decl., ¶ 16. Dr. McCabe has created a multi-staged random sampling plan to select the 500 units needed to estimate the range of the

percentage of contamination, if any, on each SKU date. McCabe Decl., ¶ 16.

With respect to the raw wheat gluten and Work-In-Progress, Dr. McCabe's plan involves randomly selecting 500 samples from each batch number of wheat gluten and recipe of Work-In-Progress. McCabe Decl., ¶¶ 17, 18. This plan will ensure that Del Monte retains enough product to allow for future testing to determine the range of percentage of contamination in each of these ingredients for each batch number or recipe, respectively. McCabe Decl., ¶¶ 17, 18.

It is clear upon reading Del Monte's Organized Recalled Pet Food inventory (Attachment 1 to the Hayes Decl.) that Del Monte has in its possession enough Organized Recalled Product to complete Dr. McCabe's sampling plan for 47 out of the 48 SKU dates that were subject to its recalls. Dr. McCabe concurs. McCabe Decl., ¶ 13; See also Exhibit 2 to McCabe Decl. Therefore, it is respectfully submitted that Del Monte's continued possession of Unorganized Inventory is not necessary. In addition to the exorbitant expense that Del Monte would incur if forced to cull recalled pet treats and food from the other irrelevant inventory that is haphazardly contained in these containers, the Unorganized Inventory is significantly infested. Hayes Decl., ¶¶ 8, 9; See also Attachment 3 to the Hayes Decl.

As explained earlier, the Unorganized Inventory contains leaking product, fly infestation and maggots. Hayes Decl., ¶ 8.

Del Monte's recalls included one SKU date, SKU 583880, for which Del Monte is not maintaining any Organized Recalled Product. Hayes Decl., ¶ 5. To the extent Plaintiffs desire to inventory and test the Unorganized Inventory in Del Monte's possession in search of units from SKU 583880, they may do so at their own expense after they take possession of the Unorganized Inventory. Del Monte has previously offered both its Organized Recalled Product and Unorganized Inventory to the Plaintiffs on several occasions, without a substantive reply. Plaintiffs failure to respond to this offer speaks volumes about the impracticality and need to sort through the Unorganized Inventory. If Plaintiffs choose not to take possession or inventory the Unorganized Inventory, Del Monte should be permitted to discard it since: (1) the FDA has so directed it; (2) a representative sample from each SKU date can be obtained from the Organized Recalled Product in Del Monte's possession; and (3) the Unorganized Inventory is the single greatest source of infestation. See Hayes Decl., ¶ 8, 15.

The preservation of all Unorganized Inventory on the chance that it includes units of SKU 583330 is also unnecessary because the percent of contamination for this SKU date can be

estimated using other data. Michael Hayes' Declaration states that this SKU date utilized ChemNutra, Inc. wheat gluten from batch number 20061101 and that this particular recipe contains 2.43% wheat gluten. Hayes Decl., ¶ 5. Del Monte is currently storing 21 full and 5 partial 55-pound bags of ChemNutra, Inc. batch number 20061101. Using Dr. McCabe's sampling plan, the range of contamination of batch number 20061101 will be available to the Plaintiffs. This, together with the percent of wheat gluten used in the manufacture of SKU 583330, provides the Plaintiffs with an accurate estimate of the percent of contamination in the finished product, if any. Given this alternate means of obtaining the information Plaintiffs may seek, Del Monte should not be burdened with preserving all of the Unorganized Inventory in its possession.

Accordingly, Del Monte asks this Court to issue an Order directing that Del Monte: (1) need only retain up to 500 units of pet treats or food per SKU date from its Organized Recalled Product in accordance with Dr. McCabe's sampling plan; (2) need only retain 500 samples per batch number of raw wheat gluten and recipe of mixtures containing recalled wheat gluten, respectively, in accordance with Dr. McCabe's sampling plan; and (3) permitting Del Monte to destroy the Unorganized Material as

well as all other Product in its possession that is not needed to execute Dr. McCabe's sampling plan.

II. Legal Argument

A. THE COURT SHOULD ISSUE AN ORDER THAT LIMITS THE REQUIRED RETENTION OF PRODUCTS TO A REPRESENTATIVE SAMPLE OF THE PRODUCTS BEING STORED BY DEL MONTE

This Court has broad power under Fed. R. Civ. P. 26(b) and (c) to "deny, limit or qualify discovery." United States v. Princeton Gamma-Tech, 817 F. Supp. 488, 493 (D.N.J. 1993) (Fisher, J.) (granting motion to limit discovery).<sup>5</sup> For good cause, this Court may order that discovery "be had only on specified terms and conditions" and "be limited to certain matters" in order to avoid the "undue burden or expense" of discovery. Fed. R. Civ. P. 26(b)(2), 26(c)(2), 26(c)(4). Good cause exists when "'the burden or expense of the proposed discovery outweighs its likely benefit.'" Maertin v. Armstrong World Indus., Inc., No. 01-5321, 2007 U.S. Dist. LEXIS 20561, at \*4, \*6 (D.N.J. Mar. 8, 2007) (Schneider, J.) (quoting Fed. R. Civ. P. 26(b)(2)(iii)) (rejecting request for insurer's claims

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<sup>5</sup> Fed. R. Civ. P. 26(c) provides: "Upon motion by a party . . . from whom discovery is sought . . . the court in which the action is pending . . . may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. . . ." While no discovery has been served, Defendants are preserving the products and raw wheat gluten, pursuant to their Fed. R. Civ. P. 26 duty, and seek relief from that requirement prior to Defendants' service of their discovery requests.



files, which were located in 27 offices, because of the "burden and expense to obtain the requested discovery").

As demonstrated below, issuing the requested Order will save Del Monte from the undue burden and expense of storing over 1 million cans of Organized Recalled Product, over 51,000 pounds of raw wheat gluten, 42,000 pounds of Work-In-Progress, and 83,526 containers of Unorganized Inventory that each present public health and safety hazards. Hayes Decl., ¶¶ 3, 10, 11.

This Court (and others in this Circuit) has limited discovery to prevent parties from incurring unnecessary expenses during discovery, especially when the burdens of providing the requested discovery outweigh any potential benefits to the party seeking discovery. Reichhold, Inc. v. U.S. Metals Refining Co., No. 03-453, 2007 U.S. Dist. LEXIS 34284, at \*5, \*27-29 (D.N.J. May 8, 2007) (Debevoise, J.) (affirming decision of magistrate judge; finding that the burden on defendants of "pursuing further information about [defendants'] lead plant was far outweighed by any potential benefits," even though plaintiffs argued that the case was worth millions of dollars and that defendants had "more resources" than plaintiffs); Quadrant EPP USA, Inc. v. Menasha Corp., No. 06-356, 2007 U.S. Dist. LEXIS 6539, at \*5-6 (E.D.Pa. Jan. 29, 2007) (denying defendant's motion to compel discovery, which, if granted, would have

required plaintiffs to review 50,000 pages of hard copy documents; "the burden borne by the plaintiffs in producing" the requested discovery "clearly outweighs any benefit the defendant might receive").

Further, discovery responses can be properly limited to statistical samples where the burden of full production outweighs its potential benefits. In Benson v. Joseph Regional Health Ctr., No. 04-04323, 2006 U.S. Dist. LEXIS 34815, at \*4-7 (S.D.Texas May 17, 2006), the District Court permitted defendant health center to produce only a "representative sample" of the requested documents. The plaintiff physician in Benson brought an antitrust action against defendant and sought the production of 1,336 patient charts (each chart ranged in length from 80 to 120 pages) to prove disparate treatment. Id. at \*4. Upon request by defendant, Benson allowed defendant to produce only a "representative sample" of the patient charts up to one fourth of the total charts (roughly 350 charts) because "imposing the full expense of producing all 1,336 charts upon Defendants would be undue and unfair." Id. at \*4-7 (granting in part defendant's motion to limit the District Court's previous order compelling discovery of a group of patient charts). The District Court explained that the marginal benefit to plaintiff of obtaining

charts beyond the representative sample was small compared to the considerable "expense of producing each chart." Id. at \*4.

Similarly, in Long v. Trans World Airlines, 761 F. Supp. 1320, 1328-30 (N.D. Il. 1991), the District Court granted plaintiffs' motion for a protective order limiting discovery regarding class-wide damages to that "extrapolat[ed] from a representative sample" of the roughly 3,000 class members. In Long, plaintiffs, flight attendants sued their employer for failing to provide designated rights letters after the plaintiffs went on strike and were not re-hired. Id. Defendant sought discovery regarding individualized damages suffered by each of the 3,000 class members. Id. Long held that the benefits of full discovery of individual damages -- even given the court's concern for protecting individual class plaintiffs -- were outweighed by the substantial burden that could be "reduced considerably by limiting discovery to a representative sample." Id. Long agreed with plaintiffs that the use of random sampling to establish damages was proper.<sup>6</sup>

As in the cases above, any benefit associated with maintaining all of the Product at issue here is far outweighed by the expense and undue burden placed on Del Monte. In

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<sup>6</sup> Long did not determine what method for obtaining the sample was proper, as the parties had not addressed that issue. 761 F. Supp. at 1326.

addition, like Benson and Long, this Court should allow Del Monte to preserve only a representative sample of Product based on the sound statistical principles used by Dr. McCabe. See Long, 761 F. Supp. at 1330 (stating that the appropriate size of the sample may be determined through expert testimony, which could be "provided initially by way of affidavits").

Dr. McCabe's conclusions show that Del Monte need not continue to incur the exorbitant expenses and burdens associated with storing enormous quantity of recalled product, particularly given the public health and safety concerns raised by the FDA. Representative sampling allows for future testing regarding the extent of contamination, if any, which results may then be extrapolated and applied to the original total population of product. McCabe Decl., ¶ 2. In weighing the burdens here, Del Monte's burden to keep all of the Product, coupled with the specter of a possible health and safety crises, "far outweighs [the products'] usefulness" because Plaintiffs can determine the extent of the contamination, if any, by inspecting and testing the representative samples. Maertin, 2007 U.S. Dist. LEXIS 20561, at \*3.

It should be noted that Dr. McCabe's representative sampling plan will yield reliable and valid results. The Reference Manual on Scientific Evidence (pp. 98-102, 2d ed.

2000) expressly approves of analytical testing on sampled units to measure the larger population, as long as the sampling is not biased. For example, in criminal drug cases, chemists are used to analyze a representative sample of the seized items "to determine the total quantity of illicit drugs in all the items seized." The Reference Manual on Scientific Evidence, p. 99 n.45. Courts consistently use results based on the testing of representative samples, even in criminal cases that "warrant[] special concern." E.g., United States v. Shonubi, 895 F. Supp. 460, 465, 518, 519-521 (E.D.N.Y. 1995) (Weinstein, J.) (for sentencing purposes, relying on statistical data from representative samples, in part, in finding that defendant "smuggled between 1,000 and 3,000 grams on his eight trips"); NutraSweet Co. v. X-L Eng'g Co., 227 F.3d 776, 782, 787, 792 (7th Cir. 2000) (affirming the District Court's conclusion that defendant was liable to NutraSweet for polluting NutraSweet's property where NutraSweet's expert tested soil samples to measure the amount of contamination).

Another factor supporting good cause for the requested Order is the "availability of other means of proof." Moore's Federal Practice § 26.104[1] (citing Brittain v. Stroh Brewery Co., 136 F.R.D. 408, 415 (M.D.N.C. 1991)). The testing of the representative sample of the Products is a sufficient

alternative available to Plaintiffs in lieu of testing all of those items. See McCabe Decl., ¶ 10. Thus, Plaintiffs have no need to test Products falling outside of the representative sample and an Order limiting the amount of retained Product is proper. McCurdy v. Wedgewood Capital Mgmt. Co., No. 97-4304, 1998 U.S. Dist. LEXIS 18875, at \*31 (E.D.Pa. Nov. 16, 1998) (explaining that "a showing of irrelevancy of the proposed discovery can satisfy the good cause requirement for a protective order").

Del Monte has presented a scientifically sound plan that can be used to select a representative sample. See McCabe Decl., ¶ 10. By following this plan, Del Monte will be able to gather and retain a random, unbiased sample of product per SKU date, batch or recipe, as appropriate, that will produce results that are statistically significant with a 95% confidence level. See McCabe Decl., ¶ 10. At this confidence level, there is only a 5% chance that the results from testing the representative sample will be due to chance alone, and a 95% chance the sampling will yield accurate results. Reference Manual on Scientific Evidence, pp. 123-25. These margins of error correspond to 95% statistical confidence, the usual level of confidence used in applied work. McCabe Decl., ¶ 10.

III. THE FDA AGREES WITH DEL MONTE THAT THE STORED RAW WHEAT GLUTEN SHOULD BE DESTROYED

The FDA is actively investigating the cause and source of the contamination of the recalled pet food.<sup>7</sup> On November 13, 2007, the FDA clearly informed Del Monte by email that it should proceed with the destruction of all of its recalled pet treats, food, raw wheat gluten and Work-In-Progress. Hayes Decl., ¶ 15; See also Attachment 2 to the Hayes Decl. The FDA stated that such destruction is necessary to prevent the recalled products from entering the marketplace. Attachment 2 to the Hayes Decl. The FDA also acknowledged that the risk of introduction into the marketplace is not due to Del Monte's handling of the product. Attachment 2 to the Hayes Decl. Instead, the FDA's experience informs it that, generally, the longer recalled product is stored, the more likely it is to be introduced into the marketplace. See Attachment 2 to the Hayes Decl.

The FDA has authority to issue the foregoing instruction to Del Monte under the Federal Food, Drug, and

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<sup>7</sup> The FDA has explained the scope of its investigation on its website and during press conferences. The FDA has stated: (1) the purpose of the "comprehensive investigation [is] to protect the nation's food supply" (Pet Food Recall, May 31, 2007); (2) the FDA's "priority now is to assure that all contaminated product is identified and removed from store shelves" (FDA Synopsis on the Pet Food Outbreak, April 7, 2007); and (3) the FDA is investigating, "sampling" and "testing" all imported "rice protein" and "wheat gluten" to determine their safety (Consumer Update: Contaminant Found in Second Pet Food Ingredient, April 23, 2007; FDA Synopsis on the Pet Food Outbreak, April 7, 2007).

Cosmetic Act (the "FDCA") and pursuant to its regulations addressing product recalls (21 C.F.R. §§ 7.40-7.59). Under the FDCA, the FDA has broad powers to protect the public health. 21 U.S.C. §§ 321, 393 (requiring the FDA to ensure that "foods are safe, wholesome, sanitary, and properly labeled," which includes "food or drink for man or other animals"). The FDA is best qualified to address "[i]ssues relating to product recalls." Restatement (Third) of Torts (Products Liability) § 11 cmt. a ("Issues relating to product recalls are best evaluated by governmental agencies capable of gathering adequate data regarding the ramifications of such undertakings.").

It is respectfully submitted that this Court should defer to the FDA's expertise and its conclusion that the continued storage of all Product by Del Monte harms the public interest. Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 230-31 (3rd Cir. 1990) ("Because 'agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise.'" (quoting McKart v. United States, 395 U.S. 185, 194 (1969))); Wells Fargo Bank of Tex. NA v. James, 321 F.3d 488, 494 (5th Cir. 2003) (stating that the FDA is "afforded deference in the interpretation of the law under which it acts"). District



Courts within the Third Circuit have deferred to FDA findings, even when the findings are not codified as formal regulations, such as in the preemption context. Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D.Pa. 2006) (explaining that the FDA's statements in the Federal Register were "dispositive" on the preemption issue and affording "significant deference" to the FDA's statements in amicus briefs); Sykes v. Glaxo-SmithKline, No. 06-1111, 2007 U.S. Dist. LEXIS 22998, at \*54-82 (E.D.Pa. Mar. 28, 2007) (giving "significant deference" to the FDA's statements in the Federal Register and relying on the FDA's statements in amicus briefs in determining that federal law preempted the state law claim).

Del Monte is not asking to destroy all Product as the FDA recommends. It seeks only to follow the FDA's sound advice as much as possible, thereby making the ongoing storage of product manageable, while preserving a sufficient quantity of same.

Del Monte requests that this Court take judicial notice of the FDA's email (In re Wellbutrin SR/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 755 (E.D. Pa. 2003) (taking judicial notice of a FDA report published on its website)), and require that Del Monte preserve only a representative sampling of its current storage of product. Del Monte is capable of

storing a representative sample of the Organized Recalled Product, raw wheat gluten and Work-In-Progress (but not all of it) without creating the risks addressed by the FDA, without significant expense to it, and without interference with its business practices.

IV. CONCLUSION

Plaintiffs have no need to inspect and test all of the Product being stored by Del Monte. Thus, Del Monte respectfully requests that this Court issue an Order that limits the amount of Organized Recalled Product, raw wheat gluten, and Work-In-Progress as follows: (1) Del Monte need only retain up to 500 units of pet treats or food per SKU date from its Organized Recalled Product in accordance with Dr. McCabe's sampling plan; (2) Del Monte need only retain 500 samples per batch number of raw wheat gluten and recipe of Work-In-Progress, respectively, in accordance with Dr. McCabe's sampling plan; and, (3) permitting Del Monte to destroy the Unorganized Material as well as all other Product in its possession that is not needed to execute Dr. McCabe's sampling plan.

A proposed Order is attached as Exhibit "A" to this Memorandum.

Dated: November 16, 2007

Respectfully submitted,

\_\_\_\_\_/s\_\_\_\_\_  
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Del Monte Foods Company

BEFORE THE UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE PET FOOD PRODUCTS	:	Civil Action No. 07-2867
LIABILITY LITIGATION	:	
	:	MDL Docket No. 1850 (ALL
	:	CASES)
	:	
	:	<b>CERTIFICATE OF SERVICE</b>
	:	

I certify that on the 16th day of November, 2007, I electronically filed the foregoing motion to Limit Del Monte's Retention of Recalled Pet Treats, Food, Raw Wheat Gluten and Mixtures Containing Recalled Wheat Gluten, and all papers and exhibit annexed thereto; the Affidavit of Richard Fama in Support; the Affidavit of Good Faith; and a proposed Order with the Clerk of Courts using the CM/ECF system which will send notification of such filing to CM/ECF participants:

Lisa J. Rodriguez  
 TRUJILLO RODRIGUEZ & RICHARDS LLC  
 8 Kings Highway West Palm Beach Haddonfield, NJ 08033  
 Telephone: (856) 795-9002  
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Dated November 16, 2007

\_\_\_\_\_/s\_\_\_\_\_  
 Richard Fama