

8-13 FORM FDA-457

1. HOME DISTRICT <b>NWE</b>	2. REPORTING UNIT SYMBOL <b>NOL</b>	3. CENTRAL FILE NO. <b>1234567</b>	4. J.D./T.A. ----	5. COUNTY ----	6. DATE <b>8-2-99</b>				
7. PRODUCT CODE <b>45AF-19</b>	8. OPERATION <b>13</b>	9. PROGRAM ASSIGNMENT CODE <b>09001</b>			10. HOURS <b>1/2</b>				
11. IDENTIFICATION (Quote pertinent labeling including Establishment name and address) <b>“NO CLUMP” BRAND ANTI-CAKING AGENT CLUMPLESS CORP. 3214 WHARF AVE. WALTHAM, MA 02154</b>									
12. MANUFACTURER CONTROL CODES (Labels, packaging and shipping containers) <b>BAGS CODED: “AC 123171”</b>		13. AMOUNT ON HAND <b>1200/100# BAGS</b>		14. DATE LOT RECEIVED <b>7-15-99</b>					
		15. ESTIMATED VALUE <b>\$ 24,000.00</b>		16. SAMPLE NO(s). <b>NONE</b>					
17. DEALER (Name, street address, city, state, and ZIP code) <b>CREOLE INDUSTRIES 239 CANAL ST. NEW ORLEANS, LA 70130</b>			18. <input type="checkbox"/> DISTRIBUTOR <input type="checkbox"/> SHIPPER <input checked="" type="checkbox"/> MANUFACTURER <input type="checkbox"/> OTHER (Name, street address, city, state, ZIP code, and telephone) <b>CLUMPLESS CORP. 3214 WHARF AVE. WALTHAM, MA 02154 (617) 765-4321</b>						
19. ESTABLISHMENT TYPE(S)		INDUSTRY CODE				20. ESTABLISHMENT SIZE (\$ VOLUME)	21. INFORMATION OBTAINED BY (Check one)		
a. <b>Manufacturer</b>		1	2	3	4		5	6	MAIL
b.									TELEPHONE
c.									XXX VISIT
22. REMARKS									
23. REPORT PREPARED BY (Type or print name and title) <b>Sidney H. Rogers, Investigator</b>			24. EMPLOYEE NO. <b>075</b>		25. PC <b>2</b>	26. SIGNATURE <i>Sidney H. Rogers</i>			
27. REPORTING UNIT ACTION <input checked="" type="checkbox"/> REFERRED TO HOME DISTRICT <input checked="" type="checkbox"/> ADD TO ACTIVE OEI <input type="checkbox"/> COLLECT OFFICIAL SAMPLE <input type="checkbox"/> ROUTINE FOLLOW-UP <input type="checkbox"/> REFERRED TO STATE OR <input type="checkbox"/> INSPECT OTHER FEDERAL AUTHORITIES <input type="checkbox"/> REINSPECT <input type="checkbox"/> MAKE INVESTIGATION <input type="checkbox"/> NO ACTION <input type="checkbox"/> REFERRED TO HDQTRS _____ (Routing Symbol)					28. NAME OF REVIEWING OFFICIAL (Type or print) <b>Harry Abelman</b>				
					29. TITLE <b>Supervisory Investigator</b>		30. DATE REVIEWED <b>9-2-99</b>		

<b>SUSPECTED VIOLATIONS</b> <i>(Check appropriate box)</i>				
<b>DRUGS – DEVICES</b>	<b>HEALTH</b>			
			Dangerous under any condition of use: 502(j).	
			Inadequate directions for use: 502(f)(1).	
			Dangerous when sold indiscriminately: 502(f).	
			Failure to bear list of active ingredients: 502(e).	
			Dangerous on account of excessive dosage: 502(j).	
			Possible variation from professed standard: 501(b), (c), (d).	
			Dangerous because of inadequate warnings: 502(f)(2).	
			Vitamin preparations – possible variation from professed standard: 501(b), (c), (d).	
			Drugs dangerous on account of impurities: 501(a)(2), (3), 502(j).	
		Extravagant therapeutic claims: 502(a)1		
<small><sup>1</sup> If descriptive or promotional material employed in sale of product bears or contains extravagant therapeutic claims, indicate (in REMARKS on front or in separate memo) source, how received, and how employed in sale of product. See Section 201(m), Labeling: 301(b), 301(k), Prohibited Acts.</small>				
<input type="checkbox"/> <b>HYGIENIC</b>				
<b>ECONOMIC</b>				
		Deceptive packaged: 502(l).		
		Suspect short weight or volume: 502(b)		
<input type="checkbox"/> <b>NEW DRUG</b>				
<b>FOODS</b>	<b>HEALTH</b>			
			Presence of poisons: 402(a)(1), (2).	
			Therapeutic claims for food: Subject to 502.	
			Dangerous and non-nutritive substances (confectionery): 402(d)	
			Vitamin claims: 403(a), (j). May also be subject to 502.	
			Poisonous containers: 402(a)(6).	
			Special dietary foods: 403(j)	
	<b>HYGIENIC</b>			
			Stored under insanitary conditions: 402(a)(4).	
			Suspected filth or decomposition: 402(a)(3).	
<b>ECONOMIC</b>				
		Deceptive packaging: 403(d).		
		Failure to declare mandatory statements: nonstandardized foods: 403(e), (f), (l), (k).		
		Short weight or volume: 403(e)(2).		
		Standardized foods, misbranding or nonconformity: 403(g), (h).		
		Misrepresentation in labeling: 403(a). See 201(m).		
	<b>X</b>	New Product, New Manufacturer		
<b>COSMETICS</b>			Dangerous cosmetics: 601(a).	
			Adulteration: 601.	
		Misbranding: 602		
<b>OTHER</b>	EXPLAIN			