#### HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:MST

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M-a-98

March 1, 2013

Implementation Date: March 15, 2013

#### TO: All Regional Food and Drug Directors Attn: Regional Milk Specialists

- FROM: Dairy and Egg Branch (HFS-316)
- SUBJECT: Official Grade "A" Pasteurized Milk Ordinance (PMO) Regulatory Laboratory Tests For Grade "A" Milk And Milk Products And Grade "A" Dairy Farm And Milk Plant Water

M-a-98 has been jointly developed and written by the NCIMS Laboratory Committee and FDA's Milk Safety Team (MST) and Laboratory Proficiency Evaluation Team (LPET). This M-a is being issued to further clarify M-I-02-8 (Laboratory Tests Not Approved For Specific Dairy Products May Not Be Used As "Official Regulatory Tests"), issued June 21, 2002, and as requested within Proposal 224 as passed at the 2005 NCIMS Conference. Proposal 224 requested FDA to issue an M-a addressing laboratory tests that have been validated by the NCIMS for the different milk matrixes. This M-a is to be updated utilizing the same procedures as FDA currently uses for the updating of M-a-85 and M-a-97. The request to study this issue was referred to the NCIMS Laboratory Committee and the information provided in the Tables that follow is based on the recommendations of the NCIMS Laboratory Committee. The following Tables are provided with this M-a for a quick and easy reference:

- Table 1. Grade "A" Milk and Milk Products Required PMO Laboratory Testing by Product Code,
- Table 2. Grade "A" Milk and Milk Products Animal Drug Residue Required PMO Laboratory Testing,
- Table 3. Grade "A" Milk and Milk Products Required PMO Laboratory Testing by Microbiological or Chemical Test Method, and
- Table 4. Grade "A" Dairy Farm and Milk Plant Water Required PMO Laboratory Testing.

**NOTE:** In the past, testing and test methods may have been utilized by State milk laboratories for certain milk and/or milk products that are listed within the Tables; however, following the NCIMS Laboratory Committee's review of the available scientific data they may not be identified as a validated test or were not validated for the specific milk matrix identified in the Tables.

Section 6-The Examination of Milk and Milk Products of the PMO makes the following statement:

"All pasteurized and ultra-pasteurized milk and milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would be no requirement for sampling. Required bacterial counts, coliform counts, drug tests, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and milk products defined in this *Ordinance* only when there are validated and accepted test methodology."

In the Tables, the wording that is being utilized equates to the terms identified below:

- "Milk" is cow milk;
- "Pasteurized" (Past.) includes Vat (Batch), High-Temperature-Short-Time (HTST) and Higher-Heat-Shorter-Time (HHST) pasteurization. (Refer to Sections 1-Definitions and 7-Standards for Grade "A" Milk and Milk Products of the PMO for applicable times and temperatures); and
- Ultra-pasteurized (UP) means thermally processed at or above 280°F (138°C) for at least two (2) seconds, so as to produce a milk and/or milk product which has an extended shelf life (ESL) under refrigerated conditions.

Directions of how to properly use the Tables that are included in this M-a:

## <u> TABLE 1:</u>

Identify the specific milk and/or milk product(s) under the "Product Description" column that you are referencing to determine which laboratory tests have methods available that are validated by FDA and accepted by the NCIMS and; therefore, are required within Section 6-The Examination of Milk and Milk Products of the PMO to be conducted in an NCIMS accredited laboratory for the specific milk and/or milk product(s).

**Example:** We are looking for the testing requirements for Pasteurized Half & Half  $(\frac{1}{2} & \frac{1}{2})$  and which **laboratory tests have methods available that are validated by FDA and accepted by the NCIMS** and; therefore, are required to be used to test Pasteurized Half & Half ( $\frac{1}{2} & \frac{1}{2}$ ).

Pasteurized Half & Half ( $\frac{1}{2}$  &  $\frac{1}{2}$ ) is identified under Product Code #4. Reading across the row it identifies that **Temperature**, **Bacteria**, **Coliform**, **Inhibitors and ALP (Alkaline Phosphatase)** testing/analysis are required to be conducted and

that the test results are to be reported to the Regulatory Agency for official regulatory purposes.

➤ Temperature<sup>2</sup> has a footnote referenced to 2 on Page 10. Footnote 2 cites Table 1. Chemical, Physical, Bacteriological and Temperature Standards of the PMO and within that Table of the PMO the temperature standard for Grade "A" Pasteurized Milk and Milk Products is "7°C (45°F) or less". The milk and milk product exceptions cited in Item 17p-Cooling of Milk and Milk Products of the PMO do not apply to Pasteurized Half & Half (½ & ½).
> Bacteria<sup>3</sup> (Refer to Table 3) has a footnote referenced to 3 on Page 10. Footnote 3 cites Table 1. Chemical, Physical, Bacteriological and Temperature Standards of the PMO and within that Table of the PMO the bacterial limits for Grade "A" Pasteurized Milk and Milk Products is "Not to Exceed 20,000 per mL, or gram\*\*\* NOTE: Tested in conjunction with the drug residue/inhibitory substance test".

substance test".

Substance test".
➤ Coliform<sup>3</sup> (Refer to Table 3) has a footnote referenced to 3 on Page 10. Footnote 3 cites Table 1. Chemical, Physical, Bacteriological and Temperature Standards of the PMO and within that Table of the PMO the coliform standard for Grade "A" Pasteurized Milk and Milk Products is "Not to Exceed 10 per mL ... NOTE: Tested in conjunction with the drug residue/inhibitory substance test".
> Inhibitors<sup>3,4</sup> (Refer to Table 2) has a footnote referenced to 3 and 4 on Page 10. Footnote 3 cites Table 1. Chemical, Physical, Bacteriological and Temperature Standards of the PMO and within that Table of the PMO the inhibitor standard for Grade "A" Pasteurized Milk and Milk Products is "No positive results on drug residue detection methods as referenced in Section 6-Laboratory Techniques which have been found to be acceptable for use with pasteurized milk and which have been found to be acceptable for use with pasteurized milk and milk products". Footnote 4 cites M-a-85 (Current Revision; MOI-96-10 (Current Revision); and M-I-02-8.

**NOTE:** Under **Inhibitors**<sup>3,4</sup> (Refer to Table 2) is X<sup>7</sup>. X<sup>7</sup> has a footnote referenced to 7 on Page 10 which cites "Delvotest P 5 Pack (Visual)-(M-I-99-3)".

➤ ALP<sup>3</sup> (Refer to Table 3) has a footnote referenced to 3 on Page 10. Footnote 3 cites Table 1. Chemical, Physical, Bacteriological and Temperature Standards of the PMO and within that Table of the PMO the phosphatase standard for Grade "A" Pasteurized Milk and Milk Products is "Less than 350 milliunits/L for fluid products and other milk products by approved electronic phosphatase procedures".

If the specific milk and/or milk product(s) under the "Product Description" column that you are referencing has an X in any of the columns across the page this identifies the laboratory tests that have methods available that are validated by FDA and accepted by the NCIMS and are required to be used for the testing of the specific milk and/or milk product. If any of the columns with an X in them have a reference to "Refer to Table 2" or "Refer to Table 3", please refer to the appropriate Table.

**NOTE:** From Table 1 it is identified that an annual vitamin assay would not be required even if vitamins would be added to the Pasteurized Half & Half ( $\frac{1}{2}$  &  $\frac{1}{2}$ ) because this Table does not identify any laboratory tests that have methods available that have been validated by FDA and accepted by the NCIMS.

In Our Example: Half & Half ( $\frac{1}{2}$  &  $\frac{1}{2}$ ), Inhibitors<sup>3,4</sup> (Refer to Table 2) has an X in the column and Bacteria<sup>3</sup> (Refer to Table 3), Coliform<sup>3</sup> (Refer to Table 3) and ALP<sup>3</sup> (Refer to Table 3) have an X in each of the columns. Please refer to Table 2 first.

## <u> TABLE 2:</u>

- Identify the specific milk and/or milk product(s) across the first row on each page of Table 2 that you are referencing to determine which drug residue test(s) is available that has been validated by FDA and accepted by the NCIMS and; therefore, is required within Section 6-The Examination of Milk and Milk Products of the PMO to be conducted in an NCIMS accredited laboratory for the specific milk and/or milk product(s).
  - In Our Example: The Past. ½ & ½ (Half & Half) column has an X in the row indentified as "DELVOTEST P 5 PACK (VISUAL)<sup>9-D3</sup>" as the only drug residue test available that has been validated by FDA and accepted by the NCIMS for Past. ½ & ½ (Half & Half). Therefore, this is the drug residue test that is required to be used to test Past. ½ & ½ (Half & Half) for drug residues (Beta lactams).

<u>NOTE:</u> <sup>9-D3</sup>(9-D3) refers to the Laboratory Procedure Code for Delvotest P 5 Pak used on the *IMS List*.

There has not been any drug residue test validated by FDA and accepted by the NCIMS for Ultra-pasteurized (UP)  $\frac{1}{2}$  &  $\frac{1}{2}$  (Half & Half).

In Our Example: From Table 1, Half & Half, Bacteria<sup>3</sup> (Refer to Table 3), Coliform<sup>3</sup> (Refer to Table 3) and ALP<sup>3</sup> (Refer to Table 3) have an X in each of the columns. Please refer to Table 3.

#### <u> TABLE 3:</u>

- Identify the specific milk and/or milk product(s) across the first row of the applicable pages of Table 3 that you are referencing to determine which Microbiological and/or Chemical Test Method (Bacterial Count, Somatic Cell Count, Coliform, Alkaline Phosphatase and Vitamins) tests are available that have been validated by FDA and accepted by the NCIMS and; therefore, are required within Section 6-The Examination of Milk and Milk Products of the PMO to be conducted in an NCIMS accredited laboratory for the specific milk and/or milk product(s).
  - In Our Example: In the Past./UP ½ & ½ (Half & Half) column it has an X in the rows indentified as "STANDARD PLATE COUNT<sup>2</sup> (SPC)" and "3M PETRIFLIM AEROBIC COUNT<sup>5</sup> (PAC)" as the only Bacterial Count Methods available that have been validated by FDA and accepted by the NCIMS for Past./UP ½ & ½ (Half & Half). Therefore, one (1) of these two (2) Bacterial Count Methods is required to be used to test Past./UP ½ & ½ (Half & Half) for Bacterial Count.

**NOTE:** <sup>2</sup>(2) refers to the Laboratory Procedure Code for Standard Plate Count and <sup>5</sup>(5) refers to the Laboratory Procedure Code for Petrifilm Aerobic Count used on the *IMS List*.

In the Past./UP ½ & ½ (Half & Half) column it has an X in the rows indentified as "3M PETRIFIM COLIFOM COUNT<sup>20</sup> (PAC)", "3M PETRIFILM HIGH

SENSITIVITY COLIFORM COUNT<sup>20</sup> (HSCC) FOR 1:10, 1:5 DILUTIONS", and "COLIFORM PLATE COUNT<sup>21</sup> (Violet Red Bile-Approved for All Products)" as the **Coliform Methods available that have been validated by FDA and accepted by the NCIMS** for Past./UP  $\frac{1}{2}$  &  $\frac{1}{2}$  (Half & Half). Therefore, any of these identified Coliform Methods would be required to be used to test Past./UP  $\frac{1}{2}$  &  $\frac{1}{2}$  (Half & Half) for Coliform.

**NOTE:** <sup>20</sup>(20) refers to the Laboratory Procedure Code for Petrifilm Coliform Count/High Sensitivity Coliform Count, and <sup>21</sup>(21) refers to the Laboratory Procedure Code for Coliform Plate Count used on the *IMS List*.

In the Past./UP  $\frac{1}{2}$  &  $\frac{1}{2}$  (Half & Half) column it has an X in the rows indentified as "FLOUROPHOS<sup>28"</sup>, "PASLITE<sup>29"</sup> and "CHARM FAST ALKALINE PHOSPHATASE (FAP)<sup>29"</sup> as the **Alkaline Phosphatase Methods available that have been validated by FDA and accepted by the NCIMS** for Past.  $\frac{1}{2}$  &  $\frac{1}{2}$  (Half & Half). Therefore, any of these identified Alkaline Phosphatase Methods would be required to be used to test Past.  $\frac{1}{2}$  &  $\frac{1}{2}$  (Half & Half) for Alkaline Phosphatase.

<u>NOTE:</u> The FLOUROPHOS<sup>28</sup>, PASLITE<sup>29</sup> and CHARM FAST ALKALINE PHOSPHATASE (FAP)<sup>29</sup> Coliform Methods have **not been validated by FDA and accepted by the NCIMS** for Ultra-pasteurized (UP)  $\frac{1}{2}$  &  $\frac{1}{2}$  (Half & Half). Therefore, UP  $\frac{1}{2}$  &  $\frac{1}{2}$  (Half & Half) is not required to be tested under Section 6 of the PMO for Alkaline Phosphatase.

<sup>28</sup>(28) refers to the Laboratory Procedure Code for Phosphatase Test-Flourophos and <sup>29</sup>(29) refers to the Laboratory Procedure Code for Phosphatase Test-Charm used on the *IMS List*.

When referring to M-I-02-8, Section 6-The Examination of Milk and Milk Products, Section 7-Standards for Grade "A" Milk and Milk Products, Table 1-Chemical, Physical, Bacteriological and Temperature Standards and Appendix N-Drug Residue Testing and Farm Surveillance of the PMO, the attached Tables shall be referenced to determine which Tests have been validated for the specific Grade "A" milk and milk product referenced and which laboratory tests are required to be conducted in accordance with the requirements of the PMO.

**NOTE:** M-I-02-8 remains in "**ACTIVE**" status and if a Regulatory Agency chooses to have a Grade "A" milk or milk product tested that is not listed as having a validated method or uses an unapproved test for "Official Regulatory" testing and the result is violative, regulatory officials shall act on the results. Appropriate action and a follow-up investigation are required to resolve the result.

Proposal 224, as passed at the 2005 NCIMS Conference, authorized FDA to issue future updates to M-a-98, which add, delete or revise these tests, without requiring a public comment period or following the protocol established in the *Procedures* document for the issuance of M-a Coded Memoranda. The issuing of future updates to this M-a will be conducted in the same manner as how updates to M-a-85 (Beta Lactam Test Methods For Use Under Appendix N And Section 6 Of The Pasteurized Milk Ordinance (PMO)) and M-

a-97 (Specified Microbial Inhibitors/Preservatives Accepted By FDA For Use In The Production Of Cottage Cheese That Will Be Filled At 13°C (55°F) Or Less, Cooled To 10°C (50°F) Or Less Within Twenty-Four (24) Hours Of Filling, And Cooled To 7°C (45°F) Or Less Within Seventy-Two (72) Hours Of Filling) are being handled. Therefore, this M-a and future updates to this M-a, as is the current practice with M-a-85 and M-a-97, will not be incorporated into the PMO.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, Regulatory/Rating Agencies, Laboratory Evaluation Officers and Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web Site at <u>http://www.fda.gov</u> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

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# TABLE 1.GRADE "A" MILK AND MILK PRODUCTS REQUIRED PMO LABORATORY TESTINGBY PRODUCT CODE

PRODUCT CODE <sup>1</sup>	PRODUCT DESCRIPTION <sup>1</sup>	TEMPERATURE <sup>2</sup>	BACTERIA <sup>3</sup> (REFER TO TABLE 3)	COLIFORM <sup>3</sup> (REFER TO TABLE 3)	INHIBITORS <sup>3,4</sup> (REFER TO TABLE 2)	SOMATIC CELL <sup>3</sup> (REFER TO TABLE 3)	ALP <sup>3</sup> (REFER TO TABLE 3)	VITAMINS <sup>5</sup> (REFER TO TABLE 3)
1	Raw Cows Milk- Dairy Farm	Х	Х		Х	Х		
1	Raw Commingled Cows Milk for Pasteurization/ Ultra- Pasteurization (UP)/Aseptic Processing and Packaging-Plant ( <u>NOTE:</u> Includes raw milk from a single source that is not commingled with other producer's raw milk.)	X	X		X			
2	Pasteurized Milk, Reduced Fat, Lowfat, or Skim	Х	Х	Х	X <sub>6</sub>		X	Х
2	Pasteurized Chocolate Milk, Reduced Fat, Lowfat, or Skim	Х	Х	Х	X <sup>7</sup>		X	Х

PRODUCT CODE <sup>1</sup>	PRODUCT DESCRIPTION <sup>1</sup>	TEMPERATURE <sup>2</sup>	BACTERIA <sup>3</sup> (REFER TO TABLE 3)	COLIFORM <sup>3</sup> (REFER TO TABLE 3)	INHIBITORS <sup>3,4</sup> (REFER TO TABLE 2)	SOMATIC CELL <sup>3</sup> (REFER TO TABLE 3)	ALP <sup>3</sup> (REFER TO TABLE 3)	VITAMINS <sup>5</sup> (REFER TO TABLE 3)
2	Pasteurized Flavored Milk, Reduced Fat, Lowfat, or Skim (Other than Chocolate)	X	Х	Х			X	
3	Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream)							
4	Pasteurized Half & Half, Coffee Cream, Creams	Х	X	X	X <sup>7</sup>		X	
5	Ultra-Pasteurized Milk and Milk Products	Х	X	X	X <sub>6</sub>			Х
5	Ultra-Pasteurized Chocolate Milk	Х	X	X	X <sup>7,12</sup>			X
5	Ultra-Pasteurized Flavored Milk Products (Other than Chocolate)	Х	Х	Х				
5	Ultra-Pasteurized Half & Half, Coffee Cream, Creams	Х	X	X				
6	Aseptic Milk and Milk Products (Including Flavored)							X (White Milk and Chocolate Flavored Milks Only-All Fat Levels)

PRODUCT CODE <sup>1</sup>	PRODUCT DESCRIPTION <sup>1</sup>	TEMPERATURE <sup>2</sup>	BACTERIA <sup>3</sup> (REFER TO TABLE 3)	COLIFORM <sup>3</sup> (REFER TO TABLE 3)	INHIBITORS <sup>3,4</sup> (REFER TO TABLE 2)	SOMATIC CELL <sup>3</sup> (REFER TO TABLE 3)	ALP <sup>3</sup> (REFER TO TABLE 3)	VITAMINS <sup>5</sup> (REFER TO TABLE 3)
7	Cottage Cheese (Including Lowfat, Nonfat or Dry Curd)	X <sup>2</sup>		X				
8	Cultured or Acidified Milk and Milk Products	X <sup>2</sup>		X				
9	Yogurt (Including Lowfat and Skim)	X <sup>2</sup>		Х				
10	Sour Cream Products (Acidified or Cultured)	X <sup>2</sup>		Х				
11	Whey (Liquid) for Condensing and/or Drying	Х						
12	Whey (Condensed)	Х		Х				
13	Whey (Dry)			Х				
14	Modified Whey Products (Condensed)	Х		X				
14	Modified Whey Products (Dry)			X				
15	Condensed Milk and Milk Products	Х		Х				
16	Nonfat Dry Milk (NFDM)		Х	Х				
17	Buttermilk (Condensed)	Х		Х				
17	Buttermilk (Dry)			Х				

PRODUCT CODE <sup>1</sup>	PRODUCT DESCRIPTION <sup>1</sup>	TEMPERATURE <sup>2</sup>	BACTERIA <sup>3</sup> (REFER TO TABLE 3)	COLIFORM <sup>3</sup> (REFER TO TABLE 3)	INHIBITORS <sup>3,4</sup> (REFER TO TABLE 2)	SOMATIC CELL <sup>3</sup> (REFER TO TABLE 3)	ALP <sup>3</sup> (REFER TO TABLE 3)	VITAMINS <sup>5</sup> (REFER TO TABLE 3)
18	Eggnog	Х		Х				
19	Lactose Reduced Milk and Milk Products (Fluid)	Х	X	X				Х
20	Low-Sodium Milk and Milk Products	Х	Х	Х			Must Be Studied	Х
21	Milk and Milk Products with Added Safe and Suitable Microbial Organisms (Such as Lactobacillus acidophilus)	X		X				Х
22	Dry Milk and Milk Products		Х	Х				
23	Anhydrous Milk Fat			Х				
24	Cholesterol Modified Anhydrous Milk Fat			X				
25	Cholesterol Modified Fluid Milk Products	Х		X				
26	Cream (Condensed)	Х		Х				
26	Cream (Dry)		Х	Х				
27	Blended Dry Products		Х	Х				
28	Whey Cream	Х		Х				

PRODUCT CODE <sup>1</sup>	PRODUCT DESCRIPTION <sup>1</sup>	TEMPERATURE <sup>2</sup>	BACTERIA <sup>3</sup> (REFER TO TABLE 3)	COLIFORM <sup>3</sup> (REFER TO TABLE 3)	INHIBITORS <sup>3,4</sup> (REFER TO TABLE 2)	SOMATIC CELL <sup>3</sup> (REFER TO TABLE 3)	ALP <sup>3</sup> (REFER TO TABLE 3)	VITAMINS <sup>5</sup> (REFER TO TABLE 3)
29	Whey Cream and Cream Blends	Х		Х				
30	Grade "A" Lactose (Dry)			X				
31	Raw Goat Milk- Dairy Farm	Х	X		X <sup>8</sup>	Х		
31	Raw Commingled Goat Milk for Pasteurization/UP /Aseptic Processing and Packaging-Plant ( <u>NOTE:</u> Includes raw milk from a single source that is not commingled with other producer's raw milk.)	X	X		X <sup>8</sup>			
32	Pasteurized Goat Milk and Milk Products (Including Flavored)	Х	X	X	X <sup>7</sup>		X	
33	Cultured Goat Milk and Milk Products	X <sup>2</sup>		X				
34	Condensed Goat Milk and Milk Products	Х		X				
34	Dry Goat Milk and Milk Products		Х	Х				

PRODUCT CODE <sup>1</sup>	PRODUCT DESCRIPTION <sup>1</sup>	TEMPERATURE <sup>2</sup>	BACTERIA <sup>3</sup> (REFER TO TABLE 3)	COLIFORM <sup>3</sup> (REFER TO TABLE 3)	INHIBITORS <sup>3,4</sup> (REFER TO TABLE 2)	SOMATIC CELL <sup>3</sup> (REFER TO TABLE 3)	ALP <sup>3</sup> (REFER TO TABLE 3)	VITAMINS <sup>5</sup> (REFER TO TABLE 3)
35	Ultra-Pasteurized Goat Milk and Milk Products	Х	X	X	X <sup>7,13</sup>			
36	Aseptic Goat Milk and Milk Products							
37	Raw Sheep Milk- Dairy Farm	Х	X		X <sub>9</sub>	Х		
37	Raw Commingled Sheep Milk for Pasteurization/UP /Aseptic Processing and Packaging-Plant ( <u>NOTE:</u> Includes raw milk from a single source that is not commingled with other producer's raw milk.)	X	X		X9			
38	Pasteurized Sheep Milk and Milk Products	Х	X	X	Must Be Studied		Must Be Studied	
39	Cultured Sheep Milk and Milk Products	X <sup>2</sup>		X				
40	Concentrated Raw Milk Products for Pasteurization	Х	X					
41	Concentrated Pasteurized Milk Products	Х	X	X				

PRODUCT CODE <sup>1</sup>	PRODUCT DESCRIPTION <sup>1</sup>	TEMPERATURE <sup>2</sup>	BACTERIA <sup>3</sup> (REFER TO TABLE 3)	COLIFORM <sup>3</sup> (REFER TO TABLE 3)	INHIBITORS <sup>3,4</sup> (REFER TO TABLE 2)	SOMATIC CELL <sup>3</sup> (REFER TO TABLE 3)	ALP <sup>3</sup> (REFER TO TABLE 3)	VITAMINS <sup>5</sup> (REFER TO TABLE 3)
42	Ultra-filtered Permeate from Milk	Х	X	X				
43	Ultra-filtered Permeate from Whey	Х		X				
44	Raw Water Buffalo Milk – Dairy Farm	Х	X		X <sup>10</sup>	Х		
44	Raw Commingled Water Buffalo Milk for Pasteurization/UP /Aseptic Processing and Packaging-Plant ( <u>NOTE:</u> Includes raw milk from a single source that is not commingled with other producer's raw milk.)	X	X		X <sup>10</sup>			
45	Pasteurized Water Buffalo Milk and Milk Products	Х	Х	Х	Must Be Studied		Must Be Studied	
46	Cultured Water Buffalo Milk and Milk Products	X <sup>2</sup>		Х				
47	Raw Camel Milk- Dairy Farm	Х	X		X <sup>11</sup>	Must Be Studied		

PRODUCT CODE <sup>1</sup>	PRODUCT DESCRIPTION <sup>1</sup>	TEMPERATURE <sup>2</sup>	BACTERIA <sup>3</sup> (REFER TO TABLE 3)	COLIFORM <sup>3</sup> (REFER TO TABLE 3)	INHIBITORS <sup>3,4</sup> (REFER TO TABLE 2)	SOMATIC CELL <sup>3</sup> (REFER TO TABLE 3)	ALP <sup>3</sup> (REFER TO TABLE 3)	VITAMINS <sup>5</sup> (REFER TO TABLE 3)
47	Raw Camel Milk for Pasteurization/ UP/Aseptic Processing and Packaging-Plant ( <u>NOTE:</u> Includes raw milk from a single source that is not commingled with other producer's raw milk.)	X	X		X <sup>11</sup>			
48	Pasteurized Camel Milk and Milk Products	X	X	X	Must Be Studied		Must Be Studied	
49	Cultured Camel Milk and Milk Products	X <sup>2</sup>		Х				

1 - Product Codes from the IMS List and Page 2 of FORM FDA 2359i-Interstate Milk Shipper's Report.

- 2 Section 6-The Examination of Milk and Milk Products, Section 7-Standards for Grade "A" Milk and Milk Products, Table 1-Chemical, Physical, Bacteriological and Temperature Standards, and Items 18r-Cooling of Raw Milk and 17p-Cooling of Milk and Milk Products of the PMO.
- 3 Section 6-The Examination of Milk and Milk Products and Section 7-Standards for Grade "A" Milk and Milk Products, Table 1-Chemical, Physical, Bacteriological and Temperature Standards of the PMO; and M-I-02-8.
- 4 M-a-85 (Current Revision); M-I-96-10 (Current Revision); and M-I-02-8.
- 5 Section 6-The Examination of Milk and Milk Products and Appendix O-Vitamin Fortification of Fluid Milk Products of the PMO.
- 6 Charm® *B. stearothermophilus* Tablet Disk Assay, Charm® II Tablet Beta Lactam Test (Competitive Assay), Charm® II Test for Cloxacillin in Milk (Competitive Assay), and Delvotest P 5 Pack (Reader and Visual)-(M-I-98-3).
- 7 Delvotest P 5 Pack (Visual)-(M-I-99-3).

- 8 Charm® *B. stearothermophilus* Tablet Disk Assay, Charm® II Tablet Beta Lactam Test (Sequential Assay), Charm® SL Beta Lactam-(M-I-03-3), and Delvo Test P/Delvotest P MINI are acceptable for testing raw, commingled goat milk.
- 9 The Charm® SL Beta Lactam Test is acceptable for testing raw, commingled sheep milk-(M-I-09-7).
- 10 -The Charm® SL Beta Lactam Test, Delvotest P/Delvotest P MINI, and Delvotest SP/ Delvotest SP MINI are acceptable for testing raw, commingled water buffalo milk-(M-I-09-6).
- 11-The IDEXX New Snap Beta Lactam Test is acceptable for testing raw, commingled camel milk-(M-I-12-13).
- 12-Not applicable to Ultra-Pasteurized chocolate milk with added stabilizers.
- 13-Not applicable to Ultra-Pasteurized goat milk and milk products with added stabilizers.
  - ALP: Alkaline Phosphatase Enzyme

## <u>TABLE 2.</u> <u>GRADE "A' MILK AND MILK PRODUCTS ANIMAL DRUG RESIDUE</u> <u>REQUIRED PMO LABORATORY TESTING</u>

BETA LACTAM SCREENING TEST <sup>1-LABORATORY</sup> PROCEDURE CODES	RAW COW MILK	RAW GOAT MILK	RAW SHEEP MILK	RAW WATER BUFFALO MILK	RAW CAMEL MILK	PAST./ UP WHOLE WHITE MILK	PAST./UP OTHER WHITE MILK (ALL FAT LEVELS)	PAST./ UP WHITE SKIM MILK	PAST./UP CHOCOLATE MILK (ALL FAT LEVELS)	PAST. 1/2 & 1/2 AND CREAM (ALL FAT LEVELS)	PAST./ UP GOAT MILK
CHARM® <i>B.</i> stearother- mophilus TABLET DISK ASSAY <sup>9-B2</sup>	X	Х				Х	Х	Х			
CHARM® II TABLET BETA LACTAM TEST (COMPETITIVE ASSAY) <sup>9-C2</sup>	Х					Х	Х	X			
CHARM® II TABLET BETA LACTAM TEST (SEQUENTIAL ASSAY) <sup>9-C3</sup>	Х	Х									
CHARM® II TABLET BETA LACTAM TEST (QUANTITATIVE ASSAY) <sup>9-C4</sup>	X										
CHARM® II TEST FOR CLOXACILLIN IN MILK (COMPETITIVE ASSAY) <sup>9-C9</sup>	X					Х					

BETA LACTAM SCREENING TEST <sup>1-LABORATORY</sup> PROCEDURE CODES	RAW COW MILK	RAW GOAT MILK	RAW SHEEP MILK	RAW WATER BUFFALO MILK	RAW CAMEL MILK	PAST./ UP WHOLE WHITE MILK	PAST./ UP OTHER WHITE MILK (ALL FAT LEVELS)	PAST./ UP WHITE SKIM MILK	PAST./ UP CHOCOLATE MILK (ALL FAT LEVELS)	PAST. 1/2 & 1/2 AND CREAM (ALL FAT LEVELS)	PAST./ UP GOAT MILK
CHARM SL BETA LACTAM TEST <sup>9-</sup> <sup>C13</sup>	Х	Х	Х	Х							
CHARM® SL6 BETA LACTAM TEST <sup>9-C14</sup>	Х										
CHARM® 3 SL3 BETA LACTAM TEST <sup>9-C15</sup>	Х										
CHARM® FLUSLBL FLUNIXIN AND BETA LACTAM TEST <sup>9-C16</sup>	Х										
DELVOTEST P 5 PACK (READER) <sup>9-D3</sup>	Х					Х	Х	X			
DELVOTEST P 5 PACK (VISUAL) <sup>9-</sup> D3	Х	Х				Х	Х	X	Х	X	Х
DELVOTEST P/ DELVOTEST P MINI <sup>9-D1</sup>	Х	Х		Х			Х				
DELVOTEST SP/ DELVOTEST SP MINI <sup>9-D1</sup>	Х	Х		Х							
NEW SNAP® BETA LACTAM TEST KIT <sup>9-11</sup>	Х				Х						
BETASTAR® BETA LACTAM TEST <sup>9-N1</sup>	Х										

SULFONAMIDE SCREENING TEST <sup>1-LABORATORY</sup> PROCEDURE CODES	RAW COW MILK	RAW GOAT MILK	RAW SHEEP MILK	RAW WATER BUFFALO MILK	RAW CAMEL MILK	PAST./ UP WHOLE WHITE MILK	PAST./ UP OTHER WHITE MILK (ALL FAT LEVELS)	PAST./ UP WHITE SKIM MILK	PAST./UP CHOCOLATE MILK (ALL FAT LEVELS)	PAST. <sup>1</sup> / <sub>2</sub> & <sup>1</sup> / <sub>2</sub> AND CREAM (ALL FAT LEVELS)	PAST./ UP GOAT MILK
CHARM II SULFONAMIDE DRUG TEST (COMPETITIVE) <sup>9-</sup>	X						/				
Refer to the <b>NOTE</b> : below.											
CHLORAM- PHENICOL SCREENING TEST <sup>1-LABORATORY</sup> PROCEDURE CODES											
CHARM II CHLORAM- PHENICOL <sup>9-C11</sup> Refer to the <u>NOTE</u> : below.	X										
TETRACYCLINE SCREENING TEST <sup>1 LABORATORY</sup> PROCEDURE CODES											
CHARM II TETRACYCLINE WITH DILUTION CONFIRMATION <sup>9</sup> -C12	Х										
Refer to the <b>NOTE</b> : below.									MS for a partia		

**NOTE:** One (1) year after test(s) have been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated tests are not acceptable for screening milk. The acceptance of these evaluated tests does not mandate any additional screening by industry or the Regulatory Agency with the evaluated method.

## <u>TABLE 3.</u> <u>GRADE "A' MILK AND MILK PRODUCTS REQUIRED PMO LABORATORY TESTING</u> <u>BY MICROBIOLOGICAL OR CHEMICAL TEST METHOD</u>

BACTERIAL COUNT METHODS – MICROBIOLOGY 1-LABORATORY PROCEDURE CODES	RAW COW MILK	RAW GOAT MILK	RAW SHEEP MILK	RAW WATER BUFFALO MILK	RAW CAMEL MILK	PAST. WHITE MILK (ALL FAT LEVELS)	PAST. CHOCOLATE MILK (ALL FAT LEVELS)	PAST. STRAW- BERRY MILK (OTHER FLAVORS-ALL FAT LEVELS)	PAST. LACTOSE REDUCED MILK AND LOW- SODIUM MILK	PAST./ UP ½ & ½ AND CREAM (ALL FAT LEVELS)	ULTRA- PASTEUR- IZED MILK (UP) (ALL FAT LEVELS)
STANDARD PLATE COUNT <sup>2</sup> (SPC) (Approved For All Products). <u>NOTE:</u> Acidified or Cultured Products Do Not Apply.)	X	X	X	X	X	X	X	X	X	X	X
PLATE LOOP COUNT <sup>3</sup> (Raw Milk Only) (SPC or PAC) **-Matrix Comparison Required	X**	X**	X**	X**	X**						
SPIRAL PLATE COUNT <sup>4</sup> (Raw Milk Only) **-Matrix Comparison Required	X**	X**	X**	X**	X**						

BACTERIAL COUNT METHODS – MICROBIOLOGY T-LABORATORY PROCEDURE CODES	RAW COW MILK	RAW GOAT MILK	RAW SHEEP MILK	RAW WATER BUFFALO MILK	RAW CAMEL MILK	PAST. WHITE MILK (ALL FAT LEVELS)	PAST. CHOCOLATE MILK (ALL FAT LEVELS)	PAST. STRAW- BERRY MILK (OTHER FLAVORS-ALL FAT LEVELS)	PAST. LACTOSE REDUCED MILK AND LOW- SODIUM MILK	PAST./ UP ½ & ½ AND CREAM (ALL FAT LEVELS)	ULTRA- PASTEUR- IZED MILK (UP) (ALL FAT LEVELS)
3M PETRIFILM AEROBIC COUNT <sup>5</sup> (PAC)	X	Х	Х	Х	Х	Х	Х	Х	Х	Х	X
FOSS BACTOSCAN FC <sup>7</sup> (Raw Milk Only) **-Matrix Comparison Required	X**	X**	X**	X**	X**						
SOMATIC CELL COUNT <sup>1-</sup> LABORATORY PROCEDURE CODES											
DIRECT SOMATIC CELL COUNT (DMSCC) <sup>12</sup>	X	Х	Х	Х	Must be Studied						
ELECTRONIC SOMATIC CELL COUNT <sup>16</sup>											
BENTLEY SOMACOUNT 150/300/500 <sup>16</sup>	X	Х	Х	Х	Must be Studied						
FOSS 250/300/360/ 400 <sup>16</sup>	X	Х	Х	Х	Must be Studied						

SOMATIC CELL COUNT <sup>1-</sup> LABORATORY PROCEDURE CODES	RAW COW MILK	RAW GOAT MILK	RAW SHEEP MILK	RAW WATER BUFFALO MILK	RAW CAMEL MILK	PAST. WHITE MILK (ALL FAT LEVELS)	PAST. CHOCOLATE MILK (ALL FAT LEVELS)	PAST. STRAW- BERRY MILK (OTHER FLAVORS-ALL FAT LEVELS)	PAST. LACTOSE REDUCED MILK AND LOW- SODIUM MILK	PAST./ UP ½ & ½ AND CREAM (ALL FAT LEVELS)	ULTRA- PASTEUR- IZED MILK (UP) (ALL FAT LEVELS)
FOSS 5000/FC <sup>16</sup>	Х	Х	Х	Х	Must be Studied						
FOSSOMATIC MINOR <sup>16</sup>	Х	Х	Х	Х	Must be Studied						
FOSS 90 <sup>16</sup>	Х	Х	Х	Х	Must be Studied						
SOMACOUNT MK II/SMART <sup>16</sup>	Х	Х	Х	Х	Must be Studied						
COILIFORM <sup>1-</sup> LABORATORY PROCEDURE CODES											
3M PETRIFILM COLIFORM COUNT <sup>20</sup> (PCC)						Х	Х	Х	Х	Х	Х
3M PETRIFILM HIGH SENSITIVITY COLIFORM COUNT <sup>20</sup> (HSCC) FOR 1:10, 1:5 DILUTIONS						X	X	X	X	X	X
COLIFORM PLATE COUNT <sup>21</sup> (Violet Red Bile- Approved for All Products.)						Х	Х	Х	Х	Х	Х

ALKALINE PHOSPHATASE <sup>1</sup> -LABORATORY PROCEDURE CODES	RAW COW MILK	RAW GOAT MILK	RAW SHEEP MILK	RAW WATER BUFFALO MILK	RAW CAMEL MILK	PAST. WHITE MILK (ALL FAT LEVELS)	PAST. CHOCOLATE MILK (ALL FAT LEVELS)	PAST. STRAW- BERRY MILK (OTHER FLAVORS-ALL FAT LEVELS)	PAST. LACTOSE REDUCED MILK AND LOW- SODIUM MILK	PAST./ UP ½ & ½ AND CREAM (ALL FAT LEVELS)	ULTRA- PASTEUR- IZED MILK (UP) (ALL FAT LEVELS)
FLOUROPHOS <sup>28</sup>						Х	Х	Х	Must be Studied	X (Except UP)	
PASLITE <sup>29</sup>						Х	Х	Must be Studied	Must be Studied	X (Except UP)	
CHARM FAST ALKALINE PHOSPHATASE (FAP) <sup>29</sup>						Х	Х	Must be Studied	Must be Studied	X (Except UP)	
VITAMINS LABORATORY PROCEDURE CODES											
VITAMIN ANALYSIS (A, D Or A & D) <sup>30</sup>						Х	Х	Must be Studied	Х		Х

### <u>TABLE 3.</u> <u>GRADE "A' MILK AND MILK PRODUCTS REQUIRED PMO LABORATORY TESTING</u> <u>BY MICROBIOLOGICAL OR CHEMICAL TEST METHOD</u>

(This Table will be revised and reissued as new information becomes available.)

#### (Continued with Different Matrixes of Grade "A" Milk and Milk Products Identified.)

BACTERIAL COUNT METHODS – MICROBIOLOGY T-LABORATORY PROCEDURE CODES	ULTRA- PASTEUR- IZED (UP) FLAVORED MILK (ALL FLAVORS AND FAT LEVELS)	ASEPTIC WHITE, CHOCOLATE AND OTHER FLAVORED MILK (ALL FAT LEVELS)	CULTURED/ ACIDIFIED MILK PRODUCTS**, SOUR CREAM, COTTAGE CHEESE, YOGURT, ACIDOPHILUS MILK AND CHOLESTEROL MODIFIED FLUID MILK (ALL FAT LEVELS)	ALL DRY MILK AND MILK PRODUCTS (INCLUDING CREAM AND GOAT)	ALL WHEY AND WHEY PRODUCTS (INCLUDING FLUID, CONDENSED, DRIED AND WHEY CREAMS)	CONDENSED MILK AND MILK PRODUCTS (INCLUDING CREAM AND GOAT)	ANHYDROUS MILK FAT (INCLUDING CHOLESTEROL MODIFIED)	PAST. GOAT MILK AND MILK PRODUCTS
STANDARD PLATE COUNT <sup>2</sup> (SPC) (Approved for all products. <u>NOTE:</u> Acidified or Cultured Products Do Not Apply.)	X			X				X
3M PETRIFILM AEROBIC COUNT <sup>5</sup> (PAC)	Х			Х				Х

COILIFORM LABORATORY PROCEDURE CODES	ULTRA- PASTEUR- IZED (UP) FLAVORED MILK (ALL FLAVORS AND FAT LEVELS)	ASEPTIC WHITE, CHOCOLATE AND OTHER FLAVORED MILK (ALL FAT LEVELS)	CULTURED/ ACIDIFIED MILK PRODUCTS**, SOUR CREAM, COTTAGE CHEESE, YOGURT, ACIDOPHILUS MILK AND CHOLESTEROL MODIFIED FLUID MILK (ALL FAT LEVELS)	ALL DRY MILK AND MILK PRODUCTS (INCLUDING CREAM AND GOAT)	ALL WHEY AND WHEY PRODUCTS (INCLUDING FLUID, CONDENSED, DRIED AND WHEY CREAMS)	CONDENSED MILK AND MILK PRODUCTS (INCLUDING CREAM AND GOAT)	ANHYDROUS MILK FAT (INCLUDING CHOLESTEROL MODIFIED)	PAST. GOAT MILK AND MILK PRODUCTS
3M PETRIFILM COLIFORM COUNT (PCC) <sup>20</sup>	X		X	Х	Х	X	Х	X
3M PETRIFILM HIGN SENSITIVITY COLIFORM COUNT (HSCC) FOR 1:10, 1:5 DILUTIONS <sup>20</sup>	X		X	Х	Х	X	X	Х
COLIFORM PLATE COUNT <sup>21</sup> (Violet Red Bile- Approved for All Products.)	X		X	X	X	X	Х	X
ALKALINE PHOSPHATASE <sup>1</sup> -LABORATORY PROCEDURE CODES								
FLOUROPHOS <sup>28</sup>								Х
PASLITE <sup>28</sup>								Х

ALKALINE PHOSPHATASE -LABORATORY PROCEDURE CODES	ULTRA- PASTEUR- IZED (UP) LAVORED MILK (ALL FLAVORS AND FAT LEVELS)	ASEPTIC WHITE, CHOCOLATE AND OTHER FLAVORED MILK (ALL FAT LEVELS)	CULTURED/ ACIDIFIED MILK PRODUCTS**, SOUR CREAM, COTTAGE CHEESE, YOGURT, ACIDOPHILUS MILK AND CHOLESTEROL MODIFIED FLUID MILK (ALL FAT LEVELS)	ALL DRY MILK AND MILK PRODUCTS (INCLUDING CREAM AND GOAT)	ALL WHEY AND WHEY PRODUCTS (INCLUDING FLUID, CONDENSED, DRIED AND WHEY CREAMS)	CONDENSED MILK AND MILK PRODUCTS (INCLUDING CREAM AND GOAT)	ANHYDROUS MILK FAT (INCLUDING CHOLESTEROL MODIFIED)	PAST. GOAT MILK AND MILK PRODUCTS
CHARM FAST ALKALINE PHOSPHATASE FAP <sup>29</sup>								Х
VITAMINS <sup>1-</sup> LABORATORY PROCEDURE CODES								
VITAMIN ANALYSIS (A, D Or A & D) <sup>30</sup>	Х	Х	X (ACIDOPHILUS MILK ONLY)					

\*\*-Includes Goat, Sheep, Water Buffalo and Camel Cultured/Acidified Milk and Milk Products.

### <u>TABLE 3.</u> <u>GRADE "A' MILK AND MILK PRODUCTS REQUIRED PMO LABORATORY TESTING</u> <u>BY MICROBIOLOGICAL OR CHEMICAL TEST METHOD</u>

(This Table will be revised and reissued as new information becomes available.)

#### (Continued with Different Matrixes of Grade "A" Milk and Milk Products Identified.)

BACTERIAL COUNT METHODS – MICROBIOLOGY T-LABORATORY PROCEDURE CODES	ULTRA- PASTEURIZED (UP) GOAT MILK	PAST. SHEEP MILK AND MILK PRODUCTS	CONCENTRATED PASTEURIZED MILK PRODUCTS/ ULTRA-FILTERED PERMEATE FROM MILK	CONCENTRATED RAW MILK PRODUCTS	ULTRA- FILTERED PERMEATE FROM WHEY	PAST. WATER BUFFALO MILK AND MILK PRODUCTS	PAST. CAMEL MILK AND MILK PRODUCTS	PAST./ UP EGG NOG (ALL FLAVORS AND FAT LEVELS)
STANDARD PLATE COUNT <sup>2</sup> (SPC) (Approved for all products.)	X	X	X	X		X	X	
3M PETRIFILM AEROBIC COUNT <sup>5</sup> (PAC)	Х	Х	Х	Х		Х	Х	
COILIFORM <sup>1-</sup> LABORATORY PROCEDURE CODES								
3M PETRIFILM COLIFORM COUNT (PCC) <sup>20</sup>	Х	Х	Х		Х	Must be Studied	Must be Studied	Х
3M PETRIFILM HIGN SENSITIVITY COLIFORM COUNT (HSCC) FOR 1:10, 1:5 DILUTIONS <sup>20</sup>	Х	Х	Х		Х	Must be Studied	Must be Studied	Х

COILIFORM <sup>1-</sup> LABORATORY PROCEDURE CODES	ULTRA- PASTEURIZED (UP) GOAT MILK	PAST. SHEEP MILK AND MILK PRODUCTS	CONCENTRATED PASTEURIZED MILK PRODUCTS/ ULTRA-FILTERED PERMEATE FROM MILK	CONCENTRATED RAW MILK PRODUCTS	ULTRA- FILTERED PERMEATE FROM WHEY	PAST WATER BUFFALO MILK AND MILK PRODUCTS	PAST CAMEL MILK AND MILK PRODUCTS	PAST./ UP EGG NOG (ALL FLAVORS AND FAT LEVELS)
COLIFORM PLATE COUNT <sup>21</sup> (Violet Red Bile- Approved for All Products.)	X	X	X		Х	Х	Х	Х
ALKALINE PHOSPHATASE <sup>1</sup> -LABORATORY PROCEDURE CODES						Must be Studied	Must be Studied	
FLOUROPHOS <sup>28</sup>								
PASLITE <sup>28</sup>								
CHARM FAST ALKALINE PHOSPHATASE FAP <sup>29</sup>								
VITAMINS <sup>1-</sup> LABORATORY PROCEDURE CODES								
VITAMIN ANALYSIS (A, D Or A & D) <sup>30</sup>								

## <u>TABLE 4.</u> <u>GRADE "A" DAIRY FARM AND MILK PLANT WATER</u> <u>REQUIRED PMO LABORATORY TESTING</u>

COLIFORM <sup>1-</sup> LABORATORY PROCEDURE CODES	POTABLE WATER	COOLING WATER (SWEET WATER)	RECIRCULATED COOLING WATER	GLYCOL
DAIRY WATER <sup>24</sup>				
MOST PROBABLE NUMBER (MPN) MULTIPLE TUBE FERMENTATION (MTF) TECHNIQUE MEDIA : LTB	Х	Х	Х	Х
MPN Chromogenic Substrate (MMO- MUG): Colilert-18, Colilert-24, and Colisure	Х			
MEMBRANE FILTRATION (MF) TECHNIQUE MEDIA: m-Endo (Broth or Agar)	Х	Х	Х	Х
WATER HETEROTROPHIC PLATE COUNT (HPC)	Х	Х	Х	
PRESENCE/ ABSENCE (PA) Chromogenic Substrate (MMO- MUG): Colilert-18, Colilert-24, and Colisure	Х			
PA COLISURE (MMO-MUG)	Х			
PA ECOLITE (XGAL- MUG)	Х			