NATIONAL MILK DRUG RESIDUE DATA BASE FISCAL YEAR 2005 ANNUAL REPORT

October 1, 2004 - September 30, 2005

Submitted by:

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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 90% of the milk supply in the United States and is regulated through the NCIMS by State Regulatory Agencies. Manufacturing grade milk is under the direction of the Regulatory Agencies in the States where it is produced and may be subject to the standards recommended by the United States Department of Agriculture (USDA). Data reported to the National Milk Drug Residue Data Base are for educational and analytical purposes and are not intended or suitable for regulatory 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 Shipper program) to ensure the sanitary quality of Grade "A" milk and milk products shipped interstate. During the 1991 meeting of the NCIMS, the Conference authorized a national program to compile the results of milk residue testing by industry and 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 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. Pursuant to this objective, during this reporting period, a presentation was given to attendees of the Dairy Practices Council (DPC) during its November 3-5, 2004, meeting in Indianapolis, Indiana. The presentation emphasized the revisions

that were made in FY 2004 to the reporting instructions distributed to the States for reporting test results to the data base.

A similar presentation was given to the participants of the 2005 meeting of the NCIMS in Columbus, Ohio, in May of 2005. In addition, data base contractor staff members participated in a number of committee activities, including the NCIMS Drug Residue Study Committee.

The web page for the NMDRD (<u>www.kandc-sbcc.com/nmdrd</u>) was revised during the reporting period to allow access to all of the annual reports compiled by the NMDRD since the beginning of the project.

SUMMARY

This report presents summary data on samples and tests conducted during Fiscal Year 2005 (October 1, 2004 to September 30, 2005). Forty-nine states and Puerto Rico submitted data for this report. No data were received from 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 **4,185,319** samples were analyzed for animal drug residues. Of these samples **2,155** were positive for a residue. A total of **4,239,718** tests were reported on the samples for **10** different groups of families or individual drugs. Thirty-six testing methods were used to analyze the samples for residues. Details are presented in the tables in this report.

SAMPLE RESULTS

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

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

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

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

A <u>POSITIVE</u> result, as used in this report, means that the sample was found to be positive for a drug residue by a test acceptable for taking regulatory action in a certified laboratory by a certified analyst or the milk was rejected on the basis of an initial 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 ResultsOctober 1, 2004 to September 30, 2005								
Source of Sample	Total Samples	Number Positive	Percent Positive	Disposition per PMO (Pounds)				
Bulk Milk Pick-Up Tanker	3,432,547	1,307	0.038%	49,444,000				
Pasteurized Fluid Milk and Milk Products	53,106	8	0.015%	60,000				
Producer	627,664	821	0.131%	2,370,000				
Other	72,002	18	0.025%	814,000				
TOTALS	4,185,319	2,155	*	52,688,000				

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 must be tested for each finished product from each plant during any consecutive six months;
- 3. <u>Producer</u> -- each producer must be tested at least four times during any consecutive six months; and
- 4. <u>Other</u> -- samples are conducted on a random basis.

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

TABLE 2 Industry and Regulatory SamplesOctober 1, 2004 to September 30, 2005									
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	3,135,589	1,173	30,053	11	3,165,642	1,184	0.037%	45,067,000	
Pasteurized Fluid Milk and Milk Products	3,622	1	47,946	7	51,568	8	0.016%	60,000	
Producer	429,953	599	157,458	172	587,411	771	0.131%	2,369,000	
Other	53,989	16	5,975	2	59,964	18	0.030%	814,000	
NON-Grade "A"									
Bulk Milk Pick-Up Tanker ¹	258,717	122	8,188	2	266,905	124	0.046%	4,377,000	
Pasteurized Fluid Milk and Milk Products	1,172	0	366	0	1,538	0	0.000%	0,000	
Producer	34,695	43	5,558	7	40,253	50	0.124%	1,000	
Other	11,208	0	830	0	12,038	0	0.000%	0,000	
TOTALS	3,928,945	1,954	256,374	201	4,185,319	2,155	*	52,688,000 ²	

¹It is a common practice in some States, including two large milk production States, that bulk milk pick-up tankers pickup milk from 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".

² Note that this represents 0.030% of the total milk supply of the United States with an annual production of 174.9 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 (4,239,718) is greater than the number of <u>samples</u> (4,185,319). 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, 2004 to September 30, 2005. 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 quantitation of drug residues in milk may be used. Table 3A presents summary results using validated tests and Table 3B presents summary results using non-validated tests.

TABLE 3 Tests ConductedOctober 1, 2004 to September 30, 2005							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,477,817	1,344	0.039				
Pasteurized Fluid Milk and Milk Products	57,700	8	0.014				
Producer	630,604	828	0.131				
Other	73,597	18	0.024				
TOTALS	4,239,718	2,198	*				

* = See Table 1 for explanation

TABLE 3A Validated Tests ConductedOctober 1, 2004 to September 30, 2005							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	3,443,010	1,336	0.039				
Pasteurized Fluid Milk and Milk Products	56,820	8	0.014				
Producer	630,317	828	0.131				
Other	73,310	18	0.025				
TOTALS	4,203,457	2,190	*				

* = See Table 1 for explanation

TABLE 3B Non-Validated Tests ConductedOctober 1, 2004 to September 30, 2005							
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive				
Bulk Milk Pick-Up Tanker	34,807	8	0.023				
Pasteurized Fluid Milk and Milk Products	880	0	0.000				
Producer	287	0	0.000				
Other	287	0	0.000				
TOTALS	36,261	8	*				

* = 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 State Regulatory Agencies October 1, 2004 to September 30, 2005							
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	3,179,198	1,201	30,266	19	3,209,464	1,220	0.038%
Pasteurized Fluid Milk and Milk Products	3,708	1	52,407	7	56,115	8	0.014%
Producer	432,526	599	157,825	179	590,351	778	0.132%
Other	54,110	16	6,206	2	60,316	18	0.030%
NON-Grade "A"							
Bulk Milk Pick-Up Tanker ¹	259,240	122	9,113	2	268,353	124	0.046%
Pasteurized Fluid Milk and Milk Products	1,219	0	366	0	1,585	0	0.000%
Producer	34,695	43	5,558	7	40,253	50	0.124%
Other	12,438	0	843	0	13,281	0	0.000%
TOTALS	3,977,134	1,982	262,584	216	4,239,718	2,198	*

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 truck. 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

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TABLE 4A Validated Tests Conducted by Industry and State Regulatory Agencies October 1, 2004 to September 30, 2005								
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	3,153,334	1,193	21,357	19	3,174,691	1,212	0.038%	
Pasteurized Fluid Milk and Milk Products	3,378	1	51,857	7	55,235	8	0.014%	
Producer	432,436	599	157,628	179	590,064	778	0.132	
Other	53,823	16	6,206	2	60,029	18	0.030%	
NON-Grade "A"								
Bulk Milk Pick-Up Tanker ¹	259,206	122	9,113	2	268,319	124	0.046%	
Pasteurized Fluid Milk and Milk Products	1,219	0	366	0	1,585	0	0.000%	
Producer	34,695	43	5,558	7	40,253	50	0.124%	
Other	12,438	0	843	0	13,281	0	0.000%	
TOTALS	3,950,529	1,974	252,928	216	4,203,457	2,190	*	

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 truck. 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 State Regulatory Agencies October 1, 2004 to September 30, 2005							
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	25,864	8	8,909	0	34,773	8	0.023%
Pasteurized Fluid Milk and Milk Products	330	0	550	0	880	0	0.000%
Producer	90	0	197	0	287	0	0.000%
Other	287	0	0	0	287	0	0.000%
NON-Grade "A"							
Bulk Milk Pick-Up Tanker ¹	34	0	0	0	34	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	26,605	8	9,656	0	36,261	8	*

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 truck. 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 family and by individual drug. Tables 5A and 5B present these data by validated and non-validated tests.

TABLE 5 Number of Tests Conducted by Family/DrugOctober 1, 2004 to September 30, 2005						
Family/Drug	Total Tests	Total Positive				
AMINOGLYCOSIDES	30	1				
AMPHENICOLS	683	0				
BETA lactams	4,160,278	2,184				
Cloxacillin	84	1				
MACROLIDES	1,077	0				
NOVOBIOCIN	80	0				
SULFONAMIDES	48,455	5				
Sulfamethazine	19,842	5				
TETRACYCLINES	9,110	2				
Tetracycline	79	0				
TOTALS	4,239,718	2,198				

TABLE 5A Number of Validated Tests Conducted by Family/Drug October 1, 2004 to September 30, 2005						
Family/Drug	Total Tests	Total Positive				
AMPHENICOLS	683	0				
BETA lactams	4,160,2789	2,184				
Cloxacillin	84	1				
SULFONAMIDES	38,485	5				
TETRACYCLINES	3,848	0				
Tetracycline	79	0				
TOTALS	4,203,457	2,190				

TABLE 5B Number of Non-Validated Tests Conducted by Family/Drug October 1, 2004 to September 30, 2005							
Family/Drug	Total Tests	Total Positive					
AMINOGLYCOSIDES	30	1					
MACROLIDES	1,077	0					
NOVOBIOCIN	80	0					
SULFONAMIDES	9,970	0					
Sulfamethazine	19,842	5					
TETRACYCLINES	5,262	2					
TOTALS	36,261	8					

Table 6 presents details on the tests used. The data in this table are comparable to Table 5, but the data are arranged by <u>tests</u> within each <u>family/drug</u>. Therefore, the Totals are the same in both tables. The testing methods with the largest use were: Charm SL - Beta lactams, which was used more than 2.4 million times, Delvotest P 5 Pack - Beta lactams used more than 638 thousand times, Idexx New Snap used more than 427 thousand times and Charm II Tablet Competitive - Beta lactams used for more than 201 thousand tests. Table 6A shows a comparison of tests conducted using Validated and Non-Validated test methods for Sulfonamides and Tetracyclines.

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TABLE 6 - Number of Tests by Method by Family/DrugOctober 1, 2004 to September 30, 2005							
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive				
AMINOGLYCOSIDES							
Charm II Tablet Competitive-N**	29	1	3.448%				
Charm II Tablet Sequential**	1	0	0.000%				
AMPHENICOLS							
Charm II Tablet Competitive	683	0	0.000%				
BETA lactams							
Charm BSDA Tablet - Beta lactams	82,574	102	0.1249				
Charm I/Cowside II Tablet - Beta lactams	6,180	5	0.0819				
Charm II Tablet Competitive	201,131	63	0.0319				
Charm II Tablet Quantitative	20,988	52	0.2489				
Charm II Tablet Sequential	125,744	77	0.0619				
Charm SL Beta lactams	2,450,317	865	0.0359				
Charm SL-6	76,104	49	0.0649				
Delvotest P 5 Pack - Beta lactams	638,572	723	0.1139				
Delvotest P/Delvotest P Mini	22,855	5	0.022				
Delvotest SP/Delvotest SP Mini	2,951	0	0.000				
Idexx New Snap	427,454	190	0.044				
Lak Tek - Beta lactams	3,671	5	0.1369				
Parallux Beta lactams Assay	76,755	30	0.039				
Parallux Cephapirin Assay	1	1	100.000				
Parallux Cillins Assay	3	2	66.667				
Penzyme III Test - Beta lactams	4,314	4	0.0939				
Penzyme Milk Test - Beta lactams	14,872	4	0.0279				
Snap (Reader) - Beta lactams	5,422	7	0.1299				
Snap (Visual) - Beta lactams	370	0	0.000				

Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive
Charm II Tablet Quantitative	7	0	0.000
Charm II Test for Cloxacillin in Milk	77	1	1.299
MACROLIDES			
Charm I/Cowside II Tablet - Macrolides**	847	0	0.000
Charm II Tablet Sequential - Macrolides**	230	0	0.000
NOVOBIOCIN			
Charm II Tablet Competitive - Novobiocin**	80	0	0.000
SULFONAMIDES			
Agri-Screen for Sulfonamides**,***	1,853	0	0.000
Charm II Tablet Competitive	38,485	5	0.013
-Charm II Tablet Sequential**	1,418	0	0.000
Parallux Sulfa Trio (Reader)**	6,699	0	0.000
SULFAMETHAZINE			
Charm SL - Sulfamethazine**	19,842	5	0.025
TETRACYCLINES			
Charm II Tablet Competitive	3,848	0	0.000
Charm SL - Tetracyclines**	1,691	2	0.118
Snap - Tetracyclines**	3,571	0	0.000
TETRACYCLINE			
HPLC Tetracyclines - Tetracycline	79	0	0.000
TOTALS	4,239,718	2,198	

TABLE 6A - Comparison of Validated and Non-Validated
Tests for Sulfonamides and Tetracyclines
October 1, 2004 to September 30, 2005

October 1, 2004 to September 50, 2005								
Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive					
VALIDATED FOR SULFONAMIDES								
Charm II Tablet Competitive	38,485	5	0.013%					
NON-VALIDATED FOR SULFONAMIDES								
Agri-Screen for Sulfonamides***	1,853	0	0.000%					
Charm II Tablet Sequential**	1,418	0	0.000%					
Parallux Sulfa Trio (Reader)**	6,699	0	0.000%					
NON-VALIDATED FOR SULFAMETHAZINE								
Charm SL - Sulfamethazine**	19,842	5	0.025%					
VALIDATED FOR TETRACYCLINES								
Charm II Tablet Competitive	3,848	0	0.000%					
VALIDATED FOR TETRACYCLINE								
HPLC Tetracyclines - Tetracycline	79	0	0.000%					
NON-VALIDATED FOR TETRACYCLINES								
Charm SL - Tetracyclines**	1,691	2	0.118%					
Snap - Tetracyclines**	3,571	0	0.000%					
TOTALS	77,486	12	*					

** 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 family 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, e.g. Beta lactams, Sulfonamides, etc.

TABLE 7-1 Grade "A" Bulk Milk Pick-Up Tanker TestingOctober 1, 2004 to September 30, 2005								
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	29	1	1	0	30	1		
AMPHENICOLS	569	0	0	0	569	0		
BETA lactams	3,111,888	1,188	21,336	19	3,133,224	1,207		
Cloxacillin	77	1	0	0	77	1		
MACROLIDES	1,043	0	0	0	1,043	0		
NOVOBIOCIN	80	0	0	0	80	0		
SULFONAMIDES	40,021	4	6,333	0	46,354	4		
Sulfamethazine	19,346	5	0	0	19,346	5		
TETRACYCLINES	6,145	2	2,596	0	8,741	2		
TOTALS	3,179,198	1,201	30,266	19	3,209,464	1,220		

TABLE 7-2 Grade "A" Pasteurized Fluid Milk and Milk Products Testing October 1, 2004 to September 30, 2005							
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	3,210	1	51,789	7	54,999	8	
MACROLIDES	0	0	34	0	34	0	
SULFONAMIDES	168	0	387	0	555	0	
Sulfamethazine	330	0	0	0	330	0	
TETRACYCLINES	0	0	129	0	129	0	
Tetracycline	0	0	68	0	68	0	
TOTALS	3,708	1	52,407	7	56,115	8	

TABLE 7-3 Grade "A" Producer TestingOctober 1, 2004 to September 30, 2005							
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	432,016	599	157,219	178	589,235	777	
Cloxacillin	0	0	7	0	7	0	
SULFONAMIDES	420	0	598	1	1,018	1	
TETRACYCLINES	90	0	0	0	90	0	
Tetracycline	0	0	1	0	1	0	
TOTALS	432,526	599	157,825	179	590,351	778	

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TABLE 7-4 Grade "A" Other Testing (milk from silos, over-the-road tankers, etc.)October 1, 2004 to September 30, 2005							
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	114	0	0	0	114	0	
BETA lactams	53,697	16	5,991	2	59,688	18	
SULFONAMIDES	17	0	205	0	222	0	
Sulfamethazine	166	0	0	0	166	0	
TETRACYCLINES	116	0	0	0	116	0	
Tetracycline	0	0	10	0	10	0	
TOTALS	54,110	16	6,208	2	60,316	18	

TABLE 7-5 Non-Grade "A" Bulk Milk Pick-Up Tanker TestingOctober 1, 2004 to September 30, 2005							
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	258,900	122	9,113	2	268,013	124	
SULFONAMIDES	306	0	0	0	306	0	
TETRACYCLINES	34	0	0	0	34	0	
TOTALS	259,240	122	9,113	2	268,353	124	

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TABLE 7-6 Non-Grade "A" Pasteurized Fluid Milk and Milk Products TestingOctober 1, 2004 to September 30, 2005						
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	1,219	0	366	0	1,585	0
TOTALS	1,219	0	366	0	1,585	0

TABLE 7-7 Non-Grade "A" Producer TestingOctober 1, 2004 to September 30, 2005						
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	34,695	43	5,558	7	40,253	50
TOTALS	34,695	43	5,558	7	40,253	50

TABLE 7-8 Non-Grade "A" Other Testing (milk from silos, over-the-road tankers, etc.)October 1, 2004 to September 30, 2005										
Family/Drug	Family/DrugNumber of IndustryNumber of PositiveNumber of RegulatoryNumber of PositiveTotal TestsTotal PositiveTestsIndustry TestsTestsRegulatory TestsTestsTests									
BETA lactams	12,438	0	843	0	13,281	0				
TOTALS	12,438	0	843	0	13,281	0				

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

Tab	Table 8-1 Number of Tests by Method by Family/Drug Grade "A" Bulk Milk Pick-Up Tanker October 1, 2004 to September 30, 2005											
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**	29	1	0	0	29	1	3.448%					
Charm II Tablet Sequential**	0	0	1	0	1	0	0.000%					
AMPHENICOLS												
Charm II Tablet Competitive	569	0	0	0	569	0	0.000%					
BETA lactams												
Charm BSDA Tablet - Beta lactams	32,899	23	142	0	33,041	23	0.070%					
Charm I/Cowside II Tablet - Beta lactams	6,180	5	0	0	6,180	5	0.081%					
Charm II Tablet Competitive	193,036	62	40	0	193,076	62	0.032%					
Charm II Tablet Quantitative	18,440	52	32	0	18,472	52	0.282%					
Charm II Tablet Sequential	117,490	70	936	0	118,426	70	0.059%					
Charm SL Beta lactams	2,194,714	750	11,814	6	2,206,528	756	0.034%					
Charm SL-6	72,822	43	37	0	72,859	43	0.059%					
Delvotest P 5 Pack - Beta lactams	8,050	1	4,214	5	12,264	6	0.049%					
Delvotest P/Delvotest P Mini	6,048	1	3,357	0	9,405	1	0.011%					
Delvotest SP/Delvotest SP Mini	748	0	0	0	748	0	0.000%					
Idexx New Snap	361,252	138	562	8	361,814	146	0.040%					
Lak Tek - Beta lactams	3,671	5	0	0	3,671	5	0.136%					
Parallux Beta lactams Assay	73,668	23	171	0	73,839	23	0.031%					

Ta	Table 8-1 Number of Tests by Method by Family/Drug Grade "A" Bulk Milk Pick-Up Tanker October 1, 2004 to September 30, 2005										
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				
Parallux Cephapirin Assay	1	1	0	0	1	1	100.000%				
Parallux Cillins Assay	3	2	0	0	3	2	66.667%				
Penzyme III Test - Beta lactams	4,314	4	0	0	4,314	4	0.093%				
Penzyme Milk Test - Beta lactams	13,067	1	23	0	13,090	1	0.008%				
Snap (Reader) - Beta lactams	5,386	7	8	0	5,394	7	0.130%				
Snap (Visual) - Beta lactams	99	0	0	0	99	0	0.000%				
CLOXACILLIN											
Charm II Test for Cloxacillin in Milk	77	1	0	0	77	1	1.299%				
MACROLIDES											
Charm I/Cowside II Tablet - Macrolides**	847	0	0	0	847	0	0.000%				
Charm II Tablet Sequential - Macrolides**	196	0	0	0	196	0	0.000%				
NOVOBIOCIN											
Charm II Tablet Competitive - Novobiocin ^{**}	80	0	0	0	80	0	0.000%				
SULFONAMIDES											
Agri-Screen for Sulfonamides ^{**,***}	1,651	0	0	0	1,651	0	0.000%				
Charm II Tablet Competitive	36,952	4	21	0	36,973	4	0.011%				
Charm II Tablet Sequential**	1,418	0	0	0	1,418	0	0.000%				
Parallux Sulfa Trio (Reader)**	0	0	6,312	0	6,312	0	0.000%				
SULFAMETHAZINE											

Table 8-1 Number of Tests by Method by Family/Drug Grade "A" Bulk Milk Pick-Up Tanker October 1, 2004 to September 30, 2005										
Tests Used by Family/DrugNumber of Industry TestsNumber of of Positive Industry TestsNumber of 										
Charm SL - Sulfamethazine**	19,346	5	0	0	19,346	5	0.026%			
TETRACYCLINES										
Charm II Tablet Competitive	3,848	0	0	0	3,848	0	0.000%			
Charm SL - Tetracyclines**	1,691	2	0	0	1,691	2	0.118%			
Snap - Tetracyclines**	606	0	2,596	0	3,202	0	0.000%			
TOTALS	3,179,198	1,201	30,266	19	3,209,464	1,220	0.038%			

** 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, 2004 to September 30, 2005										
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	788	0	1,734	0	2,522	0	0.000%				
Charm II Tablet Competitive	108	0	3,693	0	3,801	0	0.000%				
Charm II Tablet Quantitative	645	0	0	0	645	0	0.000%				
Charm II Tablet Sequential	0	0	547	4	547	4	0.731%				
Charm SL Beta lactams	333	0	276	0	609	0	0.000%				
Delvotest P 5 Pack - Beta lactams	1,336	1	44,276	3	45,612	4	0.009%				
Delvotest P/Delvotest P Mini	0	0	688	0	688	0	0.000%				
Idexx New Snap	0	0	575	0	575	0	0.000%				
MACROLIDES											
Charm II Tablet Sequential - Macrolides**	0	0	34	0	34	0	0.000%				
SULFONAMIDES											
Charm II Tablet Competitive	168	0	0	0	168	0	0.000%				
Parallux Sulfa Trio (Reader)**	0	0	387	0	387	0	0.000%				
SULFAMETHAZINE											
Charm SL - Sulfamethazine**	330	0	0	0	330	0	0.000%				
TETRACYCLINES											
Snap - Tetracyclines**	0	0	129	0	129	0	0.000%				
TETRACYCLINE											

Table 8-2 Number of Tests by Method by Family/Drug Grade "A" Pasteurized Fluid Milk and Milk Products October 1, 2004 to September 30, 2005									
Tests Used by Family/DrugNumber of Industry TestsNumber of of Positive Industry TestsNumber of 									
HPLC Tetracyclines - Tetracycline	0	0	68	0	68	0	0.000%		
TOTALS	3,708	1	52,407	7	56,115	8	0.014%		

Tab	Table 8-3 Number of Tests by Method by Family/Drug Grade "A" Producer October 1, 2004 to September 30, 2005										
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	14,794	38	22,361	25	37,155	63	0.170%				
Charm II Tablet Competitive	1,312	1	685	0	1,997	1	0.050%				
Charm II Tablet Quantitative	831	0	0	0	831	0	0.000%				
Charm II Tablet Sequential	0	0	2,125	2	2,125	2	0.094%				
Charm SL Beta lactams	7,717	27	3,497	3	11,214	30	0.268%				
Charm SL-6	3,209	6	28	0	3,237	6	0.185%				
Delvotest P 5 Pack - Beta lactams	388,326	521	125,478	143	513,804	664	0.129%				
Delvotest P/Delvotest P Mini	11,457	3	678	1	12,135	4	0.033%				
Delvotest SP/Delvotest SP Mini	196	0	0	0	196	0	0.000%				
Idexx New Snap	3,841	3	2,367	4	6,208	7	0.113%				
Penzyme Milk Test - Beta lactams	158	0	0	0	158	0	0.000%				
Snap (Visual) - Beta lactams	175	0	0	0	175	0	0.000%				
CLOXACILLIN											
Charm II Tablet Quantitative	0	0	7	0	7	0	0.000%				
SULFONAMIDES											
Agri-Screen for Sulfonamides ^{**, ***}	0	0	197	0	197	0	0.000%				
Charm II Tablet Competitive	420	0	401	1	821	1	0.122%				

Table 8-3 Number of Tests by Method by Family/Drug Grade "A" Producer October 1, 2004 to September 30, 2005										
Tests Used by Family/Drug	Number of Industry Tests	dustry of Regulatory Positive Tests Positive Positiv								
TETRACYCLINES										
Snap - Tetracyclines**	90	0	0	0	90	0	0.000%			
TETRACYCLINE										
HPLC Tetracyclines - Tetracycline	0	0	1	0	1	0	0.000%			
TOTALS	432,526	599	157,825	179	590,351	778	0.132%			

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

	Table 8-4 Number of Tests by Method by Family/DrugGrade "A" Other (milk from silos, over-the-road tankers, etc.)October 1, 2004 to September 30, 2005										
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	114	0	0	0	114	0	0.000%				
BETA lactams											
Charm BSDA Tablet - Beta lactams	1,288	2	204	0	1,492	2	0.134%				
Charm II Tablet Competitive	908	0	10	0	918	0	0.000%				
Charm II Tablet Quantitative	1,040	0	0	0	1,040	0	0.000%				
Charm II Tablet Sequential	3,644	1	81	0	3,725	1	0.027%				
Charm SL Beta lactams	35,868	7	651	0	36,519	7	0.019%				
Charm SL-6	0	0	8	0	8	0	0.000%				
Delvotest P 5 Pack - Beta lactams	4,267	0	4,592	2	8,859	2	0.023%				
Delvotest P/Delvotest P Mini	533	0	94	0	627	0	0.000%				
Delvotest SP/Delvotest SP Mini	2,007	0	0	0	2,007	0	0.000%				
Idexx New Snap	4,042	6	282	0	4,324	6	0.139%				
Parallux Beta lactams Assay	0	0	66	0	66	0	0.000%				
Penzyme Milk Test - Beta lactams	100	0	3	0	103	0	0.000%				
SULFONAMIDES											
Agri-Screen for Sulfonamides ^{**, ***}	5	0	0	0	5	0	0.000%				
Charm II Tablet Competitive	12	0	205	0	217	0	0.000%				

Table 8-4 Number of Tests by Method by Family/Drug Grade "A" Other (milk from silos, over-the-road tankers, etc.) October 1, 2004 to September 30, 2005										
Tests Used by Family/Drug	amily/Drug Number of Number of Number of Number of Regulatory Positive Tests Positive Industry Industry Tests Test									
SULFAMETHAZINE										
Charm SL - Sulfamethazine**	166	0	0	0	166	0	0.000%			
TETRACYCLINES										
Snap - Tetracyclines**	116	0	0	0	116	0	0.000%			
TETRACYCLINE										
HPLC Tetracyclines - Tetracycline	0	0	10	0	10	0	0.000%			
TOTALS	54,110	16	6,206	2	60,316	18	0.030%			

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

Tab	Table 8-5 Number of Tests by Method by Family/Drug Non-Grade "A" Bulk Milk Pick-Up Tanker October 1, 2004 to September 30, 2005										
Tests Used by Family/Drug	Number of Industry Tests	Number of Positive Industry Tests	Number of Regulatory Tests	Number of Positive Regulatory Tests	Total Tests	Total Positive Tests	Percent Positive				
BETA lactams											
Charm BSDA Tablet - Beta lactams	2,037	0	0	0	2,037	0	0.000%				
Charm II Tablet Competitive	1,338	0	0	0	1,338	0	0.000%				
Charm II Tablet Sequential	905	0	0	0	905	0	0.000%				
Charm SL Beta lactams	178,251	70	6,106	2	184,357	72	0.039%				
Delvotest P 5 Pack - Beta lactams	19,573	11	2,993	0	22,566	11	0.04 9%				
Idexx New Snap	52,335	31	12	0	52,347	31	0.059%				
Parallux Beta lactams Assay	2,818	7	0	0	2,818	7	0.248%				
Penzyme Milk Test - Beta lactams	1,519	3	2	0	1,521	3	0.197%				
Snap (Reader) - Beta lactams	28	0	0	0	28	0	0.000%				
Snap (Visual) - Beta lactams	96	0	0	0	96	0	0.000%				
SULFONAMIDES											
Charm II Tablet Competitive	306	0	0	0	306	0	0.000%				
TETRACYCLINES											
Snap - Tetracyclines**	34	0	0	0	34	0	0.000%				
TOTALS	259,240	122	9,113	2	268,353	124	0.046%				

** Non-Validated Test Method

Table 8-6 Number of Tests by Method by Family/Drug Non-Grade "A" Pasteurized Fluid Milk and Milk Products October 1, 2004 to September 30, 2005										
Tests Used by Family/Drug	Number of Industry TestsNumber of Industry TestsNumber of Regulatory 									
BETA lactams										
Charm SL Beta lactams	0	0	1	0	1	0	0.000%			
Delvotest P 5 Pack - Beta lactams	1,219	0	290	0	1,509	0	0.000%			
Idexx New Snap	Idexx New Snap 0 0 75 0 75 0 0.000%									
TOTALS	1,219	0	366	0	1,585	0	0.000%			

Table 8-7 Number of Tests by Method by Family/Drug Non-Grade "A" Producer October 1, 2004 to September 30, 2005											
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	3,826	12	2,501	2	6,327	14	0.221%				
Charm SL Beta lactams	670	0	0	0	670	0	0.000%				
Delvotest P 5 Pack - Beta lactams	29,353	31	3,057	5	32,410	36	0.111%				
Idexx New Snap	846	0	0	0	846	0	0.000%				
TOTALS	34,695	43	5,558	7	40,253	50	0.124%				

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, 2004 to September 30, 2005												
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 II Tablet Competitive	1	0	0	0	1	0	0.000%					
Charm II Tablet Sequential	16	0	0	0	16	0	0.000%					
Charm SL Beta lactams	10,402	0	17	0	10,419	0	0.000%					
Delvotest P 5 Pack - Beta lactams	754	0	794	0	1,548	0	0.000%					
Idexx New Snap	1,265	0	0	0	1,265	0	0.000%					
Parallux Beta lactams Assay	0	0	32	0	32	0	0.000%					
TOTALS	12,438	0	843	0	13,281	0	0.000%					