

NATIONAL MILK DRUG RESIDUE DATA BASE

FISCAL YEAR 2004 ANNUAL REPORT

October 1, 2003 - September 30, 2004

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Contract Number: 223-04-4299

February 11, 2005

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INTRODUCTION

The National Milk Drug Residue Data Base 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 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 National Conference on Interstate Milk Shipments (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 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 residue testing by industry and regulatory agencies.

Subsequently, FDA awarded a contract to develop a National Milk Drug Residue Data Base. 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, 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.

In December of 2003, the FDA notified the reporting states via memoranda M-I-03-18 and 19 that two Snap tests for beta lactams and the Delvo Xpress would no longer be available for use. The Snap tests were being

superceded by the Idexx New Snap test. The Delvo Xpress would have no successor. During this fiscal year, efforts were made to carefully monitor the final expiration dates for these test methods during the transition period to assure that data reporters utilized the appropriate test code for any test methods which may have replaced these defunct tests. To enhance these efforts, a revised drug code list was distributed to state data providers in January of 2004. This list included codes for two test methods which were accepted for use at the 2003 meeting of NCIMS; specifically, Charm SL-6 and Idexx New Snap.

SUMMARY

This report presents summary data on samples and tests conducted during the Fiscal Year 2004, October 1, 2003 to September 30, 2004. All 50 States and Puerto Rico submitted data for this report.

The Pasteurized Milk Ordinance (PMO), the rules which State agencies use to implement their 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 **4,410,056** samples were analyzed for animal drug residues. Of these samples **2,495** were positive for a residue. A total of **4,503,617** tests were reported on the samples for **13** different groups of families or individual drugs. **Thirty-nine** testing methods were used to analyze the samples for residues. Details are presented in the tables in this report.

SAMPLE RESULTS

A SAMPLE 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. Pasteurized Fluid Milk and Milk Products - after pasteurization; finished product in package form or bulk. Includes milk products such as milk, cream, condensed milk and dry milk products, and condensed and dry whey products.
3. Producer - raw milk obtained from the bulk tank/silo on 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 POSITIVE 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 DISPOSITION Per PMO 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, 2003 to September 30, 2004				
Source of Sample	Total Samples	Number Positive	Percent Positive	Disposition per PMO (Pounds)
Bulk Milk Pick-Up Tanker	3,589,082	1,571	0.044%	58,280,000
Pasteurized Fluid Milk and Milk Products	57,875	4	0.007%	49,000
Producer	677,507	895	0.132%	4,284,000
Other	85,592	25	0.029%	1,065,000
TOTALS	4,410,056	2,495	*	63,678,000

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 daily on receipt of every tanker;
2. Pasteurized Fluid Milk and Milk Products -- a minimum of four samples must be tested for each finished product from each plant every six months;
3. Producer -- each producer must be tested at least four times every 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 regulatory agencies. Industry samples are taken by processing facilities, receiving and transfer stations, and marketing groups or cooperatives. Industry samples 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, 2003 to September 30, 2004

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	3,289,873	1,429	22,709	14	3,312,582	1,443	0.044%	54,315,000
Pasteurized Fluid Milk and Milk Products	3,615	0	52,374	4	55,989	4	0.007%	49,000
Producer	466,649	648	163,931	184	630,580	832	0.132%	4,284,000
Other	67,842	23	7,982	1	75,824	24	0.032%	1,028,000
NON-GRADE A								
Bulk Milk Pick-Up Tanker ¹	274,865	127	1,635	1	276,500	128	0.046%	3,965,000
Pasteurized Fluid Milk and Milk Products	1,568	0	318	0	1,886	0	0.000%	0,000
Producer	36,396	47	10,531	16	46,927	63	0.134%	0,000
Other	9,021	1	747	0	9,768	1	0.010%	37,000
TOTALS	4,149,829	2,275	260,227	220	4,410,056	2,495	*	63,678,000 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 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.

² Note that this represents 0.037% of the Totals milk supply of the annual production of 170.6 billion pounds.

*= See Table 1 for explanation

TESTS CONDUCTED

An objective of the National Milk Drug Residue Data Base is to record every test run on each sample analyzed. Since some samples are analyzed for more than one drug residue, the number of tests conducted (4,503,617) is greater than the number of samples (4,410,056). To avoid duplicate reporting of samples, the number of samples analyzed is reported separately from the number of tests run in the data base.

Table 3 presents summary results of the number of tests which were conducted during October 1, 2003 to September 30, 2004. 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 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 Conducted October 1, 2003 to September 30, 2004			
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive
Bulk Milk Pick-Up Tanker	3,678,797	1,801	0.049
Pasteurized Fluid Milk and Milk Products	58,175	5	0.009
Producer	680,102	3,143	0.462
Other	86,543	25	0.029
TOTALS	4,503,617	4,974	*

* = See Table 1 for explanation

TABLE 3A -- Validated Tests Conducted October 1, 2003 to September 30, 2004			
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive
Bulk Milk Pick-Up Tanker	3,639,165	1,698	0.047
Pasteurized Fluid Milk and Milk Products	57,085	5	0.009
Producer	679,235	3,141	0.462
Other	85,867	25	0.029
TOTALS	4,461,352	4,869	*

* = See Table 1 for explanation

TABLE 3B -- Non-Validated Tests Conducted October 1, 2003 to September 30, 2004			
Source of Sample	Total Tests	Number of Tests Positive	Percent Positive
Bulk Milk Pick-Up Tanker	39,632	103	0.260
Pasteurized Fluid Milk and Milk Products	1,090	0	0.000
Producer	867	2	0.231
Other	676	0	0.000
TOTALS	42,265	105	*

* = See Table 1 for explanation

Table 4 presents additional details in terms of the tests conducted by industry and by 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, 2003 to September 30, 2004							
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	3,375,133	1,659	22,902	14	3,398,035	1,673	0.049%
Pasteurized Fluid Milk and Milk Products	3,794	0	52,495	5	56,289	5	0.009%
Producer	468,270	2,893	164,836	186	633,106	3,079	0.486%
Other	68,403	23	8,273	1	76,676	24	0.031%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	278,810	127	1,952	1	280,762	128	0.046%
Pasteurized Fluid Milk and Milk Products	1,568	0	318	0	1,886	0	0.000%
Producer	36,463	48	10,533	16	46,996	64	0.136%
Other	9,040	1	827	0	9,867	1	0.010%
TOTALS	4,241,481	4,751	262,136	223	4,503,617	4,974	*

¹ It 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 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 4A -- Validated Tests Conducted by Industry and Regulatory Agencies
October 1, 2003 to September 30, 2004

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	3,344,362	1,556	14,140	14	3,358,502	1,570	0.047%
Pasteurized Fluid Milk and Milk Products	3,367	0	51,832	5	55,199	5	0.009%
Producer	467,405	2,891	164,834	186	632,239	3,077	0.487%
Other	67,849	23	8,151	1	76,000	24	0.032%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	278,711	127	1,952	1	280,663	128	0.046%
Pasteurized Fluid Milk and Milk Products	1,568	0	318	0	1,886	0	0.000%
Producer	36,463	48	10,533	16	46,996	64	0.136%
Other	9,040	1	827	0	9,867	1	0.010%
TOTALS	4,208,765	4,646	252,587	223	4,461,352	4,869	*

¹ It 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 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 Regulatory Agencies
October 1, 2003 to September 30, 2004**

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	30,771	103	8,762	0	39,533	103	0.261%
Pasteurized Fluid Milk and Milk Products	427	0	663	0	1,090	0	0.000%
Producer	865	2	2	0	867	2	0.231%
Other	554	0	122	0	676	0	0.000%
NON-GRADE A							
Bulk Milk Pick-Up Tanker ¹	99	0	0	0	99	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	32,716	105	9,549	0	42,265	105	*

¹ It 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 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/Drug October 1, 2003 to September 30, 2004		
Family/Drug	Total Tests	Total Positive
AMINOGLYCOSIDES	296	1
Gentamicin	59	0
AMPHENICOLS	833	0
BETA lactams	4,402,823	4,850
Cloxacillin	103	0
FLORFENICOL	3	0
MACROLIDES	37	0
SULFONAMIDES	68,097	21
Sulfachloropyridazine	812	0
Sulfadimethoxine	798	0
Sulfamethazine	19,910	96
TETRACYCLINES	9,190	3
Tetracycline	656	3
TOTALS	4,503,617	4,974

**TABLE 5A -- Number of Validated Tests Conducted by
Family/Drug
October 1, 2003 to September 30, 2004**

Family/Drug	Total Tests	Total Positive
AMPHENICOLS	833	0
BETA lactams	4,402,710	4,850
Cloxacillin	103	0
SULFONAMIDES	51,942	13
Sulfachloropyridazine	812	0
TETRACYCLINES	4,296	3
Tetracycline	656	3
TOTALS	4,461,352	4,869

**TABLE 5B -- Number of Non-Validated Tests Conducted by
Family/Drug
October 1, 2003 to September 30, 2004**

Family/Drug	Total Tests	Total Positive
AMINOGLYCOSIDES	296	1
Gentamicin	59	0
BETA lactams	113	0
FLORFENICOL	3	0
MACROLIDES	37	0
SULFONAMIDES	16,155	8
Sulfadimethoxine	798	0
Sulfamethazine	19,910	96
TETRACYCLINES	4,894	0
TOTALS	42,265	105

Table 6 presents details on the tests used. The data in this table are comparable to Table 5, but the data are arranged by tests within each family/drug. Therefore, the Totals are the same in both tables. The testing methods with the largest use were Charm SL - Beta lactams used more than 2.4 million times followed by Delvotest P 5 Pack - Beta lactams used more than 674 thousand times, Snap (Reader) used more than 338 thousand times and Charm II Tablet Competitive - Beta lactams used for 286 thousand tests. Table 6A shows a comparison of tests conducted using Validated and Non-Validated test methods for Sulfonamides and Tetracyclines.

TABLE 6 - Number of Tests by Method by Family/Drug October 1, 2003 to September 30, 2004			
Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive
AMINOGLYCOSIDES			
Charm II Tablet Competitive-N**	36	1	2.778%
Charm II Tablet Sequential**	260	0	0.000%
GENTAMICIN			
ID Block - Gentamicin**	59	0	0.000%
AMPHENICOLS			
Charm II Tablet Competitive	716	0	0.000%
GC Chloramphenicol - FDA Method	117	0	0.000%
BETA lactams			
Charm BSDA Tablet - Beta lactams	75,149	86	0.114%
Charm Farm - Beta lactams**	113	0	0.000%
Charm I/Cowside II Tablet - Beta lactams	6,510	4	0.061%
Charm II Liquid - Beta lactams	2,812	3	0.107%
Charm II Tablet Competitive	286,837	150	0.052%
Charm II Tablet Quantitative	28,060	76	0.271%
Charm II Tablet Sequential	162,028	124	0.077%
Charm SL Beta lactams	2,447,584	966	0.039%
Charm SL-6	17,096	12	0.070%
Delvo-X-PRESS - Beta-Lactams	207	1	0.483%
Delvotest P 5 Pack - Beta lactams	674,343	3,010	0.446%
Delvotest P/Delvotest P Mini	29,189	1	0.003%
Delvotest SP/Delvotest SP Mini	2,194	0	0.000%
Idexx New Snap	86,786	39	0.045%
Lak Tek - Beta lactams	14,082	0	0.000%
Parallux Beta lactams Assay	104,419	53	0.051%

**TABLE 6 - Number of Tests by Method by Family/Drug
October 1, 2003 to September 30, 2004**

Tests Used by Family/Drug	Number of Tests	Number Positive	Percent Positive
Penzyme III Test - Beta lactams	15,102	6	0.040%
Penzyme Milk Test - Beta lactams	11,074	8	0.072%
Snap (Reader) - Beta lactams	338,453	252	0.074%
Snap (Visual) - Beta lactams	100,785	59	0.059%
CLOXACILLIN			
Charm I/Cowside II Tablet - Cloxacillin	54	0	0.000%
Charm II Test for Cloxacillin in Milk	49	0	0.000%
FLORFENICOL			
Florfenicol**	3	0	0.000%
MACROLIDES			
Charm II Tablet Sequential - Macrolides**	37	0	0.000%
SULFONAMIDES			
Agri-Screen for Sulfonamides**,***	13,412	7	0.052%
Charm II Tablet Competitive	51,942	13	0.025%
Charm II Tablet Sequential**	2,743	1	0.036%
SULFACHLOROPYRIDAZINE			
HPLC 8 Sulfonamides	812	0	0.000%
SULFADIMETHOXINE			
ID Block - Sulfadimethoxine**	798	0	0.000%
SULFAMETHAZINE			
Charm SL - Sulfamethazine**	19,910	96	0.482%
TETRACYCLINES			
Charm II Tablet Competitive	4,296	3	0.070%
Charm SL - Tetracyclines**	1,487	0	0.000%
Snap - Tetracyclines**	3,407	0	0.000%
TETRACYCLINE			
HPLC Tetracyclines - Tetracycline	656	3	0.457%
TOTALS	4,503,617	4,974	*

* = 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, 2003 to September 30, 2004**

Tests By Method by Family/Drug	Number of Tests	Number Positive	Percent Positive
VALIDATED FOR SULFONAMIDES			
Charm II Tablet Competitive	51,942	13	0.025%
VALIDATED FOR SULFACHLOROPYRIDAZINE			
HPLC 8 Sulfonamides	812	0	0.000%
NON-VALIDATED FOR SULFONAMIDES			
Agri-Screen for Sulfonamides** & ***	13,412	7	0.052%
Charm II Tablet Sequential**	2,743	1	0.036%
NON-VALIDATED FOR SULFADIMETHOXINE			
ID Block - Sulfadimethoxine**	798	0	0.000%
NON-VALIDATED FOR SULFAMETHAZINE			
Charm SL - Sulfamethazine**	19,910	96	0.482%
VALIDATED FOR TETRACYCLINES			
Charm II Tablet Competitive	4,296	3	0.070%
VALIDATED FOR TETRACYCLINE			
HPLC Tetracyclines - Tetracycline	656	3	0.457%
NON-VALIDATED FOR TETRACYCLINES			
Charm SL - Tetracyclines**	1,487	0	0.000%
Snap - Tetracyclines**	3,407	0	0.000%
TOTALS	99,463	123	*

** 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 Testing October 1, 2003 to September 30, 2004						
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	1	0	0	36	1
Gentamicin	59	0	0	0	59	0
AMPHENICOLS	612	0	117	0	729	0
BETA lactams	3,289,570	1,542	14,004	14	3,303,574	1,556
Cloxacillin	103	0	0	0	103	0
MACROLIDES	37	0	0	0	37	0
SULFONAMIDES	56,972	19	6,935	0	63,907	19
Sulfachloropyridazine	812	0	0	0	812	0
Sulfadimethoxine	798	0	0	0	798	0
Sulfamethazine	19,373	96	0	0	19,373	96
TETRACYCLINES	6,761	1	1,846	0	8,607	1
TOTALS	3,375,133	1,659	22,902	14	3,398,035	1,673

**TABLE 7-2 -- Grade A Pasteurized Fluid Milk and Milk Products Testing
October 1, 2003 to September 30, 2004**

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	3,196	0	51,356	2	54,552	2
SULFONAMIDES	171	0	520	0	691	0
Sulfamethazine	390	0	0	0	390	0
TETRACYCLINES	37	0	143	0	180	0
Tetracycline	0	0	476	3	476	3
TOTALS	3,794	0	52,495	5	56,289	5

**TABLE 7-3 -- Grade A Producer Testing
October 1, 2003 to September 30, 2004**

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	466,615	2,889	164,176	186	630,791	3,075
SULFONAMIDES	1,650	2	654	0	2,304	2
TETRACYCLINES	4	2	2	0	6	2
Tetracycline	1	0	4	0	5	0
TOTALS	468,270	2,893	164,836	186	633,106	3,079

**TABLE 7-4 -- Grade A Other Testing (milk from silos, over-the-road tankers, etc.)
October 1, 2003 to September 30, 2004**

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	260	0	0	0	260	0
AMPHENICOLS	104	0	0	0	104	0
BETA lactams	67,665	23	8,014	1	75,679	24
FLORFENICOL	0	0	3	0	3	0
SULFONAMIDES	153	0	198	0	351	0
Sulfamethazine	147	0	0	0	147	0
TETRACYCLINES	74	0	24	0	98	0
Tetracycline	0	0	34	0	34	0
TOTALS	68,403	23	8,273	1	76,676	24

**TABLE 7-5 -- Non-Grade A Bulk Milk Pick-Up Tanker Testing
October 1, 2003 to September 30, 2004**

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	277,668	127	1,952	1	279,620	128
SULFONAMIDES	843	0	0	0	843	0
TETRACYCLINES	299	0	0	0	299	0
TOTALS	278,810	127	1,952	1	280,762	128

**TABLE 7-6 -- Non-Grade A Pasteurized Fluid Milk and Milk Products Testing
October 1, 2003 to September 30, 2004**

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	1,568	0	318	0	1,886	0
TOTALS	1,568	0	318	0	1,886	0

**TABLE 7-7 -- Non-Grade A Producer Testing
October 1, 2003 to September 30, 2004**

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	36,322	48	10,532	16	46,854	64
SULFONAMIDES	0	0	1	0	1	0
TETRACYCLINES						
Tetracycline	141	0	0	0	141	0
TOTALS	36,463	48	10,533	16	46,996	64

**TABLE 7-8 -- Non-Grade A Other Testing (milk from silos, over-the-road tankers, etc.)
October 1, 2003 to September 30, 2004**

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	9,040	1	827	0	9,867	1
TOTALS	9,040	1	827	0	9,867	1

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 test within each family/drug 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, 2003 to September 30, 2004**

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	1	0	0	36	1	2.778%
GENTAMICIN							
ID Block - Gentamicin**	59	0	0	0	59	0	0.000%
AMPHENICOLS							
Charm II Tablet Competitive	612	0	0	0	612	0	0.000%
GC Chloramphenicol - FDA Method	0	0	117	0	117	0	0.000%
BETA lactams							
Charm BSDA Tablet - Beta lactams	19,841	16	49	1	19,890	17	0.085%
Charm I/Cowside II Tablet - Beta lactams	6,242	4	0	0	6,242	4	0.064%
Charm II Liquid - Beta lactams	14	2	0	0	14	2	14.286%
Charm II Tablet Competitive	275,946	134	22	0	275,968	134	0.049%
Charm II Tablet Quantitative	26,081	75	36	0	26,117	75	0.287%
Charm II Tablet Sequential	149,180	117	524	1	149,704	118	0.079%
Charm SL Beta lactams	2,204,330	847	4,586	0	2,208,916	847	0.038%
Charm SL-6	17,067	10	4	0	17,071	10	0.059%
Delvo-X-PRESS - Beta-Lactams	207	1	0	0	207	1	0.483%
Delvotest P 5 Pack - Beta lactams	14,786	7	3,852	12	18,638	19	0.102%

**Table 8-1 -- Number of Tests by Method by Family/Drug
Grade A Bulk Milk Pick-Up Tanker
October 1, 2003 to September 30, 2004**

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
Delvotest P/Delvotest P Mini	4,251	0	3,818	0	8,069	0	0.000%
Delvotest SP/Delvotest SP Mini	328	0	0	0	328	0	0.000%
Idexx New Snap	75,902	31	72	0	75,974	31	0.041%
Lak Tek - Beta lactams	14,082	0	0	0	14,082	0	0.000%
Parallux Beta lactams Assay	102,094	44	123	0	102,217	44	0.043%
Penzyme III Test - Beta lactams	12,019	5	0	0	12,019	5	0.042%
Penzyme Milk Test - Beta lactams	9,392	7	15	0	9,407	7	0.074%
Snap (Reader) - Beta lactams	289,501	196	609	0	290,110	196	0.068%
Snap (Visual) - Beta lactams	68,307	46	294	0	68,601	46	0.067%
CLOXACILLIN							
Charm I/Cowside II Tablet - Cloxacillin	54	0	0	0	54	0	0.000%
Charm II Test for Cloxacillin in Milk	49	0	0	0	49	0	0.000%
MACROLIDES							
Charm II Tablet Sequential - Macrolides**	37	0	0	0	37	0	0.000%
SULFONAMIDES							
Agri-Screen for Sulfonamides **,***	5,035	5	6,916	0	11,951	5	0.042%
Charm II Tablet Competitive	49,194	13	19	0	49,213	13	0.026%
Charm II Tablet Sequential**	2,743	1	0	0	2,743	1	0.036%
SULFACHLOROPYRIDAZINE							
HPLC 8 Sulfonamides	812	0	0	0	812	0	0.000%
SULFADIMETHOXINE							

**Table 8-1 -- Number of Tests by Method by Family/Drug
Grade A Bulk Milk Pick-Up Tanker
October 1, 2003 to September 30, 2004**

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
ID Block - Sulfadimethoxine**	798	0	0	0	798	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	19,373	96	0	0	19,373	96	0.496%
TETRACYCLINES							
Charm II Tablet Competitive	4,071	1	0	0	4,071	1	0.025%
Charm SL - Tetracyclines**	1,351	0	0	0	1,351	0	0.000%
Snap - Tetracyclines**	1,339	0	1,846	0	3,185	0	0.000%
TOTALS	3,375,133	1,659	22,902	14	3,398,035	1,673	0.049%

** 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, 2003 to September 30, 2004**

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	1,256	0	1,915	0	3,171	0	0.000%
Charm II Tablet Competitive	54	0	1,726	0	1,780	0	0.000%
Charm II Tablet Quantitative	631	0	0	0	631	0	0.000%
Charm II Tablet Sequential	0	0	932	0	932	0	0.000%

**Table 8-2 -- Number of Tests by Method by Family/Drug
Grade A Pasteurized Fluid Milk and Milk Products
October 1, 2003 to September 30, 2004**

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
Charm SL Beta lactams	445	0	961	0	1,406	0	0.000%
Delvotest P 5 Pack - Beta lactams	635	0	43,560	2	44,195	2	0.005%
Delvotest P/Delvotest P Mini	0	0	2,163	0	2,163	0	0.000%
Idexx New Snap	0	0	30	0	30	0	0.000%
Snap (Reader) - Beta lactams	175	0	49	0	224	0	0.000%
Snap (Visual) - Beta lactams	0	0	20	0	20	0	0.000%
SULFONAMIDES							
Agri-Screen for Sulfonamides ^{**} , ^{***}	0	0	520	0	520	0	0.000%
Charm II Tablet Competitive	171	0	0	0	171	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine ^{**}	390	0	0	0	390	0	0.000%
TETRACYCLINES							
Charm SL - Tetracyclines ^{**}	37	0	0	0	37	0	0.000%
Snap - Tetracyclines ^{**}	0	0	143	0	143	0	0.000%
TETRACYCLINE							
HPLC Tetracyclines - Tetracycline	0	0	476	3	476	3	0.630%
TOTALS	3,794	0	52,495	5	56,289	5	0.009%

** 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, 2003 to September 30, 2004**

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	19,670	30	23,229	27	42,899	57	0.133%
Charm I/Cowside II Tablet - Beta lactams	132	0	42	0	174	0	0.000%
Charm II Liquid - Beta lactams	2,795	1	0	0	2,795	1	0.036%
Charm II Tablet Competitive	2,021	16	2,438	0	4,459	16	0.359%
Charm II Tablet Quantitative	236	0	0	0	236	0	0.000%
Charm II Tablet Sequential	22	3	2,388	1	2,410	4	0.166%
Charm SL Beta lactams	5,017	34	6,274	4	11,291	38	0.337%
Charm SL-6	16	2	0	0	16	2	12.500%
Delvotest P 5 Pack - Beta lactams	418,124	2,776	122,430	154	540,554	2,930	0.542%
Delvotest P/Delvotest P Mini	11,371	1	6,012	0	17,383	1	0.006%
Delvotest SP/Delvotest SP Mini	339	0	27	0	366	0	0.000%
Idexx New Snap	781	0	352	0	1,133	0	0.000%
Parallux Beta lactams Assay	1,669	9	0	0	1,669	9	0.539%
Penzyme Milk Test - Beta lactams	234	0	0	0	234	0	0.000%
Snap (Reader) - Beta lactams	2,929	16	973	0	3,902	16	0.410%
Snap (Visual) - Beta lactams	1,259	1	11	0	1,270	1	0.079%
SULFONAMIDES							
Agri-Screen for Sulfonamides **, ***	865	2	0	0	865	2	0.231%

**Table 8-3 -- Number of Tests by Method by Family/Drug
Grade A Producer
October 1, 2003 to September 30, 2004**

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
Charm II Tablet Competitive	785	0	654	0	1,439	0	0.000%
TETRACYCLINES							
Charm II Tablet Competitive	4	2	0	0	4	2	50.000%
Snap - Tetracyclines**	0	0	2	0	2	0	0.000%
TETRACYCLINE							
HPLC Tetracyclines - Tetracycline	1	0	4	0	5	0	0.000%
TOTALS	468,270	2,893	164,836	186	633,106	3,079	0.486%

** Non-Validated Test Method

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

**Table 8-4 -- Number of Tests by Method by Family/Drug
Grade A Other (milk from silos, over-the-road tankers, etc.)
October 1, 2003 to September 30, 2004**

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 Sequential**	260	0	0	0	260	0	0.000%
AMPHENICOLS							
Charm II Tablet Competitive	104	0	0	0	104	0	0.000%
BETA lactams							
Charm BSDA Tablet - Beta lactams	1,774	0	284	0	2,058	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, 2003 to September 30, 2004**

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
Charm Farm - Beta lactams**	0	0	113	0	113	0	0.000%
Charm II Liquid - Beta lactams	0	0	3	0	3	0	0.000%
Charm II Tablet Competitive	3,422	0	243	0	3,665	0	0.000%
Charm II Tablet Quantitative	1,076	1	0	0	1,076	1	0.093%
Charm II Tablet Sequential	7,376	1	280	0	7,656	1	0.013%
Charm SL Beta lactams	36,127	3	517	0	36,644	3	0.008%
Charm SL-6	9	0	0	0	9	0	0.000%
Delvotest P 5 Pack - Beta lactams	2,749	1	5,919	1	8,668	2	0.023%
Delvotest P/Delvotest P Mini	709	0	471	0	1,180	0	0.000%
Delvotest SP/Delvotest SP Mini	1,500	0	0	0	1,500	0	0.000%
I dexx New Snap	970	2	20	0	990	2	0.202%
Parallux Beta lactams Assay	0	0	74	0	74	0	0.000%
Penzyme Milk Test - Beta lactams	0	0	5	0	5	0	0.000%
Snap (Reader) - Beta lactams	9,712	14	35	0	9,747	14	0.144%
Snap (Visual) - Beta lactams	2,241	1	50	0	2,291	1	0.044%
FLORFENICOL							
Florfenicol**	0	0	3	0	3	0	0.000%
SULFONAMIDES							
Agri-Screen for Sulfonamides**,***	73	0	3	0	76	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, 2003 to September 30, 2004**

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
Charm II Tablet Competitive	80	0	195	0	275	0	0.000%
SULFAMETHAZINE							
Charm SL - Sulfamethazine**	147	0	0	0	147	0	0.000%
TETRACYCLINES							
Charm II Tablet Competitive	0	0	21	0	21	0	0.000%
Snap - Tetracyclines**	74	0	3	0	77	0	0.000%
TETRACYCLINE							
HPLC Tetracyclines - Tetracycline	0	0	34	0	34	0	0.000%
TOTALS	68,403	23	8,273	1	76,676	24	0.031%

** Non-Validated Test Method

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

**Table 8-5 -- Number of Tests by Method by Family/Drug
Non-Grade A Bulk Milk Pick-Up Tanker
October 1, 2003 to September 30, 2004**

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	217	0	0	0	217	0	0.000%

**Table 8-5 -- Number of Tests by Method by Family/Drug
Non-Grade A Bulk Milk Pick-Up Tanker
October 1, 2003 to September 30, 2004**

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
Charm I/Cowside II Tablet - Beta lactams	94	0	0	0	94	0	0.000%
Charm II Tablet Competitive	843	0	0	0	843	0	0.000%
Charm II Tablet Sequential	1,316	1	0	0	1,316	1	0.076%
Charm SL Beta lactams	180,758	75	1,305	1	182,063	76	0.042%
Delvotest P 5 Pack - Beta lactams	20,674	6	642	0	21,316	6	0.028%
Idexx New Snap	8,239	6	0	0	8,239	6	0.073%
Parallux Beta lactams Assay	409	0	0	0	409	0	0.000%
Penzyme III Test - Beta lactams	3,083	1	0	0	3,083	1	0.032%
Penzyme Milk Test - Beta lactams	1,428	1	0	0	1,428	1	0.070%
Snap (Reader) - Beta lactams	33,466	26	1	0	33,467	26	0.078%
Snap (Visual) - Beta lactams	27,141	11	4	0	27,145	11	0.041%
SULFONAMIDES							
Charm II Tablet Competitive	843	0	0	0	843	0	0.000%
TETRACYCLINES							
Charm II Tablet Competitive	200	0	0	0	200	0	0.000%
Charm SL - Tetracyclines**	99	0	0	0	99	0	0.000%
TOTALS	278,810	127	1,952	1	280,762	128	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, 2003 to September 30, 2004**

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	0	0	36	0	36	0	0.000%
Delvotest P 5 Pack - Beta lactams	1,568	0	212	0	1,780	0	0.000%
Delvotest P/Delvotest P Mini	0	0	70	0	70	0	0.000%
TOTALS	1,568	0	318	0	1,886	0	0.000%

**Table 8-7 -- Number of Tests by Method by Family/Drug
Non-Grade A Producer
October 1, 2003 to September 30, 2004**

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	6,414	8	500	4	6,914	12	0.174%
Charm II Tablet Competitive	86	0	0	0	86	0	0.000%
Charm SL Beta lactams	1,103	1	1	0	1,104	1	0.091%
Delvotest P 5 Pack - Beta lactams	27,399	39	9,955	12	37,354	51	0.137%
Delvotest P/Delvotest P Mini	175	0	76	0	251	0	0.000%
Idexx New Snap	75	0	0	0	75	0	0.000%
Snap (Reader) - Beta lactams	977	0	0	0	977	0	0.000%
Snap (Visual) - Beta lactams	93	0	0	0	93	0	0.000%
SULFONAMIDES							

**Table 8-7 -- Number of Tests by Method by Family/Drug
Non-Grade A Producer
October 1, 2003 to September 30, 2004**

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
Charm II Tablet Competitive	0	0	1	0	1	0	0.000%
TETRACYCLINE							
HPLC Tetracyclines - Tetracycline	141	0	0	0	141	0	0.000%
TOTALS	36,463	48	10,533	16	46,996	64	0.136%

**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, 2003 to September 30, 2004**

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 Sequential	10	0	0	0	10	0	0.000%
Charm SL Beta lactams	6,105	1	55	0	6,160	1	0.016%
Delvotest P 5 Pack - Beta lactams	1,192	0	646	0	1,838	0	0.000%
Delvotest P/Delvotest P Mini	0	0	73	0	73	0	0.000%
Idexx New Snap	345	0	0	0	345	0	0.000%
Parallux Beta lactams Assay	0	0	50	0	50	0	0.000%
Snap (Reader) - Beta lactams	26	0	0	0	26	0	0.000%
Snap (Visual) - Beta lactams	1,362	0	3	0	1,365	0	0.000%
TOTALS	9,040	1	827	0	9,867	1	0.010%