NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2009 ANNUAL REPORT

October 1, 2008 - September 30, 2009

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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 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 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/index.html. Forty (40) data reporters utilized the web-based software to submit all or part of their data for the FY 2009 Annual Report.

On April 19, 2009, contractor staff made a presentation at the NCIMS meeting in Orlando, Florida, addressing the Annual Reports for FY 2007 and 2008, 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 the NCIMS meeting, 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. All of the 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 2009 (October 1, 2008 to September 30, 2009). Fifty (50) states or territories submitted data for this report. No data were received from the state Rhode Island.

The Grade "A" Pasteurized Milk Ordinance (PMO), the rules which State Regulatory Agencies use to implement 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 tanker found positive is rejected for human consumption.

During this period **3,958,455** samples were analyzed for animal drug residues. Of these samples **1,387** were positive for a residue. A total of **3,976,814** tests were reported on the samples for **ten** (10) 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 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. 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 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 regulations.

TABLE 1 Sample Results October 1, 2008 to September 30, 2009								
Source of Sample	Total Samples	Number Positive	Percent Positive	Disposition per PMO (Pounds)				
Bulk Milk Pick-Up Tanker	3,311,437	861	0.026%	35,201,000				
Pasteurized Fluid Milk and Milk Products	45,601	0	0.000%	0,000				
Producer	510,760	508	0.099%	2,018,000				
Other	90,657	18	0.020%	427,000				
TOTALS	3,958,455	1,387	*	37,646,000				

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. Bulk Milk Pick-Up Tanker Samples -- samples are taken on receipt of every tanker load;
- 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 product from each milk 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 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, 2008 to September 30, 2009

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	3,082,837	781	11,130	0	3,093,967	781	0.025%	32,140,000
Pasteurized Fluid Milk and Milk Products	3,244	0	40,801	0	44,045	0	0.000%	0,000
Producer	350,257	351	129,899	84	480,156	435	0.091%	2,007,000
Other	72,853	17	7,326	0	80,179	17	0.021%	417,000
NON-GRADE A								
Bulk Milk Pick-Up Tanker ¹	217,229	80	241	0	217,470	80	0.037%	3,061,000
Pasteurized Fluid Milk and Milk Products	1,336	0	220	0	1,556	0	0.000%	0,000
Producer	29,362	73	1,242	0	30,604	73	0.239%	11,000
Other	9,787	1	691	0	10,478	1	0.010%	10,000
TOTALS	3,766,905	1,303	191,550	84	3,958,455	1,387	*	37,646,000 ²

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".

See Table 1 for explanation

²Note that this represents <u>0.020%</u> of the total milk supply of the United States with an annual production of 189.7 billion pounds.

TESTS CONDUCTED

An objective of the NMDRD is to record every test run on each milk or milk product sample analyzed. Since some samples are analyzed for more than one drug residue, the number of <u>tests</u> conducted (3,976,814) is greater than the number of <u>samples</u> (3,958,455). 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, 2008 to September 30, 2009. 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 Conducted October 1, 2008 to September 30, 2009							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,318,609	861	0.026				
Pasteurized Fluid Milk and Milk Products	45,609	0	0.000				
Producer	521,884	511	0.098				
Other	90,712	19	0.021				
TOTALS	3,976,814	1,391	*				

^{*}See Table 1 for explanation

TABLE 3A Validated Tests Conducted October 1, 2008 to September 30, 2009							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,271,716	837	0.026				
Pasteurized Fluid Milk and Milk Products	45,363	0	0.000				
Producer	521,884	511	0.098				
Other	87,765	19	0.022				
TOTALS	3,926,728	1,367	*				

^{*}See Table 1 for explanation

TABLE 3B Non-Validated Tests Conducted October 1, 2008 to September 30, 2009							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	46,893	24	0.051				
Pasteurized Fluid Milk and Milk Products	246	0	0.000				
Producer	0	0	0.000				
Other	2,947	0	0.000				
TOTALS	50,086	24	*				

^{*}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, 2008 to September 30, 2009							
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	3,089,571	781	11,142	0	3,100,713	781	0.025%
Pasteurized Fluid Milk and Milk Products	3,244	0	40,808	0	44,052	0	0.000%
Producer	352,013	351	139,264	87	491,277	438	0.089%
Other	72,853	18	7,380	0	80,233	18	0.022%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	217,655	80	241	0	217,896	80	0.037%
Pasteurized Fluid Milk and Milk Products	1,337	0	220	0	1,557	0	0.000%
Producer	29,365	73	1,242	0	30,607	73	0.239%
Other	9,788	1	691	0	10,479	1	0.010%
TOTALS	3,775,826	1,304	200,988	87	3,976,814	1,391	*

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".

See Table 1 for explanation

TABLE 4A Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2008 to September 30, 2009								
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	3,043,772	757	10,048	0	3,053,820	757	0.025%	
Pasteurized Fluid Milk and Milk Products	3,138	0	40,668	0	43,806	0	0.000%	
Producer	352,013	351	139,264	87	491,277	438	0.089%	
Other	70,065	18	7,221	0	77,286	18	0.023%	
NON-GRADE A								
Bulk Milk Pick-Up Tanker ¹	217,655	80	241	0	217,896	80	0.037%	
Pasteurized Fluid Milk and Milk Products	1,337	0	220	0	1,557	0	0.000%	
Producer	29,365	73	1,242	0	30,607	73	0.239%	
Other	9,788	1	691	0	10,479	1	0.010%	
TOTALS	3,727,133	1,280	199,595	87	3,926,728	1,367	*	

TOTALS

3,727,133

1,280

199,595

87

3,926,728

1,367

*

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"

^{*}See Table 1 for explanation

TABLE 4B Non-Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2008 to September 30, 2009								
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	45,799	24	1,094	0	46,893	24	0.051%	
Pasteurized Fluid Milk and Milk Products	106	0	140	0	246	0	0.000%	
Producer	0	0	0	0	0	0	0.000%	
Other	2,788	0	159	0	2,947	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	48,693	24	1,393	0	50,086	24	*	

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".

^{*}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, 2008 to September 30, 2009					
Family/Drug	Total Tests	Total Positive			
AMINOGLYCOSIDES	36	0			
BETA lactams	3,904,146	1,364			
ENROFLOXACIN	5,151	2			
MACROLIDES	7,837	0			
SULFONAMIDES	22,814	3			
Sulfadimethoxine	1,612	0			
Sulfamethazine	21,467	5			
Sulfanilamide	468	1			
TETRACYCLINES	12,948	16			
Tetracycline	335	0			
TOTALS	3,976,814	1,391			

TABLE 5A Number of Validated Tests Conducted by Family/Drug October 1, 2008 to September 30, 2009						
Family/Drug Total Tests Total Positive						
BETA lactams	3,904,146	1,364				
SULFONAMIDES	19,907	2				
Sulfadimethoxine	1,612	0				
Sulfanilamide	468	1				
TETRACYCLINES	260	0				
Tetracycline	335	0				
TOTALS	3,926,728	1,367				

TABLE 5B -- Number of Non-Validated Tests Conducted by Family/Drug October 1, 2008 to September 30, 2009

Family/Drug	Total Tests	Total Positive
AMINOGLYCOSIDES	36	0
ENROFLOXACIN	5,151	2
MACROLIDES	7,837	0
SULFONAMIDES	2,907	1
Sulfamethazine	21,467	5
TETRACYCLINES	12,688	16
TOTALS	50,086	24

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 <u>2.5 million</u> times, Delvotest P 5 Pack - Beta lactams which was used more than <u>520 thousand</u> times, Idexx New Snap which was used more than <u>253 thousand</u> times and Charm II Tablet Competitive - Beta lactams which was used for more than <u>171 thousand</u> 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, 2008 to September 30, 2009									
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive						
AMINOGLYCOSIDES									
Charm II Tablet Competitive-N**	36	0	0.000%						
BETA lactams									
Charm BSDA Tablet - Beta lactams	41,851	42	0.100%						
Charm II Tablet Competitive	171,444	45	0.026%						
Charm II Tablet Quantitative	759	1	0.132%						
Charm II Tablet Sequential	103,931	34	0.033%						
Charm SL Beta lactams	2,554,779	583	0.023%						
Charm SL-3	53,544	7	0.013%						
Charm SL-6	159,314	80	0.050%						
Delvotest P 5 Pack - Beta lactams	520,286	435	0.084%						
Delvotest P/Delvotest P Mini	39,019	18	0.046%						
Delvotest SP/Delvotest SP Mini	139	0	0.000%						
Idexx New Snap	253,622	119	0.047%						
Lak Tek - Beta lactams	5,458	0	0.000%						
ENROFLOXACIN									
Charm SL-Floroquinlone**	5,151	2	0.039%						
MACROLIDES									
Charm II Tablet Sequential - Macrolides**	7,837	0	0.000%						

TABLE 6 Number of Tests by Method by Family/Drug October 1, 2008 to September 30, 2009								
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive					
SULFONAMIDES								
Agri-Screen for Sulfonamides** & ***	680	1	0.147%					
Charm II Tablet Competitive	19,901	2	0.010%					
Charm II Tablet Sequential**	2,227	0	0.000%					
TLC Sulfonamide	6	0	0.000%					
SULFADIMETHOXINE								
HPLC 8 Sulfonamides - Sulfadimethoxine	1,612	0	0.000%					
SULFAMETHAZINE								
Charm SL - Sulfamethazine**	21,467	5	0.023%					
SULFANILAMIDE								
HPLC 8 Sulfonamides - Sulfanilamide	468	1	0.214%					
TETRACYCLINES								
Charm II Tablet Competitive	260	0	0.000%					
Charm SL - Tetracyclines**	1,460	0	0.000%					
Snap - Tetracyclines**	11,228	16	0.143%					
TETRACYCLINE								
HPLC Tetracyclines - Tetracycline	335	0	0.000%					
TOTALS	3,976,814	1,391	*					

^{*} 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

TABLE 6A -- Comparison of Validated and Non-Validated Tests for Sulfonamides and Tetracyclines October 1, 2008 to September 30, 2009

Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive
VALIDATED FOR SULFONAMIDES			
Charm II Tablet Competitive	19,901	2	0.010%
TLC Sulfonamide	6	0	0.000%
VALIDATED FOR SULFADIMETHOXINE			
HPLC 8 Sulfonamides - Sulfadimethoxine	1,612	0	0.000%
VALIDATED FOR SULFANILAMIDE			
HPLC 8 Sulfonamides - Sulfanilamide	468	1	0.214%
NON-VALIDATED FOR SULFONAMIDES			
Agri-Screen for Sulfonamides** & ***	680	1	0.147%
Charm II Tablet Sequential**	2,227	0	0.000%
NON-VALIDATED FOR SULFAMETHAZINE			
Charm SL - Sulfamethazine**	21,467	5	0.023%
VALIDATED FOR TETRACYCLINES			
Charm II Tablet Competitive	260	0	0.000%
VALIDATED FOR TETRACYCLINE			
HPLC Tetracyclines - Tetracycline	335	0	0.000%
NON-VALIDATED FOR TETRACYCLINES			
Charm SL - Tetracyclines**	1,460	0	0.000%
Snap - Tetracyclines**	11,228	16	0.143%
TOTALS	59,644	25	*

^{*} 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

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., 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, 2008 to September 30, 2009									
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	3,022,054	754	10,037	0	3,032,091	754			
ENROFLOXACIN	5,151	2	0	0	5,151	2			
MACROLIDES	7,837	0	0	0	7,837	0			
SULFONAMIDES	21,906	3	11	0	21,917	3			
Sulfadimethoxine	1,612	0	0	0	1,612	0			
Sulfamethazine	20,931	5	20	0	20,951	5			
Sulfanilamide	468	1	0	0	468	1			
TETRACYCLINES	9,241	16	1,074	0	10,315	16			
Tetracycline	335	0	0	0	335	0			
TOTALS	3,089,571	781	11,142	0	3,100,713	781			

TABLE 7-2 Grade A Pasteurized Fluid Milk and Milk Products Testing October 1, 2008 to September 30, 2009								
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	2,998	0	40,668	0	43,666	0		
SULFONAMIDES	140	0	48	0	188	0		
Sulfamethazine	106	0	0	0	106	0		
TETRACYCLINES	0	0	92	0	92	0		
TOTALS	3,244	0	40,808	0	44,052	0		

TABLE 7-3 Grade A Producer Testing October 1, 2008 to September 30, 2009									
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	351,413	351	139,203	87	490,616	438			
SULFONAMIDES	600	0	57	0	657	0			
TETRACYCLINES	0	0	4	0	4	0			
TOTALS	352,013	351	139,264	87	491,277	438			

TABLE 7-4 Grade A Other Testing (milk from silos, over-the-road tankers, etc.) October 1, 2008 to September 30, 2009								
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	70,055	18	7,179	0	77,234	18		
SULFONAMIDES	10	0	42	0	52	0		
Sulfamethazine	251	0	159	0	410	0		
TETRACYCLINES	2,537	0	0	0	2,537	0		
TOTALS	72,853	18	7,380	0	80,233	18		

TABLE 7-5 Non-Grade A Bulk Milk Pick-Up Tanker Testing October 1, 2008 to September 30, 2009							
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	217,655	80	241	0	217,896	80	
TOTALS	217,655	80	241	0	217,896	80	

TABLE 7-6 Non-Grade A Pasteurized Fluid Milk and Milk Products Testing October 1, 2008 to September 30, 2009								
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 TOTALS	1,337	0	220	0	1,557 1,557	0		

TABLE 7-7 Non-Grade A Producer Testing October 1, 2008 to September 30, 2009								
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	29,365	73	1,242	0	30,607	73		
TOTALS	29,365	73	1,242	0	30,607	73		

TABLE 7-8 Non-Grade A Other Testing (milk from silos, over-the-road tankers, etc.) October 1, 2008 to September 30, 2009								
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	9,788	1	691	0	10,479	1		
TOTALS	9,788	1	691	0	10,479	1		

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.

Table 8-1 Number of Tests by Method by Family/Drug Grade A Bulk Milk Pick-Up Tanker October 1, 2008 to September 30, 2009									
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%		
BETA lactams									
Charm BSDA Tablet - Beta lactams	22,055	15	2	0	22,057	15	0.068%		
Charm II Tablet Competitive	169,180	45	4	0	169,184	45	0.027%		
Charm II Tablet Quantitative	505	1	52	0	557	1	0.180%		
Charm II Tablet Sequential	97,965	33	114	0	98,079	33	0.034%		
Charm SL Beta lactams	2,290,672	488	2,478	0	2,293,150	488	0.021%		
Charm SL-3	49,836	6	5	0	49,841	6	0.012%		
Charm SL-6	150,051	60	11	0	150,062	60	0.040%		
Delvotest P 5 Pack - Beta lactams	17,907	9	4,412	0	22,319	9	0.040%		
Delvotest P/Delvotest P Mini	3,125	2	2,336	0	5,461	2	0.037%		
Delvotest SP/Delvotest SP Mini	75	0	0	0	75	0	0.000%		
Idexx New Snap	215,225	95	623	0	215,848	95	0.044%		
Lak Tek - Beta lactams	5,458	0	0	0	5,458	0	0.000%		
ENROFLOXACIN									
Charm SL-Floroquinlone**	5,151	2	0	0	5,151	2	0.039%		
MACROLIDES									
Charm II Tablet Sequential - Macrolides**	7,837	0	0	0	7,837	0	0.000%		

Table 8-1 -- Number of Tests by Method by Family/Drug Grade A Bulk Milk Pick-Up Tanker October 1, 2008 to September 30, 2009

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
SULFONAMIDES							
Agri-Screen for Sulfonamides** & ***	632	1	0	0	632	1	0.158%
Charm II Tablet Competitive	19,047	2	11	0	19,058	2	0.010%
Charm II Tablet Sequential**	2,227	0	0	0	2,227	0	0.000%
SULFADIMETHOXINE							
HPLC 8 Sulfonamides - Sulfadimethoxine	1,612	0	0	0	1,612	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	20,931	5	20	0	20,951	5	0.024%
SULFANILAMIDE							
HPLC 8 Sulfonamides - Sulfanilamide	468	1	0	0	468	1	0.214%
TETRACYCLINES							
Charm II Tablet Competitive	256	0	0	0	256	0	0.000%
Charm SL - Tetracyclines**	1,155	0	0	0	1,155	0	0.000%
Snap - Tetracyclines**	7,830	16	1,074	0	8,904	16	0.180%
TETRACYCLINE							
HPLC Tetracyclines - Tetracycline	335	0	0	0	335	0	0.000%
TOTALS	3,089,571	781	11,142	0	3,100,713	781	0.025%

^{**} 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, 2008 to September 30, 2009

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	424	0	1,689	0	2,113	0	0.000%
Charm II Tablet Sequential	0	0	711	0	711	0	0.000%
Charm SL Beta lactams	49	0	662	0	711	0	0.000%
Charm SL-6	772	0	0	0	772	0	0.000%
Delvotest P 5 Pack - Beta lactams	1,717	0	34,136	0	35,853	0	0.000%
Delvotest P/Delvotest P Mini	0	0	2,703	0	2,703	0	0.000%
Idexx New Snap	36	0	767	0	803	0	0.000%
SULFONAMIDES							
Agri-Screen for Sulfonamides***&***	0	0	48	0	48	0	0.000%
Charm II Tablet Competitive	140	0	0	0	140	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	106	0	0	0	106	0	0.000%
TETRACYCLINES							
Snap - Tetracyclines**	0	0	92	0	92	0	0.000%
TOTALS	3,244	0	40,808	0	44,052	0	0.000%

^{**} Non-Validated Test Method

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

Table 8-3 -- Number of Tests by Method by Family/Drug Grade A Producer October 1, 2008 to September 30, 2009

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	9,415	19	5,158	1	14,573	20	0.137%
Charm II Tablet Competitive	600	0	517	0	1,117	0	0.000%
Charm II Tablet Sequential	0	0	1,862	0	1,862	0	0.000%
Charm SL Beta lactams	12,652	18	10,628	3	23,280	21	0.090%
Charm SL-6	5,106	18	0	0	5,106	18	0.353%
Delvotest P 5 Pack - Beta lactams	304,482	281	104,718	76	409,200	357	0.087%
Delvotest P/Delvotest P Mini	14,244	10	16,012	6	30,256	16	0.053%
Idexx New Snap	4,914	5	308	1	5,222	6	0.115%
SULFONAMIDES							
Charm II Tablet Competitive	600	0	57	0	657	0	0.000%
TETRACYCLINES							
Charm II Tablet Competitive	0	0	4	0	4	0	0.000%
TOTALS	352,013	351	139,264	87	491,277	438	0.089%

Table 8-4 -- Number of Tests by Method by Family/Drug Grade A Other (milk from silos, over-the-road tankers, etc.) October 1, 2008 to September 30, 2009

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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	1,054	0	199	0	1,253	0	0.000%
Charm II Tablet Competitive	1,041	0	0	0	1,041	0	0.000%
Charm II Tablet Quantitative	179	0	0	0	179	0	0.000%
Charm II Tablet Sequential	3,200	1	79	0	3,279	1	0.030%
Charm SL Beta lactams	44,671	4	481	0	45,152	4	0.009%
Charm SL-3	99	0	0	0	99	0	0.000%
Charm SL-6	3,369	2	1	0	3,370	2	0.059%
Delvotest P 5 Pack - Beta lactams	1,665	0	6,169	0	7,834	0	0.000%
Delvotest P/Delvotest P Mini	393	0	63	0	456	0	0.000%
Delvotest SP/Delvotest SP Mini	21	0	0	0	21	0	0.000%
Idexx New Snap	14,363	11	187	0	14,550	11	0.076%
SULFONAMIDES							
Charm II Tablet Competitive	10	0	36	0	46	0	0.000%
TLC Sulfonamide	0	0	6	0	6	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	251	0	159	0	410	0	0.000%
TETRACYCLINES							
Charm SL - Tetracyclines**	305	0	0	0	305	0	0.000%
Snap - Tetracyclines**	2,232	0	0	0	2,232	0	0.000%
TOTALS	72,853	18	7,380	0	80,233	18	0.022%

^{**} Non-Validated Test Method

Table 8-5 -- Number of Tests by Method by Family/Drug Non-Grade A Bulk Milk Pick-Up Tanker October 1, 2008 to September 30, 2009

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	102	0	0	0	102	0	0.000%
Charm II Tablet Competitive	102	0	0	0	102	0	0.000%
Charm II Tablet Quantitative	23	0	0	0	23	0	0.000%
Charm SL Beta lactams	184,045	69	234	0	184,279	69	0.037%
Charm SL-3	3,604	1	0	0	3,604	1	0.028%
Delvotest P 5 Pack - Beta lactams	12,591	3	7	0	12,598	3	0.024%
Delvotest P/Delvotest P Mini	39	0	0	0	39	0	0.000%
Idexx New Snap	17,149	7	0	0	17,149	7	0.041%
TOTALS	217,655	80	241	0	217,896	80	0.037%

Table 8-6 Number of Tests by Method by Family/Drug Non-Grade A Pasteurized Fluid Milk and Milk Products October 1, 2008 to September 30, 2009								
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	1,337	0	220	0	1,557	0	0.000%	
TOTALS	1,337	0	220	0	1,557	0	0.000%	

Table 8-7 -- Number of Tests by Method by Family/Drug Non-Grade A Producer October 1, 2008 to September 30, 2009

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	1,561	7	192	0	1,753	7	0.399%
Charm SL Beta lactams	531	0	0	0	531	0	0.000%
Delvotest P 5 Pack - Beta lactams	27,226	66	1,050	0	28,276	66	0.233%
Delvotest P/Delvotest P Mini	8	0	0	0	8	0	0.000%
Delvotest SP/Delvotest SP Mini	12	0	0	0	12	0	0.000%
Idexx New Snap	27	0	0	0	27	0	0.000%
TOTALS	29,365	73	1,242	0	30,607	73	0.239%

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, 2008 to September 30, 2009

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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	7,635	1	41	0	7,676	1	0.013%		
Charm SL-6	4	0	0	0	4	0	0.000%		
Delvotest P 5 Pack - Beta lactams	2,002	0	647	0	2,649	0	0.000%		
Delvotest P/Delvotest P Mini	93	0	3	0	96	0	0.000%		
Delvotest SP/Delvotest SP Mini	31	0	0	0	31	0	0.000%		
Idexx New Snap	23	0	0	0	23	0	0.000%		
TOTALS	9,788	1	691	0	10,479	1	0.010		