NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2011 ANNUAL REPORT October 1, 2010 - September 30, 2011

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NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2011 ANNUAL REPORT October 1, 2010 - September 30, 2011

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 the 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 drug 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: www.kandc-sbcc.com/nmdrd/. Forty-seven (47) data reporters utilized the web-based software to submit all or part of their data for the FY 2011 Annual Report.

At the request of one of the attendees at a meeting of the NCIMS, the contractor converted all of 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/. All of the Annual Reports are now available in portable document file (pdf), Microsoft Excel and Open Document Spreadsheet (ods) formats.

On May 1, 2011, contractor staff made a presentation to forty-one (41) attendees of the NCIMS meeting in Baltimore, Maryland, addressing the Annual Reports for FY 2009 and 2010, and the web-based reporting application. This included a demonstration of the software and a "real-time" opportunity for participants to use the application.

SUMMARY

This report presents summary data on samples and tests conducted during Fiscal Year 2011 (October 1, 2010 to September 30, 2011). All fifty (50) States and Puerto Rico submitted data for this report. We appreciate all the data provider's cooperation for this fiscal year's report.

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

During this period **3,787,251** samples were analyzed for animal drug residues. Of these samples **1,079** were positive for a drug residue. A total of **3,796,684** tests were reported on the samples for eight (8) different groups of families or individual drugs. Twenty-six (26) testing methods were used to analyze the samples for drug 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 pickup 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. Other 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.

The <u>DISPOSITION</u> per <u>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 <u>PMO</u> and/or applicable State regulations.

TABLE 1 Sample Results October 1, 2010 to September 30, 2011							
Source of Sample	Total Samples	Number Positive	Percent Positive	Disposition per PMO (Pounds)			
Bulk Milk Pick-Up Tanker	3,182,972	671	0.021%	26,874,000			
Pasteurized Fluid Milk and Milk Products	48,566	0	0.000%	0			
Producer	478,533	395	0.083%	952,000			
Other	77,180	13	0.017%	348,000			
TOTALS	3,787,251	1,079	*	28,174,000			

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 at a milk receiving facility;
- 2. <u>Pasteurized Fluid Milk and Milk Products</u> -- a minimum of four samples in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, must be tested for each finished milk or milk product from each plant during any consecutive six months;
- 3. <u>Producer</u> -- each producer must be tested at least four times in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, during any consecutive six months; and
- 4. Other -- samples are conducted on a random basis.

Table 2 presents these results in greater detail and indicates 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, 2010 to September 30, 2011

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	3,030,009	624	7,574	0	3,037,583	624	0.021%	24,979,000
Pasteurized Fluid Milk and Milk Products	4,442	0	42,668	0	47,110	0	0.000%	0
Producer	342,855	294	109,499	71	452,354	365	0.081%	952,000
Other	47,454	9	23,018	4	70,472	13	0.018%	348,000
NON-GRADE A								
Bulk Milk Pick-Up Tanker	145,378	47	11	0	145,389	47	0.032%	1,895,000
Pasteurized Fluid Milk and Milk Products	1,427	0	29	0	1,456	0	0.000%	0
Producer	25,827	28	352	2	26,179	30	0.115%	0
Other	6,612	0	96	0	6,708	0	0.000%	0
TOTALS	3,604,004	1,002	183,247	77	3,787,251	1,079	*	28,174,000²

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 0.014 % of the total milk supply of the United States with an annual production of 195.0 billion pounds.

^{*}See Table 1 for explanation

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 tests conducted (3,796,684) is greater than the number of samples (3,787,251). To avoid duplicate reporting of samples, the number of samples analyzed is reported separately from the number of tests run in the data base.

Table 3 presents summary results of the number of tests which were conducted during October 1, 2010 to September 30, 2011. 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 by FDA in accordance with the standards established for the evaluation of these types of tests and found acceptable by the NCIMS in accordance with Appendix N of the PMO. 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 Conducted by Sample Sources October 1, 2010 to September 30, 2011							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,190,984	671	0.021%				
Pasteurized Fluid Milk and Milk Products	48,776	0	0.000%				
Producer	478,795	399	0.083%				
Other	78,129	13	0.017%				
TOTALS	3,796,684	1,083	*				

^{*} See Table 1 for explanation

TABLE 3A Validated Tests Conducted October 1, 2010 to September 30, 2011							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,164,661	653	0.021%				
Pasteurized Fluid Milk and Milk Products	48,730	0	0.000%				
Producer	478,242	399	0.083%				
Other	77,111	13	0.017%				
TOTALS	3,768,744	1,065	*				

^{*} See Table 1 for explanation

TABLE 3B Non-Validated Tests Conducted October 1, 2010 to September 30, 2011							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	26,323	18	0.068%				
Pasteurized Fluid Milk and Milk Products	46	0	0.000%				
Producer	553	0	0.000%				
Other	1,018	0	0.000%				
TOTALS	27,940	18	*				

^{*} See Table 1 for explanation

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 Agencies October 1, 2010 to September 30, 2011							
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	3,037,920	624	7,674	0	3,045,594	624	0.020%
Pasteurized Fluid Milk and Milk Products	4,442	0	42,878	0	47,320	0	0.000%
Producer	342,891	298	109,723	71	452,614	369	0.082%
Other	48,102	9	23,046	4	71,148	13	0.018%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	145,379	47	11	0	145,390	47	0.032%
Pasteurized Fluid Milk and Milk Products	1,427	0	29	0	1,456	0	0.000%
Producer	25,828	28	353	2	26,181	30	0.115%
Other	6,885	0	96	0	6,981	0	0.000%
TOTALS	3,612,874	1,006	183,810	77	3,796,684	1,083	*

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".

^{*} See Table 1 for explanation

TABLE 4A Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2010 to September 30, 2011							
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	3,012,106	606	7,165	0	3,019,271	606	0.020%
Pasteurized Fluid Milk and Milk Products	4,436	0	42,838	0	47,274	0	0.000%
Producer	342,891	298	109,170	71	452,061	369	0.082%
Other	47,176	9	22,954	4	70,130	13	0.019%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	145,379	47	11	0	145,390	47	0.032%
Pasteurized Fluid Milk and Milk Products	1,427	0	29	0	1,456	0	0.000%
Producer	25,828	28	353	2	26,181	30	0.115%
Other	6,885	0	96	0	6,981	0	0.000%
TOTALS	3,586,128	988	182,616	77	3,768,744	1,065	*

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".

* See Table 1 for explanation

TABLE 4B Non-Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2010 to September 30, 2011							
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	25,814	18	509	0	26,323	18	0.068%
Pasteurized Fluid Milk and Milk Products	6	0	40	0	46	0	0.000%
Producer	0	0	553	0	553	0	0.000%
Other	926	0	92	0	1,018	0	0.000%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	0	0	0	0	0	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	26,746	18	1,194	0	27,940	18	*

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".

^{*} See Table 1 for explanation

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/Drug October 1, 2010 to September 30, 2011						
Family/Drug		Total Tests	Total Positive			
AMINOGLYCOSIDES		36	0			
BETA lactams		3,748,809	1,061			
CLOXACILLIN		102	0			
ENROFLOXACIN		776	1			
MACROLIDES		362	0			
SULFONAMIDES		24,755	5			
SULFAMETHAZINE		11,686	4			
TETRACYCLINES		10,158	12			
TOTALS	-	3,796,684	1,083			

TABLE 5A -- Number of Validated Tests Conducted by Family/Drug October 1, 2010 to September 30, 2011

Family/Drug	Total Tests	Total Positive
BETA lactams	3,748,809	1,061
CLOXACILLIN	102	0
SULFONAMIDES	19,750	4
TETRACYCLINES	83	0
TOTALS	3,768,744	1,065

TABLE 5B -- Number of Non-Validated Tests Conducted by Family/Drug October 1, 2010 to September 30, 2011

Family/Drug	Total Tests	Total Positive
AMINOGLYCOSIDES	36	0
ENROFLOXACIN	776	1
MACROLIDES	362	0
SULFONAMIDES	5,005	1
SULFAMETHAZINE	11,686	4
TETRACYCLINES	10,075	12
TOTALS	27,940	18

Table 6 presents details on the tests used. The data in this Table are comparable to Table 5, but the data are arranged by tests within each family/drug. 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 2.3 million times, Delvotest P 5 Pack - Beta lactams which was used more than 482 thousand times, Idexx New Snap which was used more than 221 thousand times and Charm 3 SL-3 Beta lactams which was used for more than 203 thousand tests. Table 6A shows a comparison of tests conducted using Validated and Non-Validated test methods for Sulfonamides and Tetracyclines.

TABLE 6 Number of Tests by Method by Family/Drug October 1, 2010 to September 30, 2011									
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive						
AMINOGLYCOSIDES									
Charm II Tablet Competitive Aminoglycosides**	36	0	0.000%						
BETA lactams									
Charm 3 SL-3	203,084	31	0.015%						
Charm BSDA Tablet - Beta lactams	29,673	26	0.088%						
Charm II Tablet Competitive	158,759	31	0.020%						
Charm II Tablet Quantitative	48	0	0.000%						
Charm II Tablet Sequential	94,421	27	0.029%						
Charm SL Beta lactams	2,326,910	411	0.018%						
Charm SL-6	170,126	55	0.032%						
Delvotest P 5 Pack - Beta lactams	482,669	358	0.074%						
Delvotest P/Delvotest P Mini	60,179	15	0.025%						
Delvotest SP/Delvotest SP Mini	111	0	0.000%						
Green Book Micro - Beta lactams	1,291	1	0.077%						
Idexx New Snap	221,074	106	0.048%						
Neogen BetaStar	464	0	0.000%						
CLOXACILLIN									
Charm II Test for Cloxacillin in Milk	102	0	0.000%						
ENROFLOXACIN									
Charm SL-Floroquinlone**	776	1	0.129%						
MACROLIDES									
Charm II Tablet Competitive - Macrolides**	47	0	0.000%						
Charm II Tablet Sequential - Macrolides**	315	0	0.000%						

TABLE 6 Number of Tests by Method by Family/Drug October 1, 2010 to September 30, 2011											
SULFONAMIDES											
Agri-Screen for Sulfonamides** & ***	936	0	0.000%								
Charm II Tablet Competitive	19,260	3	0.016%								
Charm II Tablet Sequential**	4,069	1	0.025%								
TLC Sulfonamide	490	1	0.204%								
SULFAMETHAZINE											
Charm SL - Sulfamethazine**	11,686	4	0.034%								
TETRACYCLINES											
Charm II Tablet Competitive	83	0	0.000%								
Charm SL - Tetracyclines**	915	0	0.000%								
Snap - Tetracyclines**	9,160	12	0.131%								
TOTALS	3,796,684	3,796,684	*								

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".

*** Non-Validated Test Method

 $^{^{\}ast\ast\ast}$ FDA evaluated these tests and they do not perform as labeled-see M-I -99-4

TABLE 6A -- Comparison of Validated and Non-Validated Tests for Sulfonamides and Tetracyclines October 1, 2010 to September 30, 2011

Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive
VALIDATED FOR SULFONAMIDES			
Charm II Tablet Competitive	19,260	3	0.016%
TLC Sulfonamide	490	1	0.204%
NON-VALIDATED FOR SULFONAMIDES			
Agri-Screen for Sulfonamides** & ***	936	0	0.000%
Charm II Tablet Sequential**	4,069	1	0.025%
NON-VALIDATED FOR SULFAMETHAZINE			
Charm SL - Sulfamethazine**	11,686	4	0.034%
VALIDATED FOR TETRACYCLINES			
Charm II Tablet Competitive	83	0	0.000%
NON-VALIDATED FOR TETRACYCLINES			
Charm SL - Tetracyclines**	915	0	0.000%
Snap - Tetracyclines**	9,160	12	0.131%
TOTALS	46,599	46,599	*

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".

^{**} Non-Validated Test Method

 $^{^{\}ast\ast\ast}$ 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 Testing October 1, 2010 to September 30, 2011										
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				
BETA lactams	2,993,215	602	7,049	0	3,000,264	602				
Cloxacillin	0	0	75	0	75	0				
ENROFLOXACIN	776	1	0	0	776	1				
MACROLIDES	256	0	0	0	256	0				
SULFONAMIDES	23,175	5	41	0	23,216	5				
Sulfamethazine	11,412	4	0	0	11,412	4				
TETRACYCLINES	9,050	12	509	0	9,559	12				
TOTALS	3,037,920	624	7,674	0	3,045,594	624				

TABLE 7-2 Grade A Pasteurized Fluid Milk and Milk Products Testing October 1, 2010 to September 30, 2011									
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	4,298	0	42,838	0	47,136	0			
SULFONAMIDES	138	0	0	0	138	0			
TETRACYCLINES	6	0	40	0	46	0			
TOTALS	4,442	0	42,878	0	47,320	0			

TABLE 7-3 Grade A Producer Testing October 1, 2010 to September 30, 2011									
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	342,346	298	109,106	71	451,452	369			
MACROLIDES	0	0	6	0	6	0			
SULFONAMIDES	545	0	610	0	1,155	0			
TETRACYCLINES	0	0	1	0	1	0			
TOTALS	342,891	298	109,723	71	452,614	369			

TABLE 7-4 Grade A Other Testing (Milk from silos, over-the-road tankers, etc.) October 1, 2010 to September 30, 2011										
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	47,167	9	22,782	4	69,949	13				
Cloxacillin	0	0	27	0	27	0				
MACROLIDES	100	0	0	0	100	0				
SULFONAMIDES	9	0	237	0	246	0				
Sulfamethazine	274	0	0	0	274	0				
TETRACYCLINES	552	0	0	0	552	0				
TOTALS	48,102	9	23,046	4	71,148	13				

TABLE 7-5 Non-Grade A Bulk Milk Pick-Up Tanker Testing October 1, 2010 to September 30, 2011								
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	145,379	47	11	0	145,390	47		
TOTALS	145,379	47	11	0	145,390	47		

TABLE 7-6 Non-Grade A Pasteurized Fluid Milk and Milk Products Testing October 1, 2010 to September 30, 2011							
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	1,427	0	29	0	1,456	0	
TOTALS	1,427	0	29	0	1,456	0	

TABLE 7-7 Non-Grade A Producer Testing October 1, 2010 to September 30, 2011								
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	25,828	28	353	2	26,181	30		
TOTALS	25,828	28	353	2	26,181	30		

TABLE 7-8 Non-Grade A Other Testing (Milk from silos, over-the-road tankers, etc.) October 1, 2010 to September 30, 2011								
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	6,885	0	96	0	6,981	0		
TOTALS	6,885	0	96	0	6,981	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.

Tabl	Table 8-1 Number of Tests by Method by Family/Drug for Grade A Bulk Milk Pick-Up Tanker Testing October 1, 2010 to September 30, 2011									
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					1					
Charm II Tablet Competitive Aminoglycosides**	36	0	0	0	36	0	0.000%			
BETA lactams										
Charm 3 SL-3	196,090	29	0	0	196,090	29	0.015%			
Charm BSDA Tablet - Beta lactams	12,992	11	0	0	12,992	11	0.085%			
Charm II Tablet Competitive	154,606	29	2	0	154,608	29	0.019%			
Charm II Tablet Quantitative	0	0	48	0	48	0	0.000%			
Charm II Tablet Sequential	89,336	27	89	0	89,425	27	0.030%			
Charm SL Beta lactams	2,148,867	358	1,092	0	2,149,95 9	358	0.017%			
Charm SL-6	160,583	50	42	0	160,625	50	0.031%			
Delvotest P 5 Pack - Beta lactams	19,408	5	4,428	0	23,836	5	0.021%			
Delvotest P/Delvotest P Mini	5,496	0	1,305	0	6,801	0	0.000%			
Green Book Micro - Beta lactams	1,259	1	0	0	1,259	1	0.079%			
Idexx New Snap	204,143	92	43	0	204,186	92	0.045%			
Neogen BetaStar	435	0	0	0	435	0	0.000%			
Cloxacillin										
Charm II Test for Cloxacillin in Milk	0	0	75	0	75	0	0.000%			

Table 8-1 -- Number of Tests by Method by Family/Drug for Grade A Bulk Milk Pick-Up Tanker Testing October 1, 2010 to September 30, 2011

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
Enrofloxacin							
Charm SL- Floroquinlone**	776	1	0	0	776	1	0.129%
Macrolides							
Charm II Tablet Competitive - Macrolides**	47	0	0	0	47	0	0.000%
Charm II Tablet Sequential - Macrolides**	209	0	0	0	209	0	0.000%
Sulfonamides							
Agri-Screen for Sulfonamides** & ***	390	0	0	0	390	0	0.000%
Charm II Tablet Competitive	18,318	3	41	0	18,359	3	0.016%
Charm II Tablet Sequential**	3,977	1	0	0	3,977	1	0.025%
TLC Sulfonamide	490	1	0	0	490	1	0.204%
Sulfamethazine							
Charm SL - Sulfamethazine**	11,412	4	0	0	11,412	4	0.035%
Tetracyclines							
Charm II Tablet Competitive	83	0	0	0	83	0	0.000%
Charm SL - Tetracyclines**	914	0	0	0	914	0	0.000%
Snap - Tetracyclines**	8,053	12	509	0	8,562	12	0.140%
TOTALS	3,037,920	624	7,674	0	3,037,92 0	624	0.021%

^{***} 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 for Grade A Pasteurized Fluid Milk and Milk Products Testing October 1, 2010 to September 30, 2011

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	392	0	1,483	0	1,875	0	0.000%
Charm II Tablet Sequential	0	0	471	0	471	0	0.000%
Charm SL Beta lactams	197	0	477	0	674	0	0.000%
Charm SL-6	1,618	0	443	0	2,061	0	0.000%
Delvotest P 5 Pack - Beta lactams	2,047	0	31,509	0	33,556	0	0.000%
Delvotest P/Delvotest P Mini	0	0	7,589	0	7,589	0	0.000%
Idexx New Snap	44	0	866	0	910	0	0.000%
Sulfonamides							
Charm II Tablet Competitive	138	0	0	0	138	0	0.000%
Tetracyclines							
Snap - Tetracyclines**	6	0	40	0	46	0	0.000%
TOTALS	4,442	0	42,878	0	4,442	0	0.000%

^{**} Non-Validated Test Method

Table 8-3 -- Number of Tests by Method by Family/Drug for Grade A Producer Testing October 1, 2010 to September 30, 2011

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 3 SL-3	367	0	0	0	367	0	0.000%
Charm BSDA Tablet - Beta lactams	8,279	13	2,487	2	10,766	15	0.139%
Charm II Tablet Competitive	1,009	0	76	0	1,085	0	0.000%
Charm II Tablet Sequential	0	0	1,914	0	1,914	0	0.000%
Charm SL Beta lactams	7,021	8	1,123	0	8,144	8	0.098%
Charm SL-6	4,541	5	672	0	5,213	5	0.096%
Delvotest P 5 Pack - Beta lactams	304,654	258	76,159	61	380,813	319	0.084%
Delvotest P/Delvotest P Mini	11,744	10	23,175	5	34,919	15	0.043%
Idexx New Snap	4,731	4	3,500	3	8,231	7	0.085%
Macrolides							
Charm II Tablet Sequential - Macrolides**	0	0	6	0	6	0	0.000%
Sulfonamides							
Agri-Screen for Sulfonamides** & ***	0	0	546	0	546	0	0.000%
Charm II Tablet Competitive	545	0	64	0	609	0	0.000%
Tetracyclines							
Charm SL - Tetracyclines**	0	0	1	0	1	0	0.000%
TOTALS	342,891	298	109,723	71	342,891	298	0.087%

^{**} Non-Validated Test Method

 $^{^{\}ast\ast\ast}$ 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 for Grade A Other Testing (Milk from silos, over-the-road tankers, etc.) October 1, 2010 to September 30, 2011

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 3 SL-3	103	0	0	0	103	0	0.000%
Charm BSDA Tablet - Beta lactams	2,590	0	404	0	2,994	0	0.000%
Charm II Tablet Competitive	3,066	2	0	0	3,066	2	0.065%
Charm II Tablet Sequential	2,573	0	28	0	2,601	0	0.000%
Charm SL Beta lactams	32,524	5	910	0	33,434	5	0.015%
Charm SL-6	1,953	0	256	0	2,209	0	0.000%
Delvotest P 5 Pack - Beta lactams	1,169	0	10,719	4	11,888	4	0.034%
Delvotest P/Delvotest P Mini	365	0	10,170	0	10,535	0	0.000%
Delvotest SP/Delvotest SP Mini	0	0	111	0	111	0	0.000%
Green Book Micro - Beta lactams	32	0	0	0	32	0	0.000%
Idexx New Snap	2,763	2	184	0	2,947	2	0.068%
Neogen BetaStar	29	0	0	0	29	0	0.000%
Cloxacillin							
Charm II Test for Cloxacillin in Milk	0	0	27	0	27	0	0.000%
Macrolides							
Charm II Tablet Sequential - Macrolides**	100	0	0	0	100	0	0.000%
Sulfonamides							
Charm II Tablet Competitive	9	0	145	0	154	0	0.000%
Charm II Tablet Sequential**	0	0	92	0	92	0	0.000%
Sulfamethazine							
Charm SL - Sulfamethazine**	274	0	0	0	274	0	0.000%

Table 8-4 -- Number of Tests by Method by Family/Drug for Grade A Other Testing (Milk from silos, over-the-road tankers, etc.) October 1, 2010 to September 30, 2011

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
Tetracyclines		1 ests		Tests			
Snap - Tetracyclines**	552	0	0	0	552	0	0.000%
TOTALS	48,102	9	23,046	4	48,102	9	0.019%

^{**} Non-Validated Test Method

Table 8-5 -- Number of Tests by Method by Family/Drug for Non-Grade A Bulk Milk Pick-Up Tanker Testing October 1, 2010 to September 30, 2011

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 3 SL-3	6,524	2	0	0	6,524	2	0.031%
Charm II Tablet Sequential	10	0	0	0	10	0	0.000%
Charm SL Beta lactams	130,227	40	7	0	130,234	40	0.031%
Delvotest P 5 Pack - Beta lactams	3,749	0	4	0	3,753	0	0.000%
Delvotest P/Delvotest P Mini	69	0	0	0	69	0	0.000%
Idexx New Snap	4,800	5	0	0	4,800	5	0.104%
TOTALS	145,379	47	11	0	145,379	47	0.032%

Table 8-6 -- Number of Tests by Method by Family/Drug for Non-Grade A Pasteurized Fluid Milk and Milk Products Testing October 1, 2010 to September 30, 2011

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							
Delvotest P 5 Pack - Beta lactams	1,380	0	29	0	1,409	0	0.000%
Delvotest P/Delvotest P Mini	47	0	0	0	47	0	0.000%
TOTALS	1,427	0	29	0	1,427	0	0.000%

Table 8-7 -- Number of Tests by Method by Family/Drug for Non-Grade A Producer Testing October 1, 2010 to September 30, 2011

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	1,046	0	0	0	1,046	0	0.000%
Charm SL Beta lactams	89	0	0	0	89	0	0.000%
Charm SL-6	7	0	0	0	7	0	0.000%
Delvotest P 5 Pack - Beta lactams	24,672	28	353	2	25,025	30	0.120%
Delvotest P/Delvotest P Mini	14	0	0	0	14	0	0.000%
TOTALS	25,828	28	353	2	25,828	28	0.108%

Table 8-8 -- Number of Tests by Method by Family/Drug for Non-Grade A Other Testing (Milk from silos, over-the-road tankers, etc.) October 1, 2010 to September 30, 2011

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	4,367	0	9	0	4,376	0	0.000%
Charm SL-6	11	0	0	0	11	0	0.000%
Delvotest P 5 Pack - Beta lactams	2,302	0	87	0	2,389	0	0.000%
Delvotest P/Delvotest P Mini	205	0	0	0	205	0	0.000%
TOTALS	6,885	0	96	0	6,885	0	0.000%