NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2008 ANNUAL REPORT

October 1, 2007 - September 30, 2008

Submitted by:

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October 1, 2007 - September 30, 2008

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 90% 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. Thirty-seven (37) data reporters utilized the web-based software to submit all or part of their data for the FY 2008 Annual Report.

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 2008 (October 1, 2007 to September 30, 2008). Fifty (50) states or territories submitted data for this report. No data were received from the state of Rhode Island.

The Grade "A" Pasteurized Milk Ordinance (PMO), the rules 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 **4,016,553** samples were analyzed for animal drug residues. Of these samples **1,616** were positive for a residue. Of the **1,616** positive results, three (3) were samples of pasteurized fluid milk. These were obtained from a small producer/processor which is no longer in business. A total of **4,024,536** tests were reported on the samples for **ten** (10) different groups of families or individual drugs. **Thirty** (30) 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. Bulk Milk Pick-Up Tanker 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 rules.

TABLE 1 Sample Results October 1, 2007 to September 30, 2008								
Source of Sample	Total Samples	Number Positive	Percent Positive	Disposition per PMO (Pounds)				
Bulk Milk Pick-Up Tanker	3,364,572	958	0.028%	40,551,000				
Pasteurized Fluid Milk and Milk Products	43,940	3	0.007%	113,000				
Producer	527,018	634	0.120%	1,817,000				
Other	81,023	21	0.026%	558,000				
TOTALS	4,016,553	1,616	*	43,039,000				

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;
- 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 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.

October 1, 2007 to September 30, 2008 Source of Number of Number of Number of Number of **Total** Total Total **Disposition** Sample **Industry** Positive Regulatory **Positive Samples Positive Percent** Per PMO Samples Industry Samples Regulatory **Samples Positive** (Pounds) **Samples Samples GRADE A** Bulk Milk Pick-Up 3,114,275 852 13,134 4 3,127,409 856 0.027% 36,499,000 Tanker 113,000 Pasteurized Fluid Milk 2,518 0 39,864 3 42,382 3 0.007% and Milk Products Producer 354,541 396 136,683 116 491,224 512 0.104% 1,740,000 Other 64,567 19 7,013 0 71,580 19 0.027% 529,000 **NON-GRADE A**

TABLE 2 -- Industry and Regulatory Samples

199,286

50

352

1,820

370

0

0

0

0

123

237,163

1,558

35,794

9,443

4,016,553

102

0

122

1,616

0.043%

0.000%

0.341%

0.021%

*

4,052,000

0,000

77,000

29,000

43,039,000²

237,113

1,206

33,974

9,073

3,817,267

102

0

122

1,493

2

Bulk Milk Pick-Up

and Milk Products

Pasteurized Fluid Milk

Tanker¹

Producer

Other

TOTALS

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".

²Note that this represents 0.044% of the total milk supply of the United States with an annual production of 189 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 <u>tests</u> conducted (4,024,536) is greater than the number of <u>samples</u> (4,016,553). 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, 2007 to September 30, 2008. 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, 2007 to September 30, 2008							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,370,701	959	0.028				
Pasteurized Fluid Milk and Milk Products	43,982	3	0.007				
Producer	528,641	636	0.120				
Other	81,212	23	0.028				
TOTALS	4,024,536	1,621	*				

^{*}See Table 1 for explanation

TABLE 3A Validated Tests Conducted October 1, 2007 to September 30, 2008								
Source of Sample								
Bulk Milk Pick-Up Tanker	3,328,330	940	0.028					
Pasteurized Fluid Milk and Milk Products	43,361	3	0.007					
Producer	528,609	636	0.120					
Other	78,625	22	0.028					
TOTALS	3,978,925	1,601	*					

^{*}See Table 1 for explanation

TABLE 3B Non-Validated Tests Conducted October 1, 2007 to September 30, 2008							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	42,371	19	0.045				
Pasteurized Fluid Milk and Milk Products	621	0	0.000				
Producer	32	0	0.000				
Other	2,587	1	0.039				
TOTALS	45,611	20	*				

^{*}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, 2007 to September 30, 2008							
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	3,120,091	853	13,225	4	3,133,316	857	0.027%
Pasteurized Fluid Milk and Milk Products	2,518	0	39,910	3	42,428	3	0.007%
Producer	355,186	397	136,870	116	492,056	513	0.104%
Other	64,567	19	7,185	0	71,752	19	0.026%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	237,335	102	50	0	237,385	102	0.043%
Pasteurized Fluid Milk and Milk Products	1,202	0	352	0	1,554	0	0.000%
Producer	34,764	123	1,821	0	36,585	123	0.336%
Other	9,090	4	370	0	9,460	4	0.042%
TOTALS	3,824,753	1,498	199,783	123	4,024,536	1,621	*

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. 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".

tanker.

^{*}See Table 1 for explanation

TABLE 4A Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2007 to September 30, 2008							
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	3,078,937	834	12,008	4	3,090,945	838	0.027%
Pasteurized Fluid Milk and Milk Products	2,019	0	39,788	3	41,807	3	0.007%
Producer	355,154	397	136,870	116	492,024	513	0.104%
Other	61,980	18	7,185	0	69,165	18	0.026%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	237,335	102	50	0	237,385	102	0.043%
Pasteurized Fluid Milk and Milk Products	1,202	0	352	0	1,554	0	0.000%
Producer	34,764	123	1,821	0	36,585	123	0.336%
Other	9,090	4	370	0	9,460	4	0.042%
TOTALS	3,780,481	1,478	198,444	123	3,978,925	1,601	*

TOTALS

3,780,481

1,478

198,444

123

3,978,925

1,601

*

18 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

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".

tanker.

^{*}See Table 1 for explanation

TABLE 4B Non-Validated Tests Conducted by Industry and Regulatory Agencies October 1, 2007 to September 30, 2008							
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	41,154	19	1,217	0	42,371	19	0.045%
Pasteurized Fluid Milk and Milk Products	499	0	122	0	621	0	0.000%
Producer	32	0	0	0	32	0	0.000%
Other	2,587	1	0	0	2,587	1	0.039%
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	44,272	20	1,339	0	45,611	20	*

IUTALS 44,2/2 20 1,339 0 45,611 20 *

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 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

tanker.

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, 2007 to September 30, 2008						
Family/Drug Total Tests						
AMINOGLYCOSIDES	36	0				
Gentamicin	523	0				
AMPHENICOLS	3	0				
BETA lactams	3,960,531	1,598				
ENROFLOXACIN	1,217	0				
MACROLIDES	8,174	3				
SULFONAMIDES	19,618	4				
Sulfamethazine	19,098	8				
TETRACYCLINES	15,264	8				
Tetracycline	72	0				
TOTALS	4,024,536	1,621				

TABLE 5A Number of Validated Tests Conducted by Family/Drug October 1, 2007 to September 30, 2008						
Family/Drug Total Tests Total Positive						
AMPHENICOLS	3	0				
BETA lactams	3,960,503	1,598				
SULFONAMIDES	16,274	2				
TETRACYCLINES 2,073						
Tetracycline	72	0				
TOTALS	3,978,925	1,601				

TABLE 5B -- Number of Non-Validated Tests Conducted by Family/Drug October 1, 2007 to September 30, 2008

Family/Drug	Total Tests	Total Positive
AMINOGLYCOSIDES	36	0
Gentamicin	523	0
BETA lactams	28	0
ENROFLOXACIN	1,217	0
MACROLIDES	8,174	3
SULFONAMIDES	3,344	2
Sulfamethazine	19,098	8
TETRACYCLINES	13,191	7
TOTALS	45,611	20

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 almost <u>2.6 million</u> times, Delvotest P 5 Pack - Beta lactams which was used more than <u>542 thousand</u> times, Idexx New Snap which was used more than <u>326 thousand</u> times and Charm II Tablet Competitive - Beta lactams which was used for more than <u>164 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, 2007 to September 30, 2008						
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive			
AMINOGLYCOSIDES						
Charm II Tablet Competitive-N**	36	0	0.000%			
GENTAMICIN						
ID Block - Gentamicin**	523	0	0.000%			
AMPHENICOLS						
Charm II Tablet Competitive	3	0	0.000%			
BETA lactams						
Charm BSDA Tablet - Beta lactams	42,787	43	0.100%			
Charm Farm - Beta lactams**	28	0	0.000%			
Charm I/Cowside II Tablet - Beta lactams	3,754	4	0.107%			
Charm II Tablet Competitive	164,423	43	0.026%			
Charm II Tablet Quantitative	8,949	7	0.078%			
Charm II Tablet Sequential	108,416	42	0.039%			
Charm SL Beta lactams	2,593,162	700	0.027%			
Charm SL-3	9,041	1	0.011%			
Charm SL-6	126,806	46	0.036%			
Delvotest P 5 Pack - Beta lactams	542,271	574	0.106%			
Delvotest P/Delvotest P Mini	27,388	9	0.033%			
Delvotest SP/Delvotest SP Mini	777	0	0.000%			
Green Book Micro - Beta lactams	382	0	0.000%			
Idexx New Snap	326,146	126	0.039%			
Lak Tek - Beta lactams	5,831	3	0.051%			
Penzyme Milk Test - Beta lactams	370	0	0.000%			

TABLE 6 - Number of Tests by Method by Family/Drug October 1, 2007 to September 30, 2008

Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive
ENROFLOXACIN			
Charm SL-Floroquinlone**	1,217	0	0.000%
MACROLIDES			
Charm II Tablet Sequential - Macrolides**	8,174	3	0.037%
SULFONAMIDES			
Agri-Screen for Sulfonamides**, ***	222	0	0.000%
Charm II Tablet Competitive	15,657	1	0.006%
Charm II Tablet Sequential**	3,122	2	0.064%
TLC Sulfonamide	617	1	0.162%
SULFAMETHAZINE			
Charm SL - Sulfamethazine**	19,098	8	0.042%
TETRACYCLINES			
Charm II Tablet Competitive	2,073	1	0.048%
Charm SL - Tetracyclines**	2,929	1	0.034%
Snap - Tetracyclines**	10,262	6	0.058%
TETRACYCLINE			
HPLC Tetracyclines - Tetracycline	72	0	0.000%
TOTALS	4,024,536	1,621	*

^{*} 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, 2007 to September 30, 2008

Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive
VALIDATED FOR SULFONAMIDES			
Charm II Tablet Competitive	15,657	1	0.006%
TLC Sulfonamide	617	1	0.162%
NON-VALIDATED FOR SULFONAMIDES			
Agri-Screen for Sulfonamides** & ***	222	0	0.000%
Charm II Tablet Sequential**	3,122	2	0.064%
NON-VALIDATED FOR SULFAMETHAZINE			
Charm SL - Sulfamethazine**	19,098	8	0.042%
VALIDATED FOR TETRACYCLINES			
Charm II Tablet Competitive	2,073	1	0.048%
VALIDATED FOR TETRACYCLINE			
HPLC Tetracyclines - Tetracycline	72	0	0.000%
NON-VALIDATED FOR TETRACYCLINES			
Charm SL - Tetracyclines**	2,929	1	0.034%
Snap - Tetracyclines**	10,262	6	0.058%
TOTALS	54,052	20	*

^{*} 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., 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, 2007 to September 30, 2008						
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
Gentamicin	523	0	0	0	523	0
BETA lactams	3,061,984	832	11,988	4	3,073,972	836
ENROFLOXACIN	1,217	0	0	0	1,217	0
MACROLIDES	8,174	3	0	0	8,174	3
SULFONAMIDES	18,120	3	124	0	18,244	3
Sulfamethazine	18,407	8	0	0	18,407	8
TETRACYCLINES	11,630	7	1,113	0	12,743	7
TOTALS	3,120,091	853	13,225	4	3,133,316	857

TABLE 7-2 Grade A Pasteurized Fluid Milk and Milk Products Testing October 1, 2007 to September 30, 2008						
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	1,921	0	39,744	3	41,665	3
SULFONAMIDES	98	0	0	0	98	0
Sulfamethazine	499	0	0	0	499	0
TETRACYCLINES	0	0	94	0	94	0
Tetracycline	0	0	72	0	72	0
TOTALS	2,518	0	39,910	3	42,428	3

TABLE 7-3 Grade A Producer Testing October 1, 2007 to September 30, 2008						
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	3	0	3	0
BETA lactams	354,597	397	136,799	116	491,396	513
SULFONAMIDES	557	0	68	0	625	0
Sulfamethazine	32	0	0	0	32	0
TOTALS	355,186	397	136,870	116	492,056	513

TABLE 7-4 Grade A Other Testing (milk from silos, over-the-road tankers, etc.) October 1, 2007 to September 30, 2008						
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	61,973	18	7,021	0	68,994	18
SULFONAMIDES	7	0	164	0	171	0
Sulfamethazine	160	0	0	0	160	0
TETRACYCLINES	2,427	1	0	0	2,427	1
TOTALS	64,567	19	7,185	0	71,752	19

TABLE 7-5 Non-Grade A Bulk Milk Pick-Up Tanker Testing October 1, 2007 to September 30, 2008						
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	236,855	101	50	0	236,905	101
SULFONAMIDES	480	1	0	0	480	1
TOTALS	237,335	102	50	0	237,385	102

TABLE 7-6 Non			Fluid Milk a ptember 30,		ducts Tes	ting
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	1,202	0	352	0	1,554	0
TOTALS	1,202	0	352	0	1,554	0

T			e A Produce ptember 30,	_		
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	34,764	123	1,821	0	36,585	123
TOTALS	34,764	123	1,821	0	36,585	123

TABLE 7-8 Non-Gra		0 \	ilk from silo ptember 30,		oad tank	ers, etc.)
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	9,090	4	370	0	9,460	4
TOTALS	9,090	4	370	0	9,460	4

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, 2007 to September 30, 2008

October 1, 2007 to September 30, 2008										
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%			
GENTAMICIN										
ID Block - Gentamicin**	523	0	0	0	523	0	0.000%			
BETA lactams										
Charm BSDA Tablet - Beta lactams	22,184	6	36	0	22,220	6	0.027%			
Charm I/Cowside II Tablet - Beta lactams	3,651	4	0	0	3,651	4	0.110%			
Charm II Tablet Competitive	162,397	43	2	0	162,399	43	0.026%			
Charm II Tablet Quantitative	8,635	7	6	0	8,641	7	0.081%			
Charm II Tablet Sequential	102,172	42	203	0	102,375	42	0.041%			
Charm SL Beta lactams	2,324,124	577	5,537	4	2,329,661	581	0.025%			
Charm SL-3	9,036	1	5	0	9,041	1	0.011%			
Charm SL-6	122,220	39	7	0	122,227	39	0.032%			
Delvotest P 5 Pack - Beta lactams	5,599	1	3,684	0	9,283	1	0.011%			
Delvotest P/Delvotest P Mini	3,091	0	2,356	0	5,447	0	0.000%			
Delvotest SP/Delvotest SP Mini	22	0	0	0	22	0	0.000%			
Green Book Micro - Beta lactams	382	0	0	0	382	0	0.000%			
Idexx New Snap	292,418	109	152	0	292,570	109	0.037%			

Table 8-1 -- Number of Tests by Method by Family/Drug Grade A Bulk Milk Pick-Up Tanker October 1, 2007 to September 30, 2008

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
Lak Tek - Beta lactams	5,831	3	0	0	5,831	3	0.051%
Penzyme Milk Test - Beta lactams	222	0	0	0	222	0	0.000%
ENROFLOXACIN							
Charm SL-Floroquinlone**	1,217	0	0	0	1,217	0	0.000%
MACROLIDES							
Charm II Tablet Sequential - Macrolides**	8,174	3	0	0	8,174	3	0.037%
SULFONAMIDES							
Agri-Screen for Sulfonamides**,***	222	0	0	0	222	0	0.000%
Charm II Tablet Competitive	14,880	1	20	0	14,900	1	0.007%
Charm II Tablet Sequential**	3,018	2	104	0	3,122	2	0.064%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	18,407	8	0	0	18,407	8	0.043%
TETRACYCLINES							
Charm II Tablet Competitive	2,073	1	0	0	2,073	1	0.048%
Charm SL - Tetracyclines**	2,678	1	0	0	2,678	1	0.037%
Snap - Tetracyclines**	6,879	5	1,113	0	7,992	5	0.063%
TOTALS	3,120,091	853	13,225	4	3,133,316	857	0.027%

^{**} 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, 2007 to September 30, 2008

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	632	0	1,446	0	2,078	0	0.000%
Charm Farm - Beta lactams**	0	0	28	0	28	0	0.000%
Charm I/Cowside II Tablet - Beta lactams	0	0	71	0	71	0	0.000%
Charm II Tablet Quantitative	0	0	4	0	4	0	0.000%
Charm II Tablet Sequential	0	0	456	0	456	0	0.000%
Charm SL Beta lactams	14	0	718	0	732	0	0.000%
Charm SL-6	75	0	0	0	75	0	0.000%
Delvotest P 5 Pack - Beta lactams	1,200	0	34,565	3	35,765	3	0.008%
Delvotest P/Delvotest P Mini	0	0	1,638	0	1,638	0	0.000%
Idexx New Snap	0	0	818	0	818	0	0.000%
SULFONAMIDES							
Charm II Tablet Competitive	98	0	0	0	98	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	499	0	0	0	499	0	0.000%
TETRACYCLINES							
Snap - Tetracyclines**	0	0	94	0	94	0	0.000%
TETRACYCLINE							
HPLC Tetracyclines - Tetracycline	0	0	72	0	72	0	0.000%
TOTALS	2,518	0	39,910	3	42,428	3	0.007%

^{**} Non-Validated Test Method

Table 8-3 -- Number of Tests by Method by Family/Drug Grade A Producer October 1, 2007 to September 30, 2008

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	3	0	3	0	0.000%
BETA lactams							
Charm BSDA Tablet - Beta lactams	10,670	24	3,132	2	13,802	26	0.188%
Charm I/Cowside II Tablet - Beta lactams	0	0	21	0	21	0	0.000%
Charm II Tablet Competitive	420	0	489	0	909	0	0.000%
Charm II Tablet Sequential	0	0	2,321	0	2,321	0	0.000%
Charm SL Beta lactams	6,423	14	2,005	5	8,428	19	0.225%
Charm SL-6	3,166	4	6	0	3,172	4	0.126%
Delvotest P 5 Pack - Beta lactams	314,798	344	121,108	106	435,906	450	0.103%
Delvotest P/Delvotest P Mini	12,342	8	7,279	1	19,621	9	0.046%
Delvotest SP/Delvotest SP Mini	617	0	0	0	617	0	0.000%
Idexx New Snap	6,117	3	438	2	6,555	5	0.076%
Penzyme Milk Test - Beta lactams	44	0	0	0	44	0	0.000%
SULFONAMIDES							
Charm II Tablet Competitive	420	0	68	0	488	0	0.000%
TLC Sulfonamide	137	0	0	0	137	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	32	0	0	0	32	0	0.000%
TOTALS	355,186	397	136,870	116	492,056	513	0.104%

^{**} Non-Validated Test Method

Table 8-4 -- Number of Tests by Method by Family/Drug Grade A Other (milk from silos, over-the-road tankers, etc.) October 1, 2007 to September 30, 2008

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	862	0	248	0	1,110	0	0.000%
Charm I/Cowside II Tablet - Beta lactams	0	0	11	0	11	0	0.000%
Charm II Tablet Competitive	1,115	0	0	0	1,115	0	0.000%
Charm II Tablet Quantitative	304	0	0	0	304	0	0.000%
Charm II Tablet Sequential	3,197	0	67	0	3,264	0	0.000%
Charm SL Beta lactams	42,277	11	903	0	43,180	11	0.025%
Charm SL-6	1,316	3	14	0	1,330	3	0.226%
Delvotest P 5 Pack - Beta lactams	2,114	0	5,557	0	7,671	0	0.000%
Delvotest P/Delvotest P Mini	504	0	55	0	559	0	0.000%
Delvotest SP/Delvotest SP Mini	55	0	0	0	55	0	0.000%
Idexx New Snap	10,229	4	166	0	10,395	4	0.038%
SULFONAMIDES							
Charm II Tablet Competitive	7	0	164	0	171	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	160	0	0	0	160	0	0.000%
TETRACYCLINES							
Charm SL - Tetracyclines**	251	0	0	0	251	0	0.000%
Snap - Tetracyclines**	2,176	1	0	0	2,176	1	0.046%
TOTALS	64,567	19	7,185	0	71,752	19	0.026%

^{**} 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, 2007 to September 30, 2008

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	201,975	85	39	0	202,014	85	0.042%
Charm SL-6	0	0	1	0	1	0	0.000%
Delvotest P 5 Pack - Beta lactams	18,862	8	10	0	18,872	8	0.042%
Delvotest P/Delvotest P Mini	106	0	0	0	106	0	0.000%
Idexx New Snap	15,808	8	0	0	15,808	8	0.051%
Penzyme Milk Test - Beta lactams	104	0	0	0	104	0	0.000%
SULFONAMIDES							
TLC Sulfonamide	480	1	0	0	480	1	0.208%
TOTALS	237,335	102	50	0	237,385	102	0.043%

Table 8-6 Number of Tests by Method by Family/Drug
Non-Grade A Pasteurized Fluid Milk and Milk Products
October 1, 2007 to September 30, 2008

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	1,202	0	352	0	1,554	0	0.000%
TOTALS	1,202	0	352	0	1,554	0	0.000%

Table 8-7 -- Number of Tests by Method by Family/Drug Non-Grade A Producer October 1, 2007 to September 30, 2008

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	3,006	11	571	0	3,577	11	0.308%
Charm SL Beta lactams	1,912	2	0	0	1,912	2	0.105%
Delvotest P 5 Pack - Beta lactams	29,824	110	1,250	0	31,074	110	0.354%
Delvotest SP/Delvotest SP Mini	22	0	0	0	22	0	0.000%
TOTALS	34,764	123	1,821	0	36,585	123	0.336%

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, 2007 to September 30, 2008

	Octob	er 1, 2007	to Septemb	oer 30, 2008			
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	7,202	2	33	0	7,235	2	0.028%
Charm SL-6	1	0	0	0	1	0	0.000%
Delvotest P 5 Pack - Beta lactams	1,809	2	337	0	2,146	2	0.093%
Delvotest P/Delvotest P Mini	17	0	0	0	17	0	0.000%
Delvotest SP/Delvotest SP Mini	61	0	0	0	61	0	0.000%
TOTALS	9,090	4	370	0	9,460	4	0.042%