

**Grade “A” Milk And Milk
Products Branch Update Report
EASTERN MILK SEMINAR
MADISON, WISCONSIN
OCTOBER 28-30, 2019**

Frank Flores
Office of Food Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration



TOPICS

- CFSAN/OFS/Milk & Milk Products Branch
- Coded Memorandums
- PMO's on FDA's Website
- NMDRDB Update on FDA's Website
- National Drug Residue Data Base
- IMS Electronic Reporting
- IMS Directory Updated
- International Certification Program
- Single Service Consultants
- Grade "A" Equivalency Determinations
- CBD Oil



CFSAN/Office of Food Safety

- Dr. Mark Moorman – Director, Office of Food Safety
- Bill Jones – Principle Deputy Director, OFS
- John Sheehan – Director, Division of Dairy, Egg and Meat Products
- Monica Metz – Chief, Milk & Milk Products Branch



Milk & Milk Products Branch Grade "A" Staff

- Steve Sims
- Frank Flores
- Robert Altobelli
- Randy Elsberry
- Dr. Steve Walker (Engineer)
- Laurie (Bucher) Kurtz (Labeling)
- Cindy Leonard (NCIMS APC Committee)
- Dr. Jeff Hamer (Veterinarian)
- Beth Briczinski (Senior Science Advisor)
- Charlotte Epps (IMS Electronic Administrator)



Milk & Milk Products Branch Grade “A” Staff

- Dennis Gaalswyk (Retired)
- Bob Hennes (Retired)

Two Vacant Positions



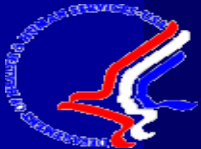
2019 NCIMS Conference

April 26 - May

1, 2019

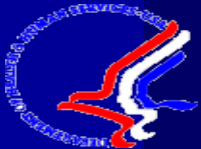
St. Louis,

Missouri



Coded Memoranda Issued in 2018

- M-I-18-16(July 7, 2018): Pre-Milking Teat Preparation DeLaval VMS™ V300 U.S.A.
- M-I-18-16 Supplement 1(June 28, 2019): Pre-Milking Teat Preparation DeLaval VMS™ V300 U.S.A.
- M-I-18-17 (July 20, 2018): 2017 Revision of Evaluation of Milk Laboratories (EML)



Coded Memoranda Issued in 2018

- M-I-18-18(August 9, 2018): 2017 Revision of Evaluation of Milk Laboratories on FDA's Web Site
- M-I-18-19 (October 10, 2018): 2359, 2359h, 2359i, 2359L, 2359m on FDA's Forms Web Site
- M-I-18-20 (November 27, 2018): Charm Sciences, Inc. CHARM® Rapid One Step Assay (ROSA®) SULF Test for Sulfonamide Drugs



Coded Memoranda Issued in 2018

- M-I-18-21 (November 27, 2018): Charm Sciences, Inc. CHARM® TRIO Test, Sulfonamides Only
- M-a-85 Revision 16 (December 20, 2018): Beta Lactam and Other Test Methods For Use Under Appendix N and Section 6 of the Grade “A” Pasteurized Milk Ordinance (PMO)
- M-b-378 (January 26, 2018): Agri-Service LLC Dairy Heritage Flow Diversion Control System Version 1.16 Model Number; 66-03400-000



Coded Memoranda Issued in 2019

- M-b-379 (October 31, 2018): Endress+Hauser Promag H 100 Series Electromagnetic Flowmeter 0.5", 1", 1 ½", 2", 2 ½", 3", 4" and 6".
- M-b-380 (October 31, 2018): Endress+Hauser Promag H 300 Series Electromagnetic Flowmeter Sizes 0.5", 1", 1 ½", 2", 2 ½", 3", 4" and 6".
- M-b-381 (October 31, 2018): Endress+Hauser Promag H 500 Series Electromagnetic Flowmeter Sizes 0.5", 1", 1 ½", 2", 2 ½", 3", 4" and 6".



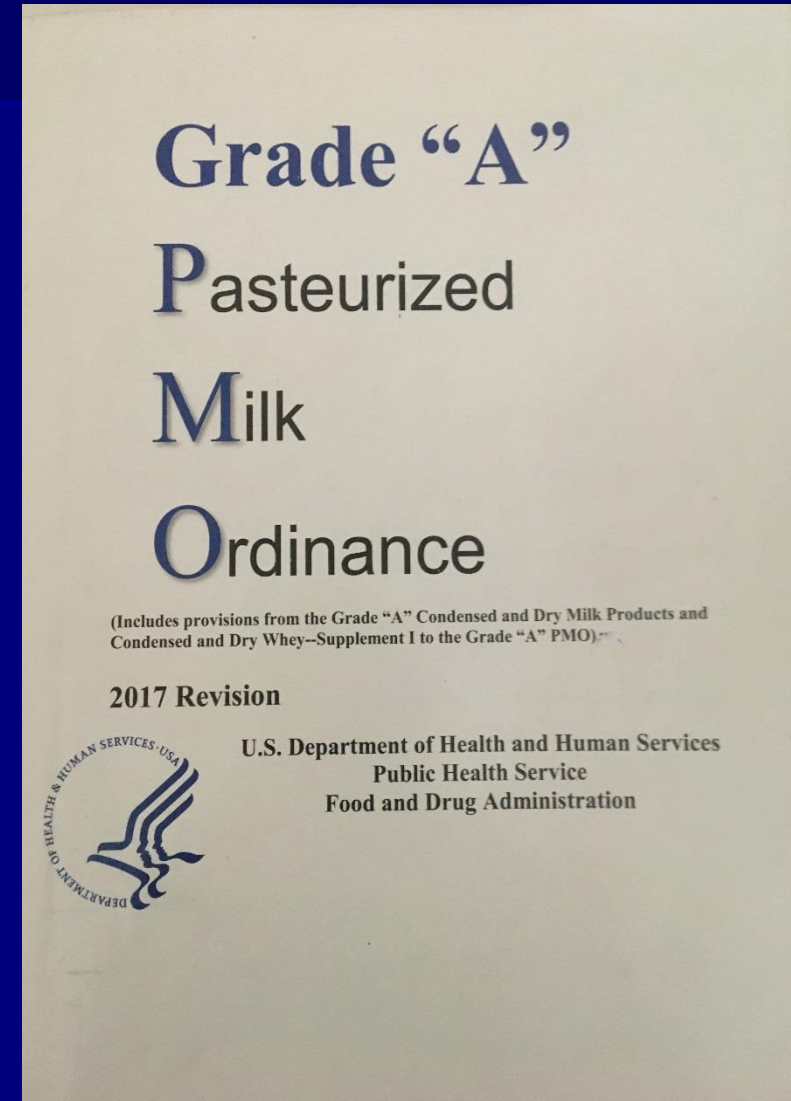
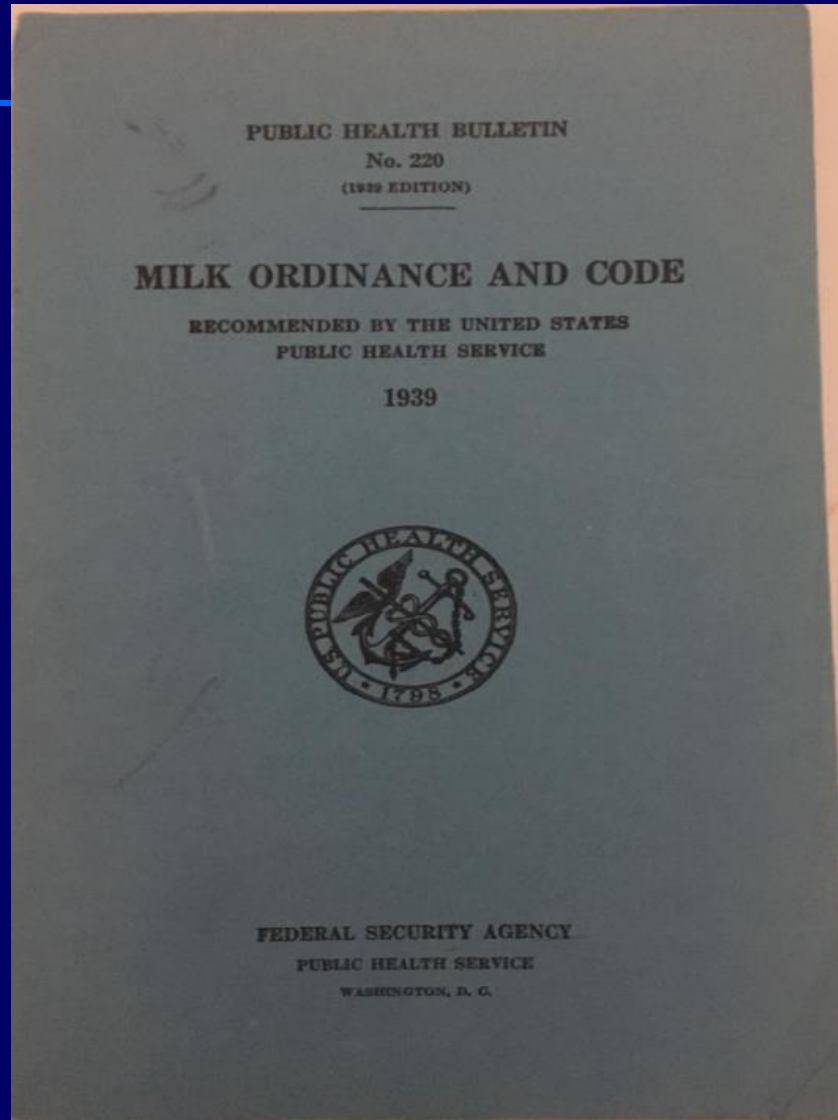
Coded Memoranda Issued in 2019

- M-I-19-1 (February 21, 2019): 2019 Revisions of the Indexes of Coded Memoranda (IMS-a, M-a, M-b and M-I).
- M-I-19-2 (February 27, 2019): Updated Information Related to Appendix N Drug Residue Testing . Option 3 not available for tetracycline and/or sulfonamides (11/27/2019).
- M-I-19-3 (June 7, 2019): Interstate Milk Shippers List (IMS) Laboratory Procedures Code(s) Update.



PMO's On FDA Website

Present/Future



FDA's Website: M-I's, M-a's, M-b's, IMS-a's Milk Program Documents & FDA Forms

<https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/milk-guidance-documents-regulatory-information>

<https://www.fda.gov/about-fda/reports-manuals-forms/forms>



2018 National Milk Drug Residue On FDA Web Site

NATIONAL MILK DRUG RESIDUE DATA BASE

**FISCAL YEAR 2018 ANNUAL REPORT
REVISED**

October 1, 2017 - September 30, 2018

Submitted by:

**GLH, Incorporated
501 V.E.S. Road, Suite W225
Lynchburg, VA 24503
434-386-3702**

Contract Number: HHSF 223 201810028C

June 7, 2019



National Drug Residue Data Base (Revised) FY 2018 (10/1/2017-9/30/2018)

- 4,042,567 Samples analyzed (4,201,236 tests)
- Five different groups of families or individual drugs
 - Beta lactams
 - Cloxacillin
 - Sulfonamides
 - Sulfamethazine
 - Tetracyclines
- Twenty-two (22) testing methods were used



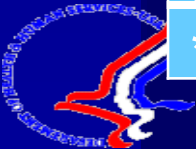
National Drug Residue Data Base (Revised)

FY 2018 (10/1/2017-9/30/2018)

**TABLE 3 -- Tests Conducted October 1, 2017 to
September 30, 2018**

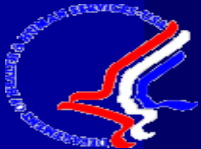
Source of Sample	Total Tests	Number of Positive Tests	Percent Positive
Bulk Milk Pickup Tanker	3,755,543	364	0.010%
Pasteurized Fluid Milk and Milk Products	32,890	4	0.012%
Producer	356,537	210	0.059%
Other	56,266	6	0.011%
TOTALS	4,201,236	584	*

*See Table 1 for explanation



IMS Electronic Reporting (State Rating Officers and Milk Specialist)

- Timing out not enough time to input information
- Not getting notification from SRO's that state ratings have been submitted
- SRO's not getting notification from MS that 2359i, 2359d have been approved or rejected



Branch 1

Branch Director

Detailee (Vacant)

Milk Specialist	Assigned States
Curt Griner	AL, FL, SC, LA, MS
Cecil Mitchel	MD, VA, WV
David Pearce	DE, PA, NJ
Marybeth Willis	GA, NC, PR, TN
Amanda Zink	CT, MA, ME, NH, NY, RI, VT



Branch 2

Branch Director

CAPT. Tim Roddy

Milk Specialist

Assigned States

Steve Himebaugh

NM, UT, NV, WY, CO, TX

Paul Klug

IA, MO, NE, AR, OK, KS

Tarsha Oliver

IL, IN

CAPT. Matthew Pitts

OH, KY, MI



Branch 3

Branch Director

Les Boian

Milk Specialist

Assigned States

Don Goldsmith

MN, ND, SD

Mark Miller

CA, AZ, HI

Joie Navarrete

OR, WA, AK, ID, MT

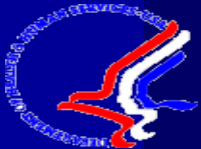
Kevin Torgerson

WI



Grade “A” CHECK RATINGS FY 2019

<u>REGION</u>	<u>BTU's</u>	<u>PLANTS</u>	<u>RS/TS</u>	<u>TOTAL</u>	<u>Single Service</u>
I-(East)	26	26	1	53	23
II-(Central)	61	38	5	104	14
III-(West)	30	28	2	60	20
TOTALS	117	92	8	217	57



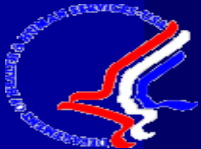
Grade "A" CHECK RATINGS FY 2018

<u>BRANCH</u>	<u>BTU's</u>	<u>PLANTS</u>	<u>RS/TS</u>	<u>TOTAL</u>	<u>Single Service</u>
I-(East)	53	29	7	89	15
II- (Cntrl)	42	43	1	86	17
III (West)	17	40	7	64	17
TOTALS	139	112	15	266	49



Grade “A” CHECK RATINGS 2009-18

FY	PLANTS	RS/TS	BTU's	TOTAL
2018	112	15	139	266
2017	130	22	206	358
2016	151	19	227	397
2015	141	11	206	358
2014	147	17	156	320
2013	146	12	183	341
2012	151	14	206	371
2011	132	7	175	314
2010	134	14	177	325
2009	122	16	186	324



TOTAL ADVERSE ACTION RATES (%) - CHECK RATINGS

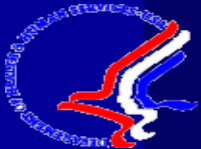
FY	PLANTS	RS/TS	BTU's	ALL
2018	10.7%	0.0%	18.0%	13.9%
2017	10.0%	9.1%	15.6%	13.2%
2016	8.6%	10.5%	22.5%	16.6%
2015	5.0%	0.0%	18.4%	12.6%
2014	6.8%	11.8%	16.7%	11.9%
2013	11.6%	16.7%	18.0%	15.2%
2012	6.6%	7.1%	20.4%	14.3%
2011	6.8%	0.0%	17.7%	12.7%
2010	6.7%	7.1%	9.6%	8.3%
2009	5.7%	6.3%	15.1%	11.1%



TOTAL WITHDRAWAL RATES (%)

CHECK RATINGS

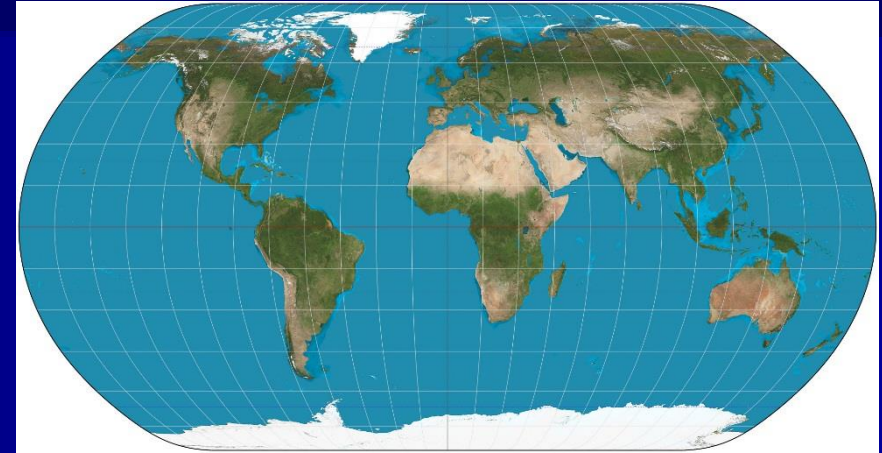
FY	PLANTS	RS/TS	BTU's	ALL
2018	5.4%	0.0%	.01%	2.2%
2017	4.6%	9.1%	3.9%	4.5%
2016	4.0%	5.3%	9.3%	7.1%
2015	3.5%	0.0%	6.8%	5.3%
2014	4.1%	5.9%	6.5%	5.3%
2013	3.4%	0.0%	3.3%	3.2%
2012	2.6%	7.1%	4.9%	4.0%
2011	1.5%	0.0%	6.9%	4.5%
2010	1.5%	0.0%	2.8%	2.2%
2009	3.3%	6.3%	4.8%	4.3%



INTERNATIONAL CERTIFICATION PROGRAM (ICP)

Two Firms to date:

**Harold Wainess and Associates
Milk Regulatory Consultants, LLC**



- 6 – CANADA (HW&A/MRC) - 4 PLANT and 2 Goat BTU**
- 3 – COLOMBIA (HW&A) - 1 PLANT and 2 BTUs**
- 2 – MEXICO (MRC) - 1 PLANT (aseptic listing) and 1 BTU**
- 2 – GREECE (MRC) - 1 PLANT and 1 BTU**



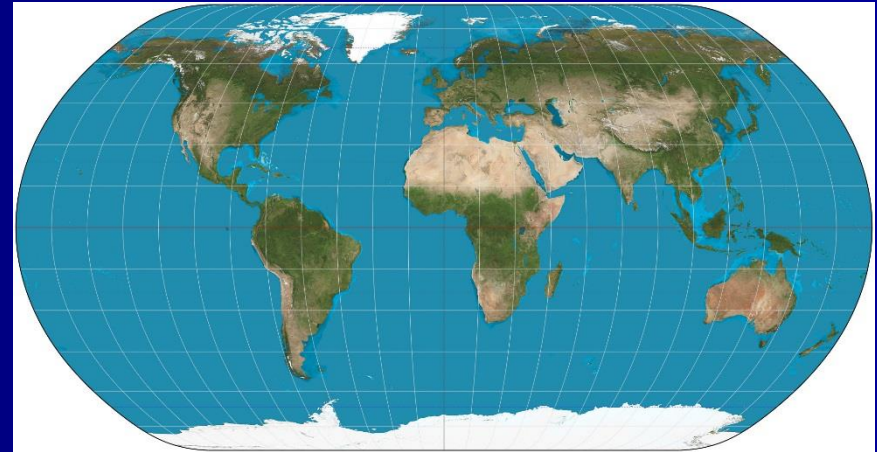
SINGLE-SERVICE CONSULTANTS

One Firm to date:

- **PACKAGING CONSULTANTS INTERNATIONAL , INC.**

FDA CERTIFIED SSCs

- Patrick Frontale - Owner
- Kathrene Dutrow



FOREIGN SINGLE-SERVICE LISTINGS

- **3 SS Certifying Firms**
 - Milk Regulatory Consultants Inc. (MRC)
 - Harold Wainess and Associates (HW&A)
 - Packaging Consultants Inc. (PCI)
- **211 Listings**
- **33 Countries**



Grade “A” Equivalency Determinations

- **Grade “A” equivalency determinations that are currently being conducted at the request of several governments and one supra-national entity:**
 - **New Zealand**
 - **European Union**
 - **Ireland**
 - **Netherlands**
 - **France**
 - **Canada**



CBD Oil (Cannabidiol)

- Extract from the flowers and buds of marijuana or hemp plants.
- Does not contain THC (tetrahydrocannabinol).
- It does not cause intoxication “marijuana high”.
- There is interest in adding CBD oil to Grade “A” milk and/or milk products.



CBD Oil (Current FDA Position)

- CBD is not permitted in any food or dietary supplement involved in interstate commerce.
- CBD cannot be added to any food product that has a standard of identity, even if it is sold in intrastate commerce.
- There are no federal standards of identity which permit CBD, and all state standards of identity are preempted by the federal standards of identity if they are not identical.
- Only non-standardized foods containing CBD can be sold in intrastate commerce if state rules allow it.



CBD Oil (FD & C Act)

FDA has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including animal food or feed) to which THC or CBD has been added, regardless of whether these substances are derived from marijuana or hemp.



QUESTIONS

