NATIONAL MILK DRUG RESIDUE DATA BASE

FISCAL YEAR 2007 ANNUAL REPORT

October 1, 2006 - September 30, 2007

Submitted by:

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Contract Number: HHSF 223 2006 400281C

February 18, 2008

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INTRODUCTION

The National Milk Drug Residue Data Base (NMDRD) is a voluntary industry reporting program. Mandatory reporting is required by State Regulatory Agencies under the National Conference on Interstate Milk Shipments (NCIMS). Data are reported on the extent of the national testing activities, the analytical methods used, the kind and extent of the animal drug residues identified, and the amount of contaminated milk that was removed from the human food supply. The system includes all milk, Grade "A" and non-Grade "A", commonly known as manufacturing grade. Grade "A" milk represents approximately 95% of the milk supply in the United States and is regulated through the NCIMS by State Regulatory Agencies. Manufacturing grade milk is under the direction of the Regulatory Agencies in the States where it is produced and may be subject to the standards recommended by the United States Department of Agriculture (USDA). Data reported to the NMDRD are for educational and analytical purposes and are not intended or suitable for regulatory action or follow-up.

BACKGROUND

The NCIMS is a voluntary organization directed and controlled by member States to promote the availability of a high quality milk supply. The Food and Drug Administration (FDA) and the NCIMS through their collaborative efforts have developed a cooperative, federal-state program (the Grade "A" Interstate Milk Shippers program) to ensure the sanitary quality of Grade "A" milk and milk products shipped in interstate commerce. During the 1991 meeting of the NCIMS, the Conference authorized a national program to compile the results of milk residue testing by industry and State Regulatory Agencies.

Subsequently, FDA awarded a contract to develop a NMDRD. The data base is operated by an independent third party, under contract to the FDA. The data base design was developed in consultation with a project advisory group with members from the FDA and a NCIMS committee representing dairy producers, dairy processors, USDA, State Regulatory Agencies, and academia. The data base was designed to promote maximum participation by the dairy industry to report on a voluntary basis all of their testing results, without compromising any confidential data. Information regarding individual firm's data is not submitted to the data base contractor.

It is important to recognize that the samples and tests reported do not necessarily represent one hundred percent (100%) of the milk supply from every State. However, as State and industry participation in the data base increased, reporting of the number of samples and tests similarly increased.

Continuing efforts are being made to ensure that there is uniform reporting among all the States and the industry and to ensure that the drugs and test methods reported are correct.

During FY 2006, a web-based version of the reporting software was developed, field evaluated, and then made available to all data reporters on September 1, 2006. Instructions for registering and using the software are posted on the contractor's web site at: <u>www.kandc-sbcc.com/nmdrd/index.html</u>. Thirty-six (36) data reporters utilized the new web-based software to submit all or part of their data for the FY 2007 Annual Report.

On May 7, 2007, contractor staff made a presentation at the NCIMS meeting in Salt Lake City, Utah, concerning the Annual Reports for FY 2005 and 2006, and the web-based reporting application. This included a demonstration of the software and a "real-time" opportunity for participants to use the application.

At the request of one of the attendees at NCIMS, the contractor converted all the tabular information from previous Annual Reports into Microsoft Excel format and posted them on the contractor's web site at: www.kandc-sbcc.com/nmdrd/index.html. Annual Reports are now available in Portable document file (pdf), Microsoft Excel and Open Document Spreadsheet (ods) formats.

SUMMARY

This report presents summary data on samples and tests conducted during Fiscal Year 2007 (October 1, 2006 to September 30, 2007). Forty-eight (48) states submitted data for this report. No data were received from Connecticut, Puerto Rico and Rhode Island.

The Grade "A" Pasteurized Milk Ordinance (PMO), the regulations which State Regulatory Agencies use to implement their Grade "A" milk program, requires that all bulk milk tankers be sampled and analyzed for animal drug residues before the milk is processed. Any tanker found positive is rejected for human consumption.

During this period **4,002,185** samples were analyzed for animal drug residues. Of these samples **1,681** were positive for a residue. A total of **4,026,485** tests were reported on the samples for **ten** (10) different groups of families or individual drugs. **Thirty-one** (31) testing methods were used to analyze the samples for residues. Details are presented in the Tables in this report.

SAMPLE RESULTS

A <u>SAMPLE</u> is defined as representing a load or lot of milk sampled and analyzed, e.g. a bulk milk pick-up tanker, producer, or over-the-road tanker, a silo, etc.

Table 1 shows the results of the samples tested by source.

Data are reported by four **SOURCES OF SAMPLES**:

- 1. <u>Bulk Milk Pick-Up Tanker</u> bulk raw milk from a dairy farm.
- 2. <u>Pasteurized Fluid Milk and Milk Products</u> after pasteurization; finished product in package form or bulk. This term includes milk products such as milk, cream, condensed and dry milk and milk products, and condensed and dry whey and whey products.
- 3. <u>Producer</u> raw milk obtained from the bulk tank/silo from a dairy farm. Samples are reported by the permitting State, rather than by the analyzing State.

4. <u>Other</u> - milk from milk plant silos, over-the-road tankers, etc.

A <u>POSITIVE</u> result, as used in this report, means that the sample was found to be positive for a drug residue by a test acceptable for taking regulatory action in a certified laboratory by a certified analyst or the milk was rejected on the basis of an initial screening test by the milk processor.

TABLE 1 Sample ResultsOctober 1, 2006 to September 30, 2007									
Source of Sample	Total Samples	Number Positive	Percent Positive	Disposition per PMO (Pounds)					
Bulk Milk Pick-Up Tanker	3,303,479	1,052	0.032%	83,121,000					
Pasteurized Fluid Milk and Milk Products	43,851	2	0.005%	40,000					
Producer	570,011	616	0.108%	2,752,000					
Other	84,844	11	0.013%	307,000					
TOTALS	4,002,185	1,681	*	86,220,000					

The <u>DISPOSITION per PMO</u> column represents the amount of milk contained in the tank or lot found to be positive and disposed of in accordance with the PMO and/or applicable State rules

The asterisk (*) notes that a summary of the percent positive cannot be provided because there is no uniformity in terms of sampling in the four categories. For example, the PMO sets forth specific sampling requirements for Beta lactams testing as follows:

- 1. <u>Bulk Milk Pick-Up Tanker Samples</u> -- samples are taken on receipt of every tanker load;
- 2. <u>Pasteurized Fluid Milk and Milk Products</u> -- a minimum of four samples must be tested for each finished product from each plant during any consecutive six months;
- 3. <u>Producer</u> -- each producer must be tested at least four times during any consecutive six months; and
- 4. <u>Other</u> -- samples are conducted on a random basis.

Table 2 presents these results in greater detail and shows the number of samples conducted by industry and by State Regulatory Agencies. Industry samples are taken by processing facilities, receiving and transfer stations, and marketing groups or cooperatives. Industry sampling and testing may be conducted to meet the industry requirements of Appendix N of the PMO which sets forth testing and reporting requirements for animal drug residues or for quality control purposes. Regulatory samples are taken by State and Local Regulatory Agencies.

TABLE 2 Industry and Regulatory Samples October 1, 2006 to September 30, 2007								
Source of Sample	Number of Industry Samples	Number of Positive Industry Samples	Number of Regulatory Samples	Number of Positive Regulatory Samples	Total Samples	Total Positive Samples	Total Percent Positive	Disposition Per PMO (Pounds)
GRADE A								
Bulk Milk Pick-Up Tanker	3,082,106	956	16,971	9	3,099,077	965	0.031%	79,917,000
Pasteurized Fluid Milk and Milk Products	2,938	0	39,135	2	42,073	2	0.005%	40,000
Producer	376,878	437	150,065	118	526,943	555	0.105%	2,540,000
Other	61,813	11	6,891	0	68,704	11	0.016%	307,000
NON-GRADE A								
Bulk Milk Pick-Up Tanker ¹	203,081	86	1,321	1	204,402	87	0.043%	3,204,000
Pasteurized Fluid Milk and Milk Products	1,471	0	307	0	1,778	0	0.000%	0,000
Producer	34,096	60	8,972	1	43,068	61	0.142%	212,000
Other	15,757	0	383	0	16,140	0	0.000%	0,000
TOTALS	3,778,140	1,550	224,045	131	4,002,185	1,681	*	86,220,000 ²

¹It is a common practice in some States, including two large milk production States, that bulk milk pick-up tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

²Note that this represents 0.047% of the total milk supply of the United States with an annual production of 184.2 billion pounds

TESTS CONDUCTED

An objective of the NMDRD is to record every test run on each sample analyzed. Since some samples are analyzed for more than one drug residue, the number of <u>tests</u> conducted (4,026,485) is greater than the number of <u>samples</u> (4,002,185). To avoid duplicate reporting of <u>samples</u>, the number of <u>samples</u> analyzed is reported separately from the number of <u>tests</u> run in the data base.

Table 3 presents summary results of the number of tests which were conducted during October 1, 2006 to September 30, 2007. The term, validated test, as used in this report, is a test used for the screening of raw milk for drug residue, which has been evaluated in accordance with Appendix N of the PMO and found acceptable by FDA in accordance with the standards established for the evaluation of these types of tests. In addition, FDA validated drug residue detection procedures for screening and quantization of drug residues in milk may be used. Table 3A presents summary results using validated tests and Table 3B presents summary results using non-validated tests.

TABLE 3 Tests ConductedOctober 1, 2006 to September 30, 2007							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,325,193	1,054	0.032				
Pasteurized Fluid Milk and Milk Products	43,919	2	0.005				
Producer	572,029	620	0.108				
Other	85,344	11	0.013				
TOTALS	4,026,485	1,687	*				

TABLE 3A – Validated Tests ConductedOctober 1, 2006 to September 30, 2007							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,294,491	1,048	0.032				
Pasteurized Fluid Milk and Milk Products	43,389	2	0.005				
Producer	571,981	620	0.108				
Other	84,055	11	0.013				
TOTALS	3,993,916	1,681	*				

*See Table 1 for explanation

TABLE 3B Non-Validated Tests ConductedOctober 1, 2006 to September 30, 2007							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	30,702	6	0.020				
Pasteurized Fluid Milk and Milk Products	530	0	0.000				
Producer	48	0	0.000				
Other	1,289	0	0.000				
TOTALS	32,569	6	*				

Table 4 presents additional details in terms of the tests conducted by industry and by State Regulatory Agencies. Tables 4A and 4B present these data by validated and non-validated tests.

TABLE 4 – Tests Conducted by Industry and Regulatory AgenciesOctober 1, 2006 to September 30, 2007							
Source of Sample	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Total Percent Positive
GRADE A							
Bulk Milk Pick-Up Tanker	3,097,777	957	17,041	9	3,114,818	966	0.031%
Pasteurized Fluid Milk and Milk Products	2,938	0	39,203	2	42,141	2	0.005%
Producer	378,828	441	150,124	118	528,952	559	0.106%
Other	61,993	11	7,208	0	69,201	11	0.016%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	209,054	87	1,321	1	210,375	88	0.042%
Pasteurized Fluid Milk and Milk Products	1,471	0	307	0	1,778	0	0.000%
Producer	34,096	60	8,981	1	43,077	61	0.142%
Other	15,760	0	383	0	16,143	0	0.000%
TOTALS	3,801,917	1,556	224,568	131	4,026,485	1,687	*

It is a common practice in some States, including two large milk production States, that bulk milk pick-up tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

TABLE 4A Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2006 to September 30, 2007							
Source of Sample	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Total Percent Positive
GRADE A							
Bulk Milk Pick-Up Tanker	3,069,052	951	15,185	9	3,084,237	960	0.031%
Pasteurized Fluid Milk and Milk Products	2,509	0	39,102	2	41,611	2	0.005%
Producer	378,780	441	150,124	118	528,904	559	0.106%
Other	60,704	11	7,208	0	67,912	11	0.016%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ⁱ	208,933	87	1,321	1	210,254	88	0.042%
Pasteurized Fluid Milk and Milk Products	1,471	0	307	0	1,778	0	0.000%
Producer	34,096	60	8,981	1	43,077	61	0.142%
Other	15,760	0	383	0	16,143	0	0.000%
TOTALS	3,771,305	1,550	222,611	131	3,993,916	1,681	*

It is a common practice in some States, including two large milk production States, that bulk milk pick-up tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

TABLE 4B Non-Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2006 to September 30, 2007							
Source of Sample	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Total Percent Positive
GRADE A							
Bulk Milk Pick-Up Tanker	28,725	6	1,856	0	30,581	6	0.020%
Pasteurized Fluid Milk and Milk Products	429	0	101	0	530	0	0.000%
Producer	48	0	0	0	48	0	0.000%
Other	1,289	0	0	0	1,289	0	0.000%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	121	0	0	0	121	0	0.000%
Pasteurized Fluid Milk and Milk Products	0	0	0	0	0	0	0.000%
Producer	0	0	0	0	0	0	0.000%
Other	0	0	0	0	0	0	0.000%
TOTALS	30,612	6	1,957	0	32,569	6	*

It is a common practice in some States, including two large milk production States, that bulk milk pick-up tankers pickup milk from both Grade "A" and non-Grade "A" milk producers on the same tanker. Then, these loads are delivered to non-Grade "A" processing facilities. Because of this commingling of the two grades of milk, all data related to these loads are reported under non-Grade "A".

Table 5 shows the number of tests conducted by the family of drugs and by individual drug. Tables 5A and 5B present these data by validated and non-validated tests.

TABLE 5 Number of Tests Conducted by Family/DrugOctober 1, 2006 to September 30, 2007						
Family/Drug	Total Tests	Total Positive				
AMINOGLYCOSIDES	36	0				
Neomycin	604	2				
AMPHENICOLS	34	0				
BETA lactams	3,963,569	1,677				
ENROFLOXACIN	1,579	0				
MACROLIDES	860	1				
SPECTINOMYCIN	14	0				
SULFONAMIDES	33,377	3				
Sulfamethazine	14,538	2				
TETRACYCLINES	11,874	2				
TOTALS	4,026,485	1,687				

TABLE 5A Number of Validated Tests Conducted by Family/Drug October 1, 2006 to September 30, 2007						
Family/Drug	Total Tests	Total Positive				
AMPHENICOLS	34	0				
BETA lactams	3,962,765	1,677				
SULFONAMIDES	28,393	3				
TETRACYCLINES	2,724	1				
TOTALS	3,993,916	1,681				

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TABLE 5B Number of Non-Validated Tests Conducted by Family/Drug October 1, 2006 to September 30, 2007								
Family/Drug	Total Tests	Total Positive						
AMINOGLYCOSIDES	36	0						
Neomycin	604	2						
BETA lactams	804	0						
ENROFLOXACIN	1,579	0						
MACROLIDES	860	1						
SPECTINOMYCIN	14	0						
SULFONAMIDES	4,984	0						
Sulfamethazine	14,538	2						
TETRACYCLINES	9,150	1						
TOTALS	32,569	6						

Table 6 presents details on the tests used. The data in this table are comparable to Table 5, but the data are arranged by <u>tests</u> within each <u>family/drug</u>. Therefore, the Totals are the same in both tables. The testing methods with the largest use were: Charm SL - Beta lactams, which was used more than 2.5 million times, Delvotest P 5 Pack - Beta lactams which was used more than 570 thousand times, Idexx New Snap which was used more than 343 thousand times and Charm II Tablet Competitive - Beta lactams which was used for more than 169 thousand tests. Table 6A shows a comparison of tests conducted using Validated and Non-Validated test methods for Sulfonamides and Tetracyclines.

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TABLE 6 Number of Tests by Method by Family/DrugOctober 1, 2006 to September 30, 2007									
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive						
AMINOGLYCOSIDES									
Charm II Tablet Competitive-N**	36	0	0.000%						
NEOMYCIN									
ID Block - Neomycin**	604	2	0.331%						
AMPHENICOLS									
Charm II Tablet Competitive	1	0	0.000%						
FDA Florfenicol-HPLC	33	0	0.000%						
BETA lactams									
Charm BSDA Tablet - Beta lactams	50,295	49	0.097%						
Charm Farm - Beta lactams**	804	0	0.000%						
Charm I/Cowside II Tablet - Beta lactams	4,446	2	0.045%						
Charm II Tablet Competitive	169,279	50	0.030%						
Charm II Tablet Quantitative	18	0	0.000%						
Charm II Tablet Sequential	115,494	48	0.042%						
Charm SL Beta lactams	2,548,087	794	0.031%						
Charm SL-6	117,963	44	0.037%						
Delvotest P 5 Pack - Beta lactams	570,572	524	0.092%						
Delvotest P/Delvotest P Mini	32,538	26	0.080%						
Delvotest SP/Delvotest SP Mini	1,974	1	0.051%						
Idexx New Snap	343,680	136	0.040%						
Lak Tek - Beta lactams	6,210	2	0.032%						
Parallux Cillins Assay	95	0	0.000%						
Penzyme III Test - Beta lactams	20	0	0.000%						
Penzyme Milk Test - Beta lactams	2,094	1	0.048%						

October 1, 2006 to September 30, 2007									
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive						
ENROFLOXACIN									
Charm SL-Floroquinlone**	1,579	0	0.000%						
MACROLIDES									
Charm II Tablet Sequential - Macrolides**	860	1	0.116%						
SPECTINOMYCIN									
Charm II Tablet Competitive**	14	0	0.000%						
SULFONAMIDES									
Agri-Screen for Sulfonamides **.***	937	0	0.000%						
Charm II Tablet Competitive	27,815	2	0.007%						
Charm II Tablet Sequential**	4,047	0	0.000%						
TLC Sulfonamide	578	1	0.173%						
SULFAMETHAZINE									
Charm SL - Sulfamethazine**	14,538	2	0.014%						
TETRACYCLINES									
Charm II Tablet Competitive	2,724	1	0.037%						
Charm SL - Tetracyclines**	4,042	0	0.000%						
Snap - Tetracyclines**	5,108	1	0.020%						
TOTALS	4,026,485	1,687	*						

TABLE 6 -- Number of Tests by Method by Family/Drug

* See Table 1 for explanation
** Non-Validated Test Method
*** FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

Tests for Sulfonamides and Tetracyclines October 1, 2006 to September 30, 2007									
Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive						
VALIDATED FOR SULFONAMIDES									
Charm II Tablet Competitive	27,815	2	0.007%						
TLC Sulfonamide	578	1	0.173%						
NON-VALIDATED FOR SULFONAMIDES									
Agri-Screen for Sulfonamides** & ***	937	0	0.000%						
Charm II Tablet Sequential**	4,047	0	0.000%						
NON-VALIDATED FOR SULFAMETHAZINE									
Charm SL - Sulfamethazine**	14,538	2	0.014%						
VALIDATED FOR TETRACYCLINES									
Charm II Tablet Competitive	2,724	1	0.037%						
NON-VALIDATED FOR TETRACYCLINES									
Charm SL - Tetracyclines**	4,042	0	0.000%						
Snap - Tetracyclines**	5,108	1	0.020%						
TOTALS	59,789	7	*						

TABLE 6A -- Comparison of Validated and Non-Validated Tests for Sulface and Tests and Tests

*** Non-Validated Test Method *** FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

Tables 7-1 to 7-8 present additional details of the testing conducted. These Tables show the testing by the family of drugs and by individual drugs and present results in terms of Grade "A" and Non-Grade "A" testing. Data on individual drugs listed in these tables, e.g., Cloxacillin, Sulfamethazine, etc., are not included in the Totals for the family of drugs, e.g., Beta lactams, Sulfonamides, etc.

TABLE 7-1 Grade A Bulk Milk Pick-Up Tanker TestingOctober 1, 2006 to September 30, 2007									
Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests			
AMINOGLYCOSIDES	36	0	0	0	36	0			
Neomycin	604	2	0	0	604	2			
AMPHENICOLS	33	0	0	0	33	0			
BETA lactams	3,039,820	947	15,158	9	3,054,978	956			
ENROFLOXACIN	1,579	0	0	0	1,579	0			
MACROLIDES	860	1	0	0	860	1			
SULFONAMIDES	32,104	3	24	0	32,128	3			
Sulfamethazine	13,981	2	0	0	13,981	2			
TETRACYCLINES	8,760	2	1,859	0	10,619	2			
TOTALS	3,097,777	957	17,041	9	3,114,818	966			

TABLE 7-2 -- Grade A Pasteurized Fluid Milk and Milk Products TestingOctober 1, 2006 to September 30, 2007

Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests
BETA lactams	2,369	0	39,102	2	41,471	2
SPECTINOMYCIN	0	0	14	0	14	0
SULFONAMIDES	140	0	0	0	140	0
Sulfamethazine	429	0	0	0	429	0
TETRACYCLINES	0	0	87	0	87	0
TOTALS	2,938	0	39,203	2	42,141	2

TABLE 7-3 Grade A Producer TestingOctober 1, 2006 to September 30, 2007								
Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests		
BETA lactams	378,180	441	150,044	118	528,224	559		
SULFONAMIDES	648	0	73	0	721	0		
TETRACYCLINES	0	0	7	0	7	0		
TOTALS	378,828	441	150,124	118	528,952	559		

TABLE 7-4 Grade A Other Testing (milk from silos, over-the-road tankers, etc.)October 1, 2006 to September 30, 2007									
Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests			
AMPHENICOLS	0	0	1	0	1	0			
BETA lactams	60,695	11	6,949	0	67,644	11			
SULFONAMIDES	9	0	258	0	267	0			
Sulfamethazine	128	0	0	0	128	0			
TETRACYCLINES	1,161	0	0	0	1,161	0			
TOTALS	61,993	11	7,208	0	69,201	11			

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TABLE 7-5 Non-Grade A Bulk Milk Pick-Up Tanker TestingOctober 1, 2006 to September 30, 2007							
Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	
BETA lactams	208,933	87	1,321	1	210,254	88	
SULFONAMIDES	121	0	0	0	121	0	
TOTALS	209,054	87	1,321	1	210,375	88	

TABLE 7-6 -- Non-Grade A Pasteurized Fluid Milk and Milk Products TestingOctober 1, 2006 to September 30, 2007

Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests
BETA lactams	1,471	0	307	0	1,778	0
TOTALS	1,471	0	307	0	1,778	0

TABLE 7-7 Non-Grade A Producer TestingOctober 1, 2006 to September 30, 2007								
Industry Positive Regulatory Positive Tests Pos						Total Positive Tests		
BETA lactams	34,096	60	8,981	1	43,077	61		
TOTALS	34,096	60	8,981	1	43,077	61		

TABLE 7-8 Non-Grade A Other Testing (milk from silos, over-the-road tankers, etc.)October 1, 2006 to September 30, 2007								
Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests		
BETA lactams	15,760	0	383	0	16,143	0		
TOTALS	15,760	0	383	0	16,143	0		

Tables 8-1 to 8-8 present details on the number of tests conducted by industry and by State Regulatory Agencies. The data are arranged by <u>test</u> within each <u>family/drug</u> and present results in terms of sample type and Grade "A" and Non-Grade "A" testing.

Tab	Table 8-1 Number of Tests by Method by Family/Drug Grade A Bulk Milk Pick-up Tanker October 1, 2006 to September 30, 2007										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive				
AMINOGLYCOSIDES											
Charm II Tablet Competitive-N ^{**}	36	0	0	0	36	0	0.000%				
NEOMYCIN											
ID Block - Neomycin**	604	2	0	0	604	2	0.331%				
AMPHENICOLS											
FDA Florfenicol-HPLC	33	0	0	0	33	0	0.000%				
BETA lactams											
Charm BSDA Tablet - Beta lactams	20,607	12	20	0	20,627	12	0.058%				
Charm Farm - Beta lactams**	804	0	0	0	804	0	0.000%				
Charm I/Cowside II Tablet - Beta lactams	4,332	2	0	0	4,332	2	0.046%				
Charm II Tablet Competitive	168,233	50	4	0	168,237	50	0.030%				
Charm II Tablet Sequential	108,209	48	220	0	108,429	48	0.044%				
Charm SL Beta lactams	2,302,239	692	5,389	0	2,307,628	692	0.030%				
Charm SL-6	114,203	34	8	0	114,211	34	0.030%				
Delvotest P 5 Pack - Beta lactams	6,067	4	4,974	0	11,041	4	0.036%				
Delvotest P/Delvotest P Mini	7,704	3	2,220	0	9,924	3	0.030%				
Delvotest SP/Delvotest SP Mini	1,269	1	0	0	1,269	1	0.079%				
Idexx New Snap	298,233	99	2,321	9	300,554	108	0.036%				
Lak Tek - Beta lactams	6,210	2	0	0	6,210	2	0.032%				

Table 8-1 Number of Tests by Method by Family/Drug
Grade A Bulk Milk Pick-up Tanker
October 1, 2006 to September 30, 2007

	Octob	er 1, 2000	to Septemb	er 30, 2007	l.	-	October 1, 2006 to September 30, 2007									
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive									
Penzyme III Test - Beta lactams	20	0	0	0	20	0	0.000%									
Penzyme Milk Test - Beta lactams	1,690	0	2	0	1,692	0	0.000%									
ENROFLOXACIN																
Charm SL-Floroquinlone**	1,579	0	0	0	1,579	0	0.000%									
MACROLIDES																
Charm II Tablet Sequential - Macrolides**	860	1	0	0	860	1	0.116%									
SULFONAMIDES																
Agri-Screen for Sulfonamides ^{**, ***}	889	0	0	0	889	0	0.000%									
Charm II Tablet Competitive	26,711	2	24	0	26,735	2	0.007%									
Charm II Tablet Sequential**	3,926	0	0	0	3,926	0	0.000%									
TLC Sulfonamide	578	1	0	0	578	1	0.173%									
SULFAMETHAZINE																
Charm SL - Sulfamethazine**	13,981	2	0	0	13,981	2	0.014%									
TETRACYCLINES																
Charm II Tablet Competitive	2,714	1	3	0	2,717	1	0.037%									
Charm SL - Tetracyclines**	4,042	0	0	0	4,042	0	0.000%									
Snap - Tetracyclines**	2,004	1	1,856	0	3,860	1	0.026%									
TOTALS	3,097,777	957	17,041	9	3,114,818	966	0.031%									

** Non-Validated Test Method *** FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

Table 8-2 Number of Tests by Method by Family/Drug Grade A Pasteurized Fluid Milk and Milk Products October 1, 2006 to September 30, 2007									
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive		
BETA lactams									
Charm BSDA Tablet - Beta lactams	1,248	0	1,396	0	2,644	0	0.000%		
Charm I/Cowside II Tablet - Beta lactams	0	0	67	0	67	0	0.000%		
Charm II Tablet Sequential	0	0	525	0	525	0	0.000%		
Charm SL Beta lactams	9	0	726	0	735	0	0.000%		
Delvotest P 5 Pack - Beta lactams	1,092	0	33,502	2	34,594	2	0.006%		
Delvotest P/Delvotest P Mini	0	0	2,139	0	2,139	0	0.000%		
Idexx New Snap	20	0	747	0	767	0	0.000%		
SPECTINOMYCIN									
Charm II Tablet Competitive**	0	0	14	0	14	0	0.000%		
SULFONAMIDES									
Charm II Tablet Competitive	140	0	0	0	140	0	0.000%		
SULFAMETHAZINE									
Charm SL - Sulfamethazine**	429	0	0	0	429	0	0.000%		
TETRACYCLINES									
Snap - Tetracyclines**	0	0	87	0	87	0	0.000%		
TOTALS	2,938	0	39,203	2	42,141	2	0.005%		

** Non-Validated Test Method

Table 8-3 Number of Tests by Method by Family/Drug Grade A Producer October 1, 2006 to September 30, 2007										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive			
BETA lactams										
Charm BSDA Tablet - Beta lactams	9,529	25	7,155	1	16,684	26	0.156%			
Charm I/Cowside II Tablet - Beta lactams	1	0	35	0	36	0	0.000%			
Charm II Tablet Competitive	600	0	0	0	600	0	0.000%			
Charm II Tablet Sequential	0	0	2,543	0	2,543	0	0.000%			
Charm SL Beta lactams	5,448	25	2,016	5	7,464	30	0.402%			
Charm SL-6	3,215	9	38	0	3,253	9	0.277%			
Delvotest P 5 Pack - Beta lactams	335,588	355	133,624	112	469,212	467	0.100%			
Delvotest P/Delvotest P Mini	15,657	23	4,319	0	19,976	23	0.115%			
Delvotest SP/Delvotest SP Mini	624	0	0	0	624	0	0.000%			
Idexx New Snap	7,477	4	314	0	7,791	4	0.051%			
Penzyme Milk Test - Beta lactams	41	0	0	0	41	0	0.000%			
SULFONAMIDES										
Agri-Screen for Sulfonamides ^{**, ***}	48	0	0	0	48	0	0.000%			
Charm II Tablet Competitive	600	0	73	0	673	0	0.000%			
TETRACYCLINES										
Charm II Tablet Competitive	0	0	7	0	7	0	0.000%			
TOTALS	378,828	441	150,124	118	528,952	559	0.106%			

** Non-Validated Test Method *** FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

	Table 8-4 Number of Tests by Method by Family/Drug Grade A Other (milk from silos, over-the-road tankers, etc.) October 1, 2006 to September 30, 2007										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive				
AMPHENICOLS											
Charm II Tablet Competitive	0	0	1	0	1	0	0.000%				
BETA lactams											
Charm BSDA Tablet - Beta lactams	1,461	0	171	0	1,632	0	0.000%				
Charm I/Cowside II Tablet - Beta lactams	0	0	11	0	11	0	0.000%				
Charm II Tablet Competitive	442	0	0	0	442	0	0.000%				
Charm II Tablet Quantitative	0	0	18	0	18	0	0.000%				
Charm II Tablet Sequential	3,927	0	70	0	3,997	0	0.000%				
Charm SL Beta lactams	45,101	8	639	0	45,740	8	0.017%				
Charm SL-6	128	0	141	0	269	0	0.000%				
Delvotest P 5 Pack - Beta lactams	2,145	0	5,642	0	7,787	0	0.000%				
Delvotest P/Delvotest P Mini	419	0	53	0	472	0	0.000%				
Delvotest SP/Delvotest SP Mini	0	0	27	0	27	0	0.000%				
Idexx New Snap	6,977	3	177	0	7,154	3	0.042%				
Parallux Cillins Assay	95	0	0	0	95	0	0.000%				
SULFONAMIDES											
Charm II Tablet Competitive	9	0	258	0	267	0	0.000%				
SULFAMETHAZINE											
Charm SL - Sulfamethazine ^{**}	128	0	0	0	128	0	0.000%				

Table 8-4 Number of Tests by Method by Family/DrugGrade A Other (milk from silos, over-the-road tankers, etc.)October 1, 2006 to September 30, 2007								
Tests Used by Family/Drug	ed by Family/Drug Number of Number of Industry Of Positive Tests Positive Tests Test							
TETRACYCLINES								
Snap - Tetracyclines**	1,161	0	0	0	1,161	0	0.000%	
TOTALS	61,993	11	7,208	0	69,201	11	0.016%	

** Non-Validated Test Method

Table 8-5 Number of Tests by Method by Family/DrugNon-Grade A Bulk Milk Pick-up TankerOctober 1, 2006 to September 30, 2007										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive			
BETA lactams										
Charm BSDA Tablet - Beta lactams	214	0	0	0	214	0	0.000%			
Charm SL Beta lactams	171,409	63	639	1	172,048	64	0.037%			
Delvotest P 5 Pack - Beta lactams	9,956	2	513	0	10,469	2	0.019%			
Idexx New Snap	26,993	21	169	0	27,162	21	0.077%			
Penzyme Milk Test - Beta lactams	361	1	0	0	361	1	0.277%			
SULFONAMIDES										
Charm II Tablet Sequential ^{**}	121	0	0	0	121	0	0.000%			
TOTALS	209,054	87	1,321	1	210,375	88	0.042%			

** Non-Validated Test Method

Table 8-6 Number of Tests by Method by Family/Drug Non-Grade A Pasteurized Fluid Milk and Milk Products October 1, 2006 to September 30, 2007									
Tests Used by Family/DrugNumber of IndustryNumber of ofNumber of RegulatoryNumber of PositiveTotal TestsTotal PositivePercent 									
BETA lactams									
Delvotest P 5 Pack - Beta lactams	1,471	0	307	0	1,778	0	0.000%		
TOTALS	1,471	0	307	0	1,778	0	0.000%		

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Table 8-7 Number of Tests by Method by Family/Drug Non-Grade A Producer October 1, 2006 to September 30, 2007										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive			
BETA lactams										
Charm BSDA Tablet - Beta lactams	2,939	11	5,555	0	8,494	11	0.130%			
Charm SL Beta lactams	867	0	45	0	912	0	0.000%			
Charm SL-6	225	1	0	0	225	1	0.444%			
Delvotest P 5 Pack - Beta lactams	29,999	48	3,372	1	33,371	49	0.147%			
Delvotest P/Delvotest P Mini	27	0	0	0	27	0	0.000%			
Delvotest SP/Delvotest SP Mini	13	0	0	0	13	0	0.000%			
Idexx New Snap	26	0	9	0	35	0	0.000%			
TOTALS	34,096	60	8,981	1	43,077	61	0.142%			

Table 8-8 Number of Tests by Method by Family/Drug Non-Grade A Other (milk from silos, over-the-road tankers, etc.) October 1, 2006 to September 30, 2007									
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive		
BETA lactams									
Charm SL Beta lactams	13,510	0	50	0	13,560	0	0.000%		
Charm SL-6	0	0	5	0	5	0	0.000%		
Delvotest P 5 Pack - Beta lactams	1,992	0	328	0	2,320	0	0.000%		
Delvotest SP/Delvotest SP Mini	41	0	0	0	41	0	0.000%		
Idexx New Snap	217	0	0	0	217	0	0.000%		
TOTALS	15,760	0	383	0	16,143	0	0.000%		