UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE PET FOODS PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 1850 Case No. 07-2867 (NHL) Judge Noel L. Hillman **CHEMNUTRA, INC.'S NOTICE OF MOTION AND MOTION TO DESTROY RETAINED WHEAT GLUTEN; DECLARATION OF KAREN M. FIRSTENBERG; DECLARATION OF ANTHONY G. BRAZIL AND DECLARATION OF STEPHEN S. MILLER; AND [PROPOSED] ORDER**

PLEASE TAKE NOTICE that pursuant to Fed. R. Civ. P. 26(b)(2)(C)(iii) and 26(c)(1), and upon any additional briefing that may be determined by this Court, Defendant ChemNutra, Inc. ("ChemNutra") will and does hereby move in the United States District Court, for the District of New Jersey, Michell 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 allowing ChemNutra to destroy the recalled raw wheat gluten purchased from XuZhou Anying Biologic Technology Development Co. Ltd. ("XuZhou Anying") (collectively "Wheat Gluten") that ChemNutra is currently storing in compliance with preservation orders previously issued by this Court.

ChemNutra now moves to seek modification of this Court's prior preservation orders to allow ChemNutra to destroy the recalled Wheat Gluten that it has been storing because (1) the FDA has already conducted reliable, independent and valid sampling and testing of ChemNutra's Wheat Gluten, the results of which are publically available and attached hereto; (2) the FDA has

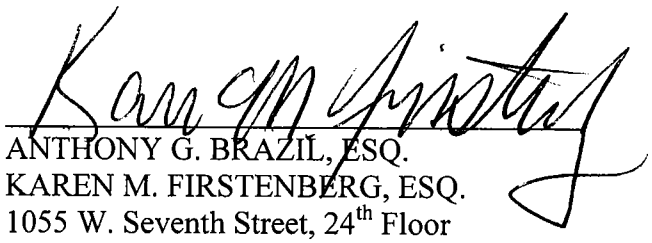
requested that ChemNutra destroy the recalled Wheat Gluten in its possession due to public health and safety concerns associated with the continued storage of large quantities of recalled wheat gluten, including but not limited to cross-infestation and inadvertent re-entry into the stream of commerce; (3) the substantial financial burden and costs associated with retaining ChemNutra's Wheat Gluten far exceed any benefit to retaining the Wheat Gluten since the FDA has already conducted reliable, independent and valid sample and testing of the Wheat Gluten; (4) both the FDA and the US Attorneys office support ChemNutra's request to destroy its Wheat Gluten, (5) the destruction would be done in accordance with and under the supervision of the FDA.

Accordingly, ChemNutra seeks an Order allowing it to destroy its Wheat Gluten in accordance with and under the supervision of the FDA.

PLEASE TAKE FURTHER NOTICE that in support of its Motion, ChemNutra will rely upon the accompanying Memorandum of Points and Authorities; the Declaration of Karen M. Firstenberg, Declaration of Anthony G. Brazil and Declaration of Stephen S. Miller, and all other papers filed with this Court in this litigation and [proposed] Order.

DATED: September 5, 2008

MORRIS POLICH & PURDY LLP



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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF CHEMNUTRA, INC.'S UNOPPOSED MOTION TO DESTROY ITS INVENTORY OF WHEAT GLUTEN

I. INTRODUCTION AND SUMMARY

On April 2, 2007 ChemNutra, Inc. ("ChemNutra") recalled its entire raw wheat gluten inventory that had been supplied by XuZhou Anying Biologic Technology Development Co. Ltd. ("XuZhou Anying") (collectively "Wheat Gluten") due to possible contamination. It is this recall that serves as the basis of ChemNutra's inclusion in this litigation. Since this recall, ChemNutra has retained, pursuant to the preservation order of this Court, its remaining inventory of Wheat Gluten in three warehouses located in Missouri, New Jersey and Pennsylvania. *See* Declaration of Stephen S. Miller ("Miller") ¶¶ 2 and 3.

In December, 2007, this Court granted Motions by Menu Foods and DelMonte related to a sampling, testing and destruction plan for the retained inventory pet food products recalled and retained by those companies. Pursuant to this Court's order, representative samples of the allegedly containment pet foods to which pets were exposed were to be retained and the remainder of which was authorized for destruction. It is the contents of those finished product samples that will determine whether or not a specific pet consumed contaminated food.

ChemNutra now seeks an order to destroy its remaining inventory of recall Wheat Gluten since commencing in March, 2007, the Food and Drug Administration ("FDA") commenced a detailed and independent sampling and inspection of ChemNutra's Wheat Gluten. This inspection resulted in the FDA obtaining samples and testing of various bags of ChemNutra's Wheat Gluten. The FDA's sampling and tests resulted in reliable, independent and valid results, all of which are publically available from the FDA and attached hereto.

Accordingly, ChemNutra now seeks to destroy its remaining Wheat Gluten that is currently being stored in Missouri, New Jersey and Pennsylvania. Good cause supports the granting of this Motion since (1) the FDA has already conducted reliable, independent and valid sampling and testing of ChemNutra's Wheat Gluten, the results of which are publically available

and attached hereto; (2) the FDA has requested that ChemNutra destroy the recalled Wheat Gluten in its possession due to public health and safety concerns associated with the continued storage of large quantities of recalled wheat gluten, including but not limited to cross-infestation and inadvertent re-entry into the stream of commerce; (3) the substantial financial burden and costs associated with retaining ChemNutra's Wheat Gluten far exceed any benefit to retaining the Wheat Gluten since the FDA has already conducted reliable, independent and valid sample and testing of the Wheat Gluten; (4) both the FDA and the US Attorneys office support ChemNutra's request to destroy its Wheat Gluten, (5) the destruction would be done in accordance with and under the supervision of the FDA.

Accordingly, ChemNutra requests that this Court grant ChemNutra's Motion and Order that its Wheat Gluten be destroyed in accordance with and under the supervision of the FDA.

II. GOOD CAUSE SUPPORTS THE ORDER ALLOWING CHEMNUTRA TO DESTROY ITS WHEAT GLUTEN

This Court has broad power to limit discovery when good cause is shown. Fed. R. Civ. P. 26(b)(2), 26(C)(2), 26(c)(4); *United States v. Princeton Gamma-Tec* (D.N.J.) 817 F.Supp. 488, 493 (granting motion to limit discovery). This court may limit discovery when "the burden or expense of the proposed discovery outweighs its likely benefit" to the party seeking discovery. *Maertin v. Armstrong World Indus., Inc.* No. 01-5321, 2007 U.S. Dist. LEXIS 20561, at *4, 6 (D. N.J. Mar. 8, 2007)(Schenieder, J.)(internal quotation marks omitting)(rejecting request for insurer's claims files, which were located in 27 offices, because of the "burden and expense to obtain the requested discovery").

Courts have agreed to limit discovery to statistical samples where, like here, the burden of full production outweigh its potential benefits. *E.g. Benson v. St. Joseph Reg'l Health Ctr.*, No. H-04-04323, 2006 U.S. Dist. LEXIS 34815, at *4-7 (S.D. Tex. May 17, 2006)(permitting defendant health center to produce only 350 of the 1,336 requests patient charts – a

"representative sample" because "imposing the full expense of producing all 1,336 charts upon Defendants would be undue and unfair")

Here, more than in *Benson*, the need to destroy the remaining supply of ChemNutra's Wheat Gluten is more compelling. ChemNutra continues to store its Wheat Gluten in three warehouse facilities located in Missouri, New Jersey and Pennsylvania. *Miller* ¶¶ 3, 4, 6 and 7. This burden and expense associated with the continued storage of ChemNutra's Wheat Gluten far exceeds any benefit since ChemNutra's Wheat Gluten has already undergone independent, reliable and valid sampling and testing by the FDA, the results of which are publically available. Moreover, since conducting these samplings and testing, the FDA has requested that ChemNutra destroy its Wheat Gluten for public health reasons. Both the FDA and the US Attorneys office support ChemNutra's request to destroy its Wheat Gluten and the destruction would be done in accordance with and under the supervision of the FDA. In fact, ChemNutra's grounds for requesting this relief are even more compelling than the requests of Menu and Del Monte previously granted by this Court in that the sampling and testing plan for ChemNutra's Wheat Gluten has already been independently created and completed by the FDA and the results thereof have been provided to the Plaintiffs and this Court.

A. The FDA Has Conducted An Independent Reliable Sampling and Testing Of ChemNutra's Wheat Gluten.

Commencing in March, 2007 the FDA developed and implemented a detailed sampling, inspection and testing of ChemNutra's Wheat Gluten stored at its MoKan Container Service, Inc.'s warehouse located in Kansas City, Missouri. *Miller,* ¶ 5. The FDA's methodology and plan for sampling and testing the Wheat Gluten was thorough and consistent with the plans previously proposed by co-defendants retained expert, Dr. McCabe and previously approved by this Court in connection with its Orders pertaining to retained inventory of finished products. *See* Declaration of Anthony G. Brazil ("Brazil"), ¶ 5; *See* Declaration of Karen M. Firstenberg ("Firstenberg"), ¶ 4.

As evidenced by the final report consisting of 134 pages (*See Exhibit 2* to Firstenberg Dec.) the FDA was methodical in documenting its sampling and testing procedures. These test reports contain, *inter alia*, the following information: (a) the date of collection; (b) product code; (c) FIS sample number; (d) hours spent related to each sampling; (e) country of origin for each sample; (f) a product description; (g) batch identification; (h) reason for each sampling; (i) lot size; (j) description of sample; (k) method of collection; (l) preparation procedures for each sampling; (m) remarks; and (n) lab conclusions. *See Firstenberg*, ¶ 3; *Exhibit 2* to *Firstenberg* Dec.

Pursuant to Fed. R. Evid. 201(b), ChemNutra requests this Court to take judicial notice of the FDA's final report attached as Exhibit 2 to Firstenberg Dec. *See Noble Asset Management v. Allos Therapeutics, Inc.* (D, Colo. 2005) 2005 WL 161977, *2 (holding that a court may take judicial notice of FDA documents which are publically available).

The FDA's testing and sampling results generated reliable, independent and valid results, all of which are publically available and were obtained by request to the FDA by means of the Freedom of Information Act. *See Firstenberg,* ¶ 2; *See also* Exhibit A to *Firstenberg* Dec.

Since the FDA's sampling plan and tests were conducted as an independent, federal agency these results are reliable and valid. *See Reference Manual on Scientific Evidence* (pp. 98 – 102, 2d ed. 2000) expressly approving analytical testing on sample units to measure the larger population, as long as the sampling is not biased. For example, in criminal drug cases, chemist are used to analyze a representative sample of the seized items to "determine the total quantity of illicit drugs in all of 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* (E.D.N.Y. 1995) 895 F.Supp.460, 465, 518, 519-521, 524 (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"); *see also NutraSweet Co. v. X-L Eng'g Co.* (7th Cir. 2000) 227 F.3d 776, 782, 787, 792 (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).

Accordingly, since the FDA has already conducted independent, reliable and valid sampling and testing, the results of which have been well documented, provided herein and are publically available, good cause now supports the destruction of ChemNutra's Wheat Gluten.

B. The FDA Has Indicated That It Believes That ChemNutra's Retained Raw Wheat Gluten Is A Public Health Hazard And That ChemNutra's Wheat Gluten Should Be Destroyed

As part of the FDA's active investigation related to ChemNutra's recall of its Wheat Gluten, the FDA specifically informed ChemNutra by letter that ChemNutra should not continue to store its Wheat Gluten for fear of public safety. Specifically, on or bout June 29, 2007, the FDA sent to ChemNutra a letter expressing its concerns regarding the "public health risks" associated with ChemNutra's storing of their approximately 430 metric tons of wheat gluten. The FDA stated that "until the product is **destroyed**, there is a risk of reintroduction into interstate commerce, whether intentional or not, and/or risk of expert." The FDA then urged ChemNutra to "seek whatever relief is appropriate from the Court." *Miller*, ¶ 8; *see also* Exhibit A to Miller Dec. (emphasis added). Since receipt of the FDA's request for destruction of its Wheat Gluten, ChemNutra has received numerous follow up requests seeking the status of destruction of its Wheat Gluten. *Miller,* ¶ 9. Counsel for ChemNutra has been working for over six months with co-defendants, plaintiffs counsel and the FDA's office of chief counsel in efforts to comply with the FDA's requests to ChemNutra to destroy its inventory of Wheat Gluten. *Brazil,* ¶ 2.

The FDA has the authority to issue its letter, as the Federal Food, Drug and Cosmetic Act requires the FDA to keep foods "for man or other animals . . . safe, wholesome, [and] sanitary." 21 U.S.C. §§ 321, 393. This Court should take judicial notice of the FDA's letter dated June 29, 2007 and defer to the FDA's conclusion that the current quantity of raw wheat gluten stored is creating health risks to the public and recommendations that ChemNutra destroy its inventory of

wheat gluten. *See In re Wellbutrin SR/Zyban Antitrust Litig.*, (E.D. Pa. 2003) 281 F.Supp.2d 751, 755 n.2 (taking judicial notice of a FDA report published on its website). *See also Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.* (3rd Cir. 1990) 902 F.2d 222, 230-31 (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* (1996) 395 U.S. 185, 194; *see also Wells Fargo Bank of Tex. NA v. James* (E.D. Pa. 2006)484 F.Supp.2d 289, 308-17 (giving "significant deference" to the FDA).

ChemNutra seeks to follow the FDA's sound advice. Since ChemNutra's Wheat Gluten has been appropriately sampled, well tested and documented, good cause now supports the destruction of ChemNutra's Wheat Gluten and its Motion should be granted. Both the FDA and the US Attorneys office have approved of this request for destruction by ChemNutra. *Brazil,* ¶¶5, 6.

C. The Financial Costs And Expense For ChemNutra To Store Its Wheat Gluten Far Exceed Any Potential Benefits And The Wheat Gluten Should Be Destroyed.

Despite the independent, reliable sampling and testing conducted by the FDA, ChemNutra continues to store its Wheat Gluten in three warehouses located in Missouri, New Jersey and Pennsylvania. *Miller*, ¶3.

The majority of ChemNutra's Wheat Gluten is being stored at MoKan Container Service, Inc. located in Kansas City, Missouri, where there is over 277 metric tons of Wheat Gluten. ChemNutra incurs great expense and costs each month associated with the storage of this Wheat Gluten. *Miller* ¶¶ 4, 10.

ChemNutra is also storing Wheat Gluten at the Steven Shannon Warehouse in Bloomsburg, Pennsylvania. All of the wheat gluten at this location comes from the XuZhou Batch Number 20070106. ChemNutra did not sell, distribute or supply any portion of the wheat gluten from Batch Number 20070106 to any person or entity. Therefore, no pets would have

been exposed to food containing ChemNutra supplied wheat gluten from this Batch number. *Miller*, ¶ 7.

In addition, approximately 80 metric tons of Wheat Gluten are being stored by ChemNutra at the Standard Warehouse and Distribution Co., Ltd. ("Standard Warehouse") in Pennsauken, New Jersey. For over six months, Standard Warehouse has demanded that ChemNutra immediately remove its Wheat Gluten from this facility. As of July 1, 2008, Standard Warehouse substantially increased its storage costs. These increased storage costs as well as the on going storage costs for the Missouri and Pennsylvania facilities have been a severe economic burden on ChemNutra.

In addition to the storage facility costs, if ChemNutra is required to continue its retention of its Wheat Gluten, ChemNutra would be compelled to incur additional costs and great expenses.

In light of the testing conducted by the FDA and the availability of such testing to the Plaintiffs herein, this Court should weight ChemNutra's "economic considerations . . . to remain faithful to its responsibilities to prevent 'undue burden and expense' to it. *McPeek v. Ashcroft* (D.D.C. 2001) 202 F.R.D. 31, 34 (limiting additional discovery to a sampling or test run of data on backup tapes); *see also Powell v. S. Jersey Marina, Inc.* (M.D. Pa. Aug. 1, 2007) No. 3:CV-04-2611, 2007 U.S. Dist. LEXIS 55849 at *18-20 (denying motion to compel deposition testimony of defendant's president because plaintiffs already had discovery on the issue, holding that the "benefit to [p]laintiffs' case appear[ed] non-existent"). Significantly, because there are documents available detailing the sampling and testing conducted by the FDA, there remains no good reason for ChemNutra to continue to incur the great expense and burden to continue to store its Wheat Gluten and ChemNutra's Motion should be granted.

D. This Motion Is Supported By the FDA and the US Attorneys Office

Neither the FDA's Office of Chief Counsel nor the US Attorneys office opposes ChemNutra's Motion. *Brazil,¶¶ 5 and 6.* Further, it is agreed that if this Court grants ChemNutra's Motion, ChemNutra will implement the destruction of its Wheat Gluten in

accordance with and under the supervision of the FDA. *Brazil*, ¶¶ 2, 5, 6; *see also* Exhibits "C" and "D" to Brazil Dec.; *see also Miller*, ¶ 12.

III. CONCLUSION

ChemNutra respectfully requests that this Court issue an Order allowing ChemNutra to destroy its XuZhou Anying Wheat Gluten in accordance with and under the supervision of the FDA. A proposed Order is attached as Exhibit 1 to this Memorandum.

DATED: September 5, 2008

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