ATTACHMENT A EXAMPLES OF TWO FDA CENTERS' QUESTIONNAIRES

CFSAN – MILK SURVEY:

Volume^{FN4}

of Days Processed

Plant Code Number: _____

Form Approved: OMB Number 0910-0500 Expiration Date: 11/30/2007

Date of Data Collection: _____

Pasteurization Holding Time and Temperature Data Collection

NOT FOR PUBLIC DISTRIBUTION

State Program Manag	er:							
gg		(Name)		(Telepho	ne)	(E-mail)		
(IDFA). 2) We have of temperatures are raising terms. 4) We do not raising terms. 5) We have i	ent milk pa urization t ndations p concerns a res/times. economic nperatures t have end nperatures n the past onsequen e them ag	emperature rovided by about the for constraint stimes. Stimes. It tried higher ain.	n tempe es/times the Inter ormation s (e.g., e ation reg er paster e do not	meet or ex rnational D of off flavo energy, equ garding the urization ten have any p	d/or time aceed the airy Foo ors/taste uipment) risk or l mperatu dans at t	s. Circle all eds Associa at higher associated penefits of res/times w	that tion I with	
-								
								
Unit Processed OnFN1:								
	Whole	Whole Flavored	2%	2% Flavored	1%	1% Flavored	Skim	Skim Flavored
Processing Temperature ^{FN2}								
Time ^{FN3}								

Unit Processed OnFN1:	
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	Whole	Whole	2%	2%	1%	1%	Skim	Skim
		Flavored		Flavored		Flavored		Flavored
Processing								
Temperature ^{FN2}								
Time ^{FN3}								
Volume ^{FN4}								
# of Days								
Processed								

Please do not provide data on non-bovine (e.g., goat's, sheep, etc) milk, cream and cream products, cultured milk and milk products, milk and milk products to be cultured, and vat pasteurized, ultra-pasteurized, or aseptically processed Grade "A" milk and milk products.

FN 1 Unit Processed On: i.e., HTST #1 or #2 or HTST N or S or HHST #1 or HHST #2.

FN 2 Temperature: Record actual operating/processing temperature (°F).

FN 3 Time: Obtain from the most recent pasteurization equipment validation (seconds).

FN 4 Volume: On a daily average (gallons). If multiple flavored products per fat level are being produced, combine the product volumes to report only one daily volume for all these flavored products per fat level.

Public reporting burden for this collection of information is estimated to average 31 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing burden to:

Food and Drug Administration Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway, HFS-007 College Park, Maryland 20740

CDRH - NEGATIVE PRESSURE WOUND THERAPY

Paperwork Reduction Act Statement -- OMB Number: 0910-0500; expiration 1/31/2011

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer (HFA-710) 5600 Fishers Lane Rockville, MD 20857

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

- 1. Please select the clinical setting that best describes your affiliation or place of employment.
 - -- Hospital
 - -- Independent home health agency
 - -- Home health agency affiliated with hospital
 - -- Hospice
 - -- Nursing home
 - -- Private practice
 - -- Other _____
- 2. What makes and models of negative pressure wound therapy systems (NPWT) does your organization use? Please check all that apply.

Manufacturer	Trade/Brand Names	Chec k
Blue Sky Medical Group	V1STA Negative Wound	
(Blue Sky Medical Group is	Therapy (portable unit)	
now owned by Smith &	EZCARE Negative Wound	
Nephew, Inc.)	Therapy (stationary unit)	
	Unsure of brand name	
Boehringer Wound Systems, LLC	Engenex® Advanced NPWT System	
Innovative Therapies Inc.	SVEDMAN™ Wound	
	Treatment Systems	
	SVED™ Wound Treatment	
	System	
	Unsure of brand name	
Kalypto Medical	NPD 1000 Negative	
	Pressure Wound Therapy	
	System	
KCI, USA Inc. (Kinetic	InfoV.A.C.® Therapy Unit	
Concepts, Inc.)	(stationary unit)	
	ActiV.A.C.® Therapy Unit	
	(portable unit)	
	V.A.C.® Freedom™	
	V.A.C.® ATS™	
	V.A.C.® Instill System	
	(delivery of topical	
	solutions)	
	Unsure of brand name	
Premco Medical Systems,	Prodigy™ NPWT System	
Inc.	(PMS-800)	

	Prodigy™ NPWT System (PMS-800V)				
	Unsure of brand name				
Prospera	PRO-I™ (stationary and				
(Prospera Technologies LLC	portable)				
owns the Prospera NPWT	PRO-II™ (portable)				
systems and brand)	PRO-III™ (stationary and				
	portable)				
	Unsure of brand name				
Smith & Nephew, Inc.	V1STA Negative Pressure				
	Wound Therapy (portable				
	unit)				
	EZCARE Negative Pressure				
	Wound Therapy (stationary				
	unit)				
	RENASYS™ EZ Negative				
	Pressure Wound Therapy				
	Unsure of brand name				
Talley Group, Ltd.	Venturi™ Negative				
	Pressure Wound Therapy				
	(portable or stationary)				

> Device performance and experience

- 3. Have you or your patients experienced any of the following issues with the NPWT system(s) your organization uses? Please check all that apply.
 - o Dressing's foam adhered to or imbedded in the wound
 - o Foreign body (dressing's foam pieces) retained in the wound
 - o Bleeding
 - o Infection
 - o Vascular graft failure due to improper system function
 - o Death
 - o Other, specify:
 - o None of the above
 - o Don't know
- 4a. As far as you know, have any of the wound therapy systems your organization uses resulted in better patient outcomes, i.e., better wound healing, no infection?

YES (Go to Q4b) NO (Go to Q5)

4b. Which system(s) have resulted in better patient outcomes?

SHORT ANSWER

5. For which conditions or diagnoses is NPWT prescribed? Please check all that apply.

Chronic and Acute Wounds

- o Diabetic foot ulcers
- o Pressure ulcers
- o Vascular ulcers (venous and arterial ulcers)
- o Burn wounds
- o Surgical wounds (sternal wounds)
- o Trauma-induced wounds
- o Abdominal wound closure
- o Excised wounds
- o Deep abrasions

Subacute wounds

- o Dehiscence
- o Open wounds
- o Skin grafts
- o Skin flaps

Other, specify: