ConAgra Foods®

May 11, 2007

VIA HAND DELIVERY

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Re: April 24, 2007 Hearing

Dear Chairman Stupak and Ranking Member Whitfield:

ConAgra Foods, Inc. ("ConAgra") appreciated the opportunity to testify before the Subcommittee on Oversight and Investigations ("Subcommittee") on April 24, 2007 regarding the company's recent recall of its peanut butter products. During the hearing and in subsequent discussions with Subcommittee staff, we were asked to provide the following additional information for the hearing record:

1. Copies of any inspection reports for ConAgra's Sylvester, GA facility for 2000 to present.

2. Details on any prior situations where ConAgra did not provide the Food and Drug Administration (FDA) with records it requested, whether verbally or in writing.

3. Details for the past five years of any positive pathogen findings for finished products from any routine testing conducted by ConAgra for its current food businesses at its manufacturing facilities.

ConAgra is still reviewing its internal records in order to fully respond to the Subcommittee's request with respect to positive pathogen findings; however, we anticipate being able to provide this information by the end of the thirty (30) day period in which the hearing record is open (i.e., by May 24, 2007). In the interim, what follows is our response to the first two requests outlined above.

In response to the first request, in Attachment A to this letter, we provide copies of the reports associated with inspections of our Sylvester, GA facility by FDA and the Georgia Department of Agriculture for 2000 through 2003. We previously provided the Subcommittee with copies of such inspection reports for 2004 forward.

Providing a response to the second request outlined above is particularly challenging given the size of ConAgra and its numerous facilities (almost 100 in the U.S.) that are subject to regulatory inspection. However, we are able to provide the Subcommittee with the following information:

- Upon checking with the appropriate company personnel, to the best of our knowledge, we are not aware of any situation in the past in which ConAgra refused to provide FDA with certain records in response to a written request from the Agency.

- With regard to verbal requests for records from FDA, there likely have been instances in the past where FDA made a verbal request for records in connection with a plant inspection, was asked by ConAgra's plant personnel (consistent with company policy at the time) to make the request in writing, but did not follow up with a written request -- so that the records were not provided. To the extent any such requests were not in writing, it is not possible to track and keep a record of them. Indeed, this along with the ability to provide any responsive records in a manner that protects them from inappropriate disclosure under the Freedom of Information Act are the primary reasons why ConAgra has historically asked that FDA put requests for the company's information in writing. In that regard, consistent with our historical policy, we would not have refused to provide FDA with the information verbally requested; rather, we would have simply responded by asking that the request be made in writing.

- We believe our historical policy is consistent with long-standing practice in the food industry. Even where there is no statutory authority granting FDA access to records, it has been industry's experience that FDA inspectors will make verbal requests for them.[1] In response, it has been a long-standing industry practice to ask that these types of requests be made in writing.[2]

- We also believe our historical policy is consistent with the relevant law in this area. Specifically, Section 703 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 373) provides that it is unlawful to deny FDA access to records concerning interstate shipment of FDA-regulated articles *when such request is accompanied by a statement in writing.* The regulation implementing Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) also makes clear that requests for records pursuant to the Act will be made by *written notice*.[3] We further note that FDA regulations provide for agency access to company records for low-acid canned foods and acidified foods, yet the regulations granting this authority make clear that all such requests are to be made *in writing* on a designated FDA form.[4] ConAgra believes, therefore, that it should not be considered unreasonable for companies to ask for written requests from FDA for company records, particularly in those situations where the agency has no explicit statutory or regulatory authority granting access to such records.

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[1] *See e.g.*, James T. O'Reilly, FOOD AND DRUG ADMINISTRATION, 2ed. (2006) 20-56; James W. Swanson, *How To Handle and FDA Inspection–The Investigator's View*, 33 FOOD DRUG COSM. L.J. 109 (1978); Laurie Burg, *A Trade Association View of the FDA Food Inspection Programs*, 35 FOOD DRUG COSM. L.J. 170 (1980). A copy of these articles is included in Attachment B to this letter.

[2] *See e.g.*, Arthur W. Hansen, *An FDA Inspection: Preparing for the Inevitable*, 36 FOOD DRUG COSM. L.J. 641 (1981); see also, Stephen H. McNamara, *The FDA Inspection: What You Need to Know to Protect Your Company*, 36 FOOD DRUG COSM. L.J. 245 (1981). A copy of both articles is included in Attachment B to this letter.

[3] 21 C.F.R. § 1.361; this written notice is further evidenced in a records access guidance document found at http://www.cfsan.fda.gov/~dms/secgui13.html. The designated FDA form (Form FDA 482c) for providing this written notice also indicates that the records being requested are to be described on the form.

[4] 21 C.F.R. §§ 108.25(g) and 108.35(h).

- Notwithstanding industry practice, ConAgra provided the Subcommittee on April 23, 2007 with a letter confirming that the company's current policy for providing FDA with access to company information would be formalized to reflect the approach the company followed in connection with its recent peanut butter recall. Specifically, we will suspend any written request requirement in a recall-related situation, provide on-site review of records for routine inspections, and provide copies of routine, non-sensitive information (i.e., non-confidential and non-proprietary information) upon a verbal request from FDA. Understandably, we will continue to ask for a written request for copies of any sensitive proprietary company information.

Should you have any questions regarding this additional information, please let us know.

Very truly yours,

Leo A. Knowles
Senior Vice President

Attachments A and B

ATTACHMENT A

Copy of Inspection Reports

☐ New
☐ Change
☐ Delete

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

Commissioner

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC, 2 — PRIVATE

FIRM NAME Hunt Wesson Inc. DATE 6-26-06

ADDRESS 111 South Seabreeze Dr.

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

ESTABLISHMENT NO. 29646 GRID CODE _____ LICENSE NO. _____

Insp. Begin 1020
Time End 1100

Misc.
Time Hrs. _____

Travel Miles _____

ASSISTING INSPECTOR NO. _____ ASSISTING INSPECTOR'S NAME _____ CHIEF INSPECTOR C. Brand NO. 45-33

FIRM TYPE CODE 371 OWNER/MANAGER Lavon Ackley

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION		CODE	
1. Outside Premises		16. Shelves		31. Ingredients			46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing			47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement			48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test	Pos.	Neg.	49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test	Pos.	Neg.	50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave	Pos.	Neg.	51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected			52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted			53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment	YES		54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$		55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES		56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES		57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$		58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES		59.	
15. Transportation		30. Packaging		45. No. Scales Checked			60.	

REMARKS History. No violations noted on the previous inspection. 3-17-06

Current inspection. No Violations noted on this inspection

Follow up. Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

Lavon Ackley — REPORT RECEIVED BY

Operations Manager — TITLE

SANITARIAN'S SIGNATURE

GEORGIA DEPARTMENT OF AGRICULTURE
Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

Commissioner

☐ New
☑ Change
☐ Delete

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC 2 — PRIVATE

FIRM NAME Thrift Wilson Tax. DATE 6-30-00

ADDRESS 111 [illegible]

CITY [illegible] STATE GA ZIP 31791 COUNTY Worth

Insp. Time Begin 1115 End 1230

Misc. Time Hrs.

Travel Miles

ESTABLISHMENT NO. 29646 GRID CODE LICENSE NO.

ASSISTING INSPECTOR NO. ASSISTING INSPECTOR'S NAME CHIEF INSPECTOR Board NO. 485

FIRM TYPE CODE 371 OWNER/MANAGER Lavon Ackley

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave Pos. Neg.		51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected		52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted		53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment YES		54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction $		55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withheld from Sale YES		56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued YES		57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements $		58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports YES		59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS History: No violations noted on the previous inspection 1-26-00

Current inspection: [illegible]

Follow up Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

Lavon Ackley — REPORT RECEIVED BY

Operations Manager — TITLE

[signature] — SANITARIAN'S SIGNATURE

☐ New
☐ Change
☐ Delete

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

Commissioner
☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 0 — PUBLIC, 2 — PRIVATE

FIRM NAME Hunt Wesson Inc. DATE 12-2000

ADDRESS 101 South Seabrook Dr

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

ESTABLISHMENT NO. 29646 GRID CODE LICENSE NO.

Insp. Time Begin 1015 End 1215

Misc. Time Hrs.

Travel Miles

ASSISTING INSPECTOR NO. ASSISTING INSPECTOR'S NAME CHIEF INSPECTOR Beard NO. 4633

FIRM TYPE CODE 371 OWNER/MANAGER L. Akins

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave Pos. Neg.		51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected		52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted		53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment YES		54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction $		55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale YES		56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued YES		57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements $		58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports YES		59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS History: NO violations noted on the previous inspection 8-30-00.
Current inspection: NO violations noted on this inspection.

Follow up: Routine.

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

Lavon Ashley — REPORT RECEIVED BY
Operations Manager — TITLE
SANITARIAN'S SIGNATURE

☐ New
☒ Change
☐ Delete

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

Commissioner

☒ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE 1 — PUBLIC, 2 — PRIVATE

FIRM NAME ConAgra Grocery Products Co DATE 3-22-01

ADDRESS 101 S. Seabrook Dr.

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

Insp. Time Begin 1230 End 1400

Misc. Time Hrs.

Travel Miles

ESTABLISHMENT NO. GRID CODE LICENSE NO.

ASSISTING INSPECTOR NO. ASSISTING INSPECTOR'S NAME CHIEF INSPECTOR C Beard NO. 4833

FIRM TYPE CODE 371 OWNER/MANAGER Patrick M. Ryan Pre

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave Pos. Neg.		51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected		52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted		53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment YES		54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction $		55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale YES		56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued YES		57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements $		58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports YES		59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS History: Formerly Hunt Wesson Inc. No violations Noted on the previous inspection 12-20-00
Current inspection: Change in ownership ROC filed
No violations noted on this inspection:

Follow up: Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

X Kevin Ashley — REPORT RECEIVED BY
Operations Manager — TITLE
SANITARIAN'S SIGNATURE

☐ New
☐ Change
☐ Delete

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

Commissioner
☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC, 2 — PRIVATE _____

FIRM NAME ConAgra Grocery Products Co DATE 6-25-01

ADDRESS 111 Seabrook

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

ESTABLISHMENT NO. 29646 GRID CODE _____ LICENSE NO. _____

Insp. Begin 8:30
Time End 10:00
Misc.
Time Hrs. _____
Travel Miles _____

ASSISTING INSPECTOR NO. _____ ASSISTING INSPECTOR'S NAME _____ CHIEF INSPECTOR Girard NO. YE 22

FIRM TYPE CODE 371 OWNER/MANAGER Mike Hall QC Manager

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION		CODE	
1. Outside Premises		16. Shelves		31. Ingredients			46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing			47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement			48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test	Pos.	Neg.	49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test	Pos.	Neg.	50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave	Pos.	Neg.	51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected			52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted			53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment	YES		54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$		55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES		56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES		57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$		58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES		59.	
15. Transportation		30. Packaging		45. No. Scales Checked			60.	

REMARKS History: No Violations noted on the previous inspection. 2 22 01
Current inspection: No violations noted on the current inspection.

Follow up Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

Mike Hall — REPORT RECEIVED BY
QC Manager — TITLE
SANITARIAN'S SIGNATURE

☐ New.
☐ Change
☐ Delete

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

Commissioner

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE (1) — PUBLIC, 2 — PRIVATE

FIRM NAME Contagra Grocery, Pickle Co. DATE 9-20-01

ADDRESS 111 Seabrook

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

Insp. Begin 11:30
Time End 12:30

Misc. Time Hrs.

Travel Miles

ESTABLISHMENT NO. 29646 GRID CODE LICENSE NO.

ASSISTING INSPECTOR NO. ASSISTING INSPECTOR'S NAME CHIEF INSPECTOR C Board NO. 4433

FIRM TYPE CODE 371 OWNER/MANAGER P Ryan

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION		CODE	
1. Outside Premises		16. Shelves		31. Ingredients			46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing			47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement			48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test	Pos.	Neg.	49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test	Pos.	Neg.	50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave	Pos.	Neg.	51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected			52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted			53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment	YES		54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$		55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES		56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES		57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$		58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES		59.	
15. Transportation		30. Packaging		45. No. Scales Checked			60.	

REMARKS History NO violations noted on the previous inspection 6-25-01
Current inspection: NO violations noted on this inspection

Follow up Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

X Lisa Libby — REPORT RECEIVED BY
Assistant Mgr. — TITLE
Chris Ellis — SANITARIAN'S SIGNATURE

☐ New
☐ Change
☐ Delete

GEORGIA DEPARTMENT OF AGRICULTURE

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

THOMAS T. IRVIN
Commissioner

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC, 2 — PRIVATE _____

FIRM NAME Ca Agra Grp Products C DATE 3-25-02

ADDRESS 101 Seabrook Dr.

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

ESTABLISHMENT NO. 29646 GRID CODE _____ LICENSE NO. _____

Insp. Begin 1350
Time End 1530

Misc.
Time Hrs. _____

Travel Miles _____

ASSISTING INSPECTOR NO. _____ ASSISTING INSPECTOR'S NAME _____ CHIEF INSPECTOR C Beard NO. 4833

FIRM TYPE CODE 371 OWNER/MANAGER L Ackey

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave Pos. Neg.		51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected		52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted		53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment	YES	54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$	55. No. Samples Collected	1
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES	56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES	57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$	58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES	59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS History NO violations noted on the previous inspection- 9-27-01
Current inspection: No violations noted on this inspection

Follow up: Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

X Leon Ackley — REPORT RECEIVED BY

Operations Manager — TITLE

C Beard — SANITARIAN'S SIGNATURE

GEORGIA DEPARTMENT OF AGRICULTURE

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

THOMAS T. IRVIN
Commissioner

☐ New
☐ Change
☐ Delete

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC, 2 — PRIVATE _____

FIRM NAME Con Agra Grocery Products Co DATE 6 20 02

ADDRESS 101 Seabrook Rd

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

Insp. Begin 1145
Time End 1345

Misc. Time Hrs. _____

Travel Miles _____

ESTABLISHMENT NO. 29646 GRID CODE _____ LICENSE NO. _____

ASSISTING INSPECTOR NO. _____ ASSISTING INSPECTOR'S NAME _____ CHIEF INSPECTOR Beard NO. 4833

FIRM TYPE CODE 371 OWNER/MANAGER Mr Mike Watts

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave Pos. Neg.		51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected		52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted		53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment	YES	54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$	55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES	56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES	57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$	58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES	59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS History: No Violations noted on the previous inspection 3-25-02
Current Inspection: No violations noted on this inspection.

Follow up: Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

Mike Watts — REPORT RECEIVED BY
QC Manager — TITLE
[signature] — SANITARIAN'S SIGNATURE

☐ New
☐ Change
☐ Delete

GEORGIA DEPARTMENT OF AGRICULTURE

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

THOMAS T. IRVIN
Commissioner

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC, 2 — PRIVATE _____

FIRM NAME ConAgra Grocery Products Co. DATE 9-27-02

ADDRESS 101 Seahawk

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

ESTABLISHMENT NO. 29646 GRID CODE _____ LICENSE NO. _____

Insp. Begin 1145
Time End 1400

Misc.
Time Hrs. _____

Travel Miles _____

ASSISTING INSPECTOR NO. _____ ASSISTING INSPECTOR'S NAME _____ CHIEF INSPECTOR C Beard NO. 4733

FIRM TYPE CODE 371 OWNER/MANAGER Mike Watts GC.

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave Pos. Neg.		51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected		52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted		53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment	YES	54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$	55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES	56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES	57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$	58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES	59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS History. NO violations noted on the previous inspection 6-20-02.
Current inspection: NO violations noted on this inspection.

Follow up: Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

X RA Yarn
REPORT RECEIVED BY

TITLE

SANITARIAN'S SIGNATURE

GEORGIA DEPARTMENT OF AGRICULTURE

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

THOMAS T. IRVIN
Commissioner

☐ New
☐ Change
☐ Delete

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC, 2 — PRIVATE

FIRM NAME ConAgra Grocery Products DATE 2-4-03

ADDRESS 101 Seabrook dr

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

ESTABLISHMENT NO. 29646 GRID CODE LICENSE NO.

Insp. Time Begin 1145 End 1400

Misc. Time Hrs.

Travel Miles

ASSISTING INSPECTOR NO. ASSISTING INSPECTOR'S NAME CHIEF INSPECTOR C Beard NO. 4233

FIRM TYPE CODE 371 OWNER/MANAGER L Ackley

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave Pos. Neg.		51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected		52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted		53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment	YES	54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$	55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES	56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES	57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$	58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES	59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS History: No violations noted on the previous inspection 9-27-02

Current inspection: No violations noted on this inspection

Follow up: Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

X [signature]
REPORT RECEIVED BY

P. A. Manager
TITLE

[signature]
SANITARIAN'S SIGNATURE

☐ New
☐ Change
☐ Delete

GEORGIA DEPARTMENT OF AGRICULTURE

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

THOMAS T. IRVIN
Commissioner

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC, 2 — PRIVATE _____

FIRM NAME ConAgra Grocery Products Co DATE 6/25/03

ADDRESS 101 Seaboard

CITY Shiloh STATE GA ZIP 31791 COUNTY Wilkes

Insp. Time Begin 0830 End 1130

Misc. Time Hrs. _____

Travel Miles _____

ESTABLISHMENT NO. 29644 GRID CODE _____ LICENSE NO. _____

ASSISTING INSPECTOR NO. 497x ASSISTING INSPECTOR'S NAME [illegible] CHIEF INSPECTOR C Beard NO. 4533

FIRM TYPE CODE 371 OWNER/MANAGER Mike Matis

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
6. Ceilings		21. Rodents		36. Microwave Pos. Neg.		51. No. Doz. Eggs Inspected	
7. Windows		22. Insects		37. Violations Corrected		52. No. Doz. Eggs Withheld	
8. Doors		23. Contamination		38. Adv. Submitted		53. License Check	YES
9. Screens		24. Adulteration		39. Rejected Equipment	YES	54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$	55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES	56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES	57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$	58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES	59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS History no violations noted on the previous inspection 2-4-03
Current Inspection: NO violations noted on this inspection.

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

[illegible] Lewis Ashley — REPORT RECEIVED BY

Production Manager — TITLE

[illegible] — SANITARIAN'S SIGNATURE

GEORGIA DEPARTMENT OF AGRICULTURE

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia 30334

THOMAS T. IRVIN
Commissioner

☐ New
☐ Change
☐ Delete

☑ Routine
☐ Follow-up
☐ Complaint
☐ Investigation
☐ Misc.

WATER SOURCE: 1 — PUBLIC 2 — PRIVATE 1

FIRM NAME ConAgra Grocery Products DATE 10-29-03

ADDRESS 101 Seabrook

CITY Sylvester STATE GA ZIP 31791 COUNTY Worth

Insp. Begin 0800
Time End 1015

Misc.
Time Hrs.

Travel Miles

ESTABLISHMENT NO. 29646 GRID CODE _____ LICENSE NO. _____

ASSISTING INSPECTOR NO. 4335 ASSISTING INSPECTOR'S NAME M Pickett QC CHIEF INSPECTOR CB Pond NO. 4833

FIRM TYPE CODE 371 ~~OWNER~~/MANAGER Mike Mathis

ESTABLISHMENT INSPECTION

CODE	VIOLATION	CODE	VIOLATION	CODE	VIOLATION	CODE	
1. Outside Premises		16. Shelves		31. Ingredients		46. No. Scales Rejected	
2. Roof		17. Storage Area		32. Processing		47. No. Pkg. Weighed	
3. Equipment		18. Water Temp.		33. False Advertisement		48. No. Pkg. Errors	
4. Utensils		19. Soiled Linen		34. Fat Test Pos. Neg.		49. No. Scanner Items Ck'd.	
5. Walls		20. Temperature		35. Sulfite Test Pos. Neg.		50. No. Scanner Errors	
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9. Screens		24. Adulteration		39. Rejected Equipment	YES	54. No. Water Samples	
10. Floors		25. Distressed Food		40. Food Destruction	$	55. No. Samples Collected	
11. Restrooms		26. Employee Cleanliness		41. Withhold from Sale	YES	56. No. Labels Collected	
12. Lavatories		27. Hair Restraint		42. Abatement Issued	YES	57. Flesh Garbage Disposal	YES
13. Ventilation		28. Use of Tobacco		43. Improvements	$	58. No. Outdated Items	
14. Lighting		29. Labeling		44. Special Reports	YES	59.	
15. Transportation		30. Packaging		45. No. Scales Checked		60.	

REMARKS

History: 6-25-03 No Violations

Current: No Violations

Follow-up: Routine

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE AND YOU ARE NOTIFIED OF THE INDICATED VIOLATIONS. THESE VIOLATIONS ARE TO BE CORRECTED.

Laura Ashley — Charles Pond

REPORT RECEIVED BY — TITLE — SANITARIAN'S SIGNATURE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NO.
60 8th Street NE
Atlanta, GA 30309
404-253-1161

TO

2. NAME AND TITLE OF INDIVIDUAL
Mr. S. T. Camp, Plant Manager

3. DATE
7/05/07

4. FIRM NAME
ConAgra Grocery Products

5. HOUR
10:42 a.m. / p.m.

6. NUMBER AND STREET
101 Seaboard Drive

7. CITY AND STATE & ZIP CODE
Sylvester, GA 31791

8. PHONE # & AREA CODE
912-776-8011

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
[signature]

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
Jackie M. Douglas
Investigator

[1]**Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:**

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**
Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 512 (i)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.
(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2]**Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:**

Part F - Licensing - Biological Products and Clinical Laboratories
and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

(f) "The Secretary may by regulation (1) require dealers and disbributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
60 8th St. NE
Atlanta, GA 30309
404-253-1161

2. NAME AND TITLE OF INDIVIDUAL	3. DATE	4. SAMPLE NUMBER
Mr. Michael J. Mathis, QC Manager	7/25/00	81267/81269

5. FIRM NAME	6. FIRM'S DEA NUMBER
Conagra Grocery Products	N/A

7. NUMBER AND STREET	8. CITY AND STATE *(Include Zip Code)*
101 Seabrook Drive	Sylvania, GA 31791

9. SAMPLE COLLECTED *(Describe fully. List lot, serial, model numbers and other positive identification)*

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(c)) and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act (21 USC 360ii(b)) and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(NOTE: *If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.*)

1. ~~81267~~ 85267
12/28 oz plastic jars of peanut butter labeled in part "Peter Pan Peanut Butter Creamy xxx Net Wt 28 oz xxx Nutrition Facts xxx Ingredients xxx Hunt-Wesson Inc. P.O. Box 4800, Fullerton, CA 92634," coded 507J1.

2. ~~81268~~ 85268
12/28 oz plastic jars of peanut butter labeled in part "Peter Pan Peanut Butter Crunchy xxx Net Wt. 28 oz xxx Nutrition Facts xxx Ingredients xxx Hunt-Wesson, Inc. P.O. Box 4800, Fullerton, CA 92634," coded 507K1.

10. SAMPLES WERE	11. AMOUNT RECEIVED FOR SAMPLE	12. SIGNATURE *(Persons receiving payment for sample or person providing sample to FDA at no charge.)*
☒ PROVIDED AT NO CHARGE ☐ PURCHASED ☐ BORROWED *(To be returned)*	N.C. ☐ CASH ☐ BILLED ☐ VOUCHER ☐ CREDIT CARD	Michael J. Mathis

13. COLLECTOR'S NAME *(Print or Type)*	14. COLLECTOR'S TITLE *(Print or Type)*	15. COLLECTOR'S SIGNATURE
Julie M. Douglas	Investigator	

FORM FDA 484 (5/98) PREVIOUS EDITION IS OBSOLETE **RECEIPT FOR SAMPLES** PAGE OF PAGES EF

October 23, 2000

S.T. Camp
Plant Manager
ConAgra Grocery Products
P.O. Box 585
101 South Seabrook Drive
Sylvester, GA 31791

Dear Mr. Camp:

On 7/25/00, Investigator Jackie M. Douglas of the Food and Drug Administration (FDA) conducted an inspection of your facility. This inspection covered peanut butter.

The areas inspected appear to be in compliance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and implementing regulations.

Based on these findings, the Agency is prepared to endorse export certificates for products manufactured that were specifically inspected at your facility. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The Agency may separately inspect your firm's facilities to address Current Good Manufacturing Practices in these areas.

Your firm has an on-going responsibility to ensure you are continuing to comply with the FD&C Act and applicable regulations governing your firm's product(s).

We are enclosing a copy of the establishment inspection report (EIR). This report is being provided to you for information purposes. This new procedure is applicable to EIRs for inspections conducted on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report. This copy may also reflect redactions made by the Agency in accordance with the FOIA and Title 21, Code of Federal Regulations, Part 20.

Sincerely,

Ballard H. Graham, Director
Atlanta District

Enclosure

Summary of Findings

The current inspection of this large peanut butter manufacturer is conducted in response to complaint 1-03038, received at Tifton RP on 7/24/00. An anonymous caller, reportedly a production employee of the firm, alleged that rest rooms and locker rooms used by production employees were poorly maintained, "filthy", and often without necessary supplies including soap, hand towels, toilet paper, and toilet seat covers. Also, the caller stated that handwashing facilities in production areas often lacked soap and hand towels.

This was a limited inspection conducted per PAC 03R801 in order to follow up this complaint. Additionally, in response to an outstanding surveillance assignment, routine samples of peanut butter were to be collected for mycotoxin analysis per PAC 07001.

Credentials were shown to Messrs. S. T. ("Tom") Camp, Plant Manager, and Michael J. Matis, Quality Control Manager. The FD 482, Notice of Inspection, was issued to Mr. Camp along with the "Resources for Regulated Businesses" document.

I explained the purposes of the inspection and provided the two with details of the complaint concerning the rest room, handwashing, and locker room facilities. I briefly recounted the allegations made by the complainant, whom I told them was anonymous. Although both expressed understanding of the GMP implications, a copy of 21 CFR 110 was provided to them.

Both expressed surprise and indicated being unaware of any problems in this area, having received no complaints internally. Mr. Camp reported the contractor responsible for these production areas also serviced the office rest rooms and usually the ladies in the office immediately brought any such problems to his attention.

Mr. Matis advised he occasionally checks these areas and the firm's Sanitation Supervisor, Mr. Dave Wilcox, more frequently checks them. He said nothing had been observed or mentioned regarding any problems.

The areas are service daily at around 5:00 PM by B & S Cleaning, a Sylvester, GA contractor. Mr. Camp reported a personnel change with the cleaning company (due to a death) about 6 weeks ago while speculating if that might have something to do with the complaint. I told him I didn't know, but the complainant reported that conditions have been going downhill gradually for about a year, at about the time the current contractor was employed. He confirmed that was about how long the current contractor had been used.

Mr. Camp and Mr. Matis accompanied me to the production employee rest rooms and we inspected these facilities. The men's rest room was found clean with functional sinks,

disposable toilet seat covers. A trash container was available and not overflowing. The women's rest room was found in similar condition, although the disposable seat cover dispenser was empty.

We passed through the employee break room to visit the locker rooms. A break was occurring at the time and several people were present. The break room did not appear particularly dirty or littered.

Sanitation in both locker rooms appeared adequate. In the women's locker room a towel dispenser was removed from the wall and resting on the trash container top. However, it was functional and contained towels. In the men's locker room, 1 soap dispenser was empty, but another filled one was available for use.

A few discarded hand towels were observed on the floors in a couple of areas.

Mr. Matis accompanied me into the production areas and showed me the handwashing sinks. Both were properly equipped with soap and hand towels. He also advised of the availability of large wipes used to wipe hands, clean up spills, etc. in these areas, and as I looked about, I saw several containers of these wipes throughout.

Following the tour I advised the two that I had not seen anything other than the minor deficiencies mentioned above. Mr. Camp indicated he had seen these and indicated these would be corrected.

I recommended the firm initiate a routine inspection of these areas and to consider posting in a conspicuous place the results of the inspection. I told them I thought this might demonstrate to the firm's employees the firm's concern for these areas. I also suggested the firm discuss the complaint with the cleaning contractor. Mr. Camp indicated the firm agreed with these recommendations.

Mr. Matis accompanied me to the firm's warehouse and assisted in the collection of mycotoxin surveillance samples. 85267, Peter Pan Creamy Peanut Butter, and 85268, Peter Pan Crunchy Peanut Butter, were collected and are submitted to SRL under separate cover for analysis. Mr. Matis reported the firm intends to hold the 2 lots sampled pending FDA analysis. I told him I would attempt to ascertain analytical results as quickly as possible and advise him.

The FD 484, Receipt for Samples, was issued to Mr. Matis. (Note at the time of issuance, I entered incorrect sample numbers of 81267 and 81268 on the FD 484 - on 7/26/00 I telephoned Mr. Matis and provided him with the correct sample numbers - left as a voice mail message.)

Note this firm has undergone a name change from Hunt-Wesson, Inc. to ConAgra Grocery Products. Mr. Camp reported ConAgra has owned the facility for several years, but the name remained Hunt-Wesson until a year or so ago. ConAgra Grocery Products is headquartered in Fullerton, CA.

The firm continues to manufacture Peter Pan peanut butter under the Hunt-Wesson label. The firm also manufactures a few private labels including Panner, Giant, and Super Value. At present there are 100+ employees here, and the firm is running 2 ten-hour shifts per day, 4 to 5 days per week (depending on orders).

No specific warnings were issued and no FD 483 was issued.

Exhibits

1 - Copy of FDA Form 2516/2516a, Complaint 1-03038

Jackie M. Douglas
ATL-DO/ Tifton RP

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
FDA
60 8th St., N.E.
Atlanta, GA 30309

TO

2. NAME AND TITLE OF INDIVIDUAL
Mr. Lavan McKley, Operations Manager

3. DATE
3/21/01

4. FIRM NAME
Con Agra Grocery Products Co.

5. HOUR
11:00 a.m.
p.m.

6. NUMBER AND STREET
101 S. Seabrook Dr.

7. CITY AND STATE & ZIP CODE
Sylvester, GA 31791

8. PHONE # & AREA CODE
(229) 776-8811

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
Janet B. Kay

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
Janet B. Kay/CSO

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**
Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.
(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories
and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

Resources for FDA Regulated Businesses

The U.S. Food and Drug Administration strives to protect, promote and enhance the health of the American people, while minimizing the regulatory burden on the industries it regulates. You have a right to disagree with any agency decision, action, or operation without fear of retaliation. You also have a right to be treated with appropriate courtesy and respect If you are dissatisfied with any agency decision or action, you may appeal to the supervisor of the employee who made the decision or took the action. If the issue is not resolved at the first supervisor's level, you may request that the matter be reviewed at the next higher supervisory level. This process may continue through the agency's chain of command.

To resolve a problem with your company's interaction with FDA, or if you have questions or concerns about FDA rules or procedures, we suggest that you first write or call your district office to explain your concerns. If you are not satisfied with the help provided by the district office, you may take your complaint or concern to the regional office. If that effort is not satisfactory, contact FDA's Office of the Chief Mediator and Ombudsman for further assistance and guidance.

Contact the **District Office** if you have a concern or question about an inspection, an import or export issue, or any other action taken by an FDA field representative. The District Office will provide you with the name and phone number of someone who will review the matter and provide assistance.

District	Telephone
Atlanta	(404) 253-1161
Baltimore	(410) 962-3396
Buffalo	(716) 551-4461
Chicago	(312) 353-5863
Cincinnati	(513) 679-2700
Dallas	(214) 655-5310
Denver	(303) 236-3000
Detroit	(313) 226-6260
Florida	(407) 475-4700
Kansas City	(913) 752-2100
Los Angeles	(949) 798-7600

District	Telephone
Minneapolis	(612) 334-4100
Nashville	(615) 781-5385
New England	(781) 279-1675
New Jersey	(973) 526-6000
New Orleans	(504) 589-6344
New York	(718) 340-7000
Philadelphia	(215) 597-4390
San Francisco	(510) 337-6700
San Juan	(787) 729-6844
Seattle	(425) 486-8788

Contact the **Regional Office** for further help if you were not able to effectively resolve the issue with the assistance of the district office. Telephone numbers for the regional offices and a list of the states covered by each region are on the Internet at http://www.fda.gov/ora/hier/ora_field_names.txt.

Contact the **Office of the Chief Mediator and Ombudsman** at 301-827-3390 if you have been unsuccessful in resolving a problem at the district and regional levels. The office's home page is on the Internet at http://www.fda.gov/oc/ombudsman/homepage.htm.

The Small Business Administration also has an ombudsman. The **Small Business and Agriculture Regulatory Enforcement Ombudsman** and 10 Regional Fairness Boards receive comments from all kinds of small businesses about federal agency enforcement actions and annually evaluate the enforcement actions of FDA, call 1-888-734-3247. The ombudsman's home page is on the Internet at http://www.sba.gov/regfair.

Small Business Guide to FDA
Internet at http://www.fda.gov/opacom/morechoices/smallbusiness/toc.html

Office of Regulatory Affairs (ORA)
Internet at http://www.fda.gov/ora/ora_home_page.html

Food and Drug Administration (FDA)
Internet at http://www.fda.gov

Food and Drug Administration
Atlanta District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

60 Eighth Street, N.E.
Atlanta, Georgia 30309

June 12, 2001

Michael J. Matis
Quality Control Manager
Conagra Grocery Products
P.O. Drawer 585
Sylvester, GA 31791

Dear Mr. Matis:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises during 3/21/01, by Investigator Janet B. Gray of the U.S. Food and Drug Administration (FDA). This report is being provided to you for information purposes. This new procedure is applicable to EIRs for inspections conducted on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report. This copy may also reflect redactions made by the Agency in accordance with the FOIA and Title 21, Code of Federal Regulations, Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there are any questions about the released information, feel free to contact Carlos A. Bonnin, Compliance Officer, at (404) 253-1163 or write to the address noted in the letterhead.

Sincerely,

Ballard H. Graham

Ballard H. Graham, Director
Atlanta District

Enclosure

CONAGRA GROCERY PRODUCTS
101 S. Seabrook Dr.
Sylvester, GA 31791

3/21/01
JBG

SUMMARY OF FINDINGS

The current inspection of this peanut butter manufacturer was conducted in accordance with Compliance Program (CP) 7303.803, Domestic Food Safety, and ATL-DO's FY' 01 workplans.

The previous inspection of this firm on 8/3/00 was conducted as per an assignment issued by the ATL-DO for the follow-up of a sample of peanut butter with 4 ppb of Aflatoxin B1. The previous inspection was classified as no action indicated (NAI).

The current inspection found the firm to be manufacturing peanut butter into various size containers. Peanut butter is the only product produced at this firm, and it is produced under private labels such as Great Value, Peter Pan, and Panner. No objectionable conditions were observed during the inspection.

HISTORY OF BUSINESS

This firm started operations in 1986, and was purchased by ConAgra Food, Inc. in 1990. This inspection found that the firm is a division of ConAgra Grocery Products, and the corporate office is located at ConAgra Foods, Inc., 7000 W. Center, Omaha, Nebraska 68103. The president of the firm is Mr. Ray Deriggi, and he maintains an office at the company's headquarters located at ConAgra Grocery Products Co., P.O. Box 57078, Irvine, CA 92619.

The firm's office hours are 8:00 a.m. to 5:00 p.m., Monday through Friday. The firm operates with 3 shifts, 6:00 a.m. to 2:00 a.m., Monday through Thursday. The firm has approximately 125 employees.

PERSONS INTERVIEWED/INDIVIDUAL RESPONSIBILITY

Credentials were presented to and the FDA-482, Notice of Inspection (with attached Resources for FDA Regulated Businesses addendum), was issued to Mr. Lavon Ackley, Operations Manager and the most responsible individual present at the firm. Also present during the initiation of the inspection was Mr. Michael J. Matis, Quality Control Manager. At this time, I explained the purpose of my visit. Mr. Ackley and Mr. Matis each provided me with the requested

information pertaining to the firm. Mr. Ackley demonstrated his authority by giving instructions to employees and accepting the Notice of Inspection.

According to Mr. Ackley, he is responsible for managing all operations at this firm, and he reports to Mr. Tom Camp, Plant Manager. Mr. Camp was not present at the firm during the inspection and he did not participate in the inspection. Mr. Tom Camp reports to Mr. Jim Warfield, Director of Field Operations, in Irvine, CA.

Mr. Matis stated that he was responsible for the quality control programs at the firm, and he also reports to Mr. Tom Camp. Mr. Matis accompanied me throughout the inspection of the facility and answered any questions concerning operations at the firm. Mr. Matis requested that any FDA correspondence be sent to him at P.O. Drawer 585, Sylvester, GA 31791.

MANUFACTURING CODES

The peanut butter manufactured by the firm is lot coded with the production date and the shift. For example;

"S1272"= S- plant location
1- 2001
2- month
7- day
2- shift

The lot code is stamped in dot matrix on the lids of smaller containers and on the bottom of the larger bulk containers.

TRAINING

According to Mr. Matis, the firm's employees are trained in areas such as safety and general Good Manufacturing Practices. Most of the training is on-the-job training.

COMPLAINTS AND RECALLS

According to Mr. Ackley, all complaints are evaluated and handled by Pat Ryan, the firm's attorney who maintains an office at the firm's headquarters in Irvine, CA. Mr. Matis informed me that there have been no recalls issued for their product.

CONAGRA GROCERY PRODUCTS
101 S. Seabrook Dr.
Sylvester, GA 31791

3/21/01
JBG

GUARANTEES AND LABELING AGREEMENTS

Management stated that they offer no guarantees or labeling agreements for their products.

RAW MATERIALS AND COMPONENTS

The primary raw material received by the firm is raw, un-shelled peanuts received in bulk from tractor-trailer tanks. According to management, the peanuts are purchased from various peanut shellers in the local area such as Golden Peanut Co. and Bird Song Co. According to Mr. Ackley, 70-80 % of the peanuts are purchased within Georgia, and the other peanuts are purchased from Alabama and Florida.

OPERATIONS AND EQUIPMENT

Raw peanuts are received at the dock entrance of the plant in tractor-trailer tanks. The peanuts are blown into the plant through a chute and stored in large storage bins until processing. The nuts are cleaned by a series of equipment operations such as the scalper or shaper, then through the destoner. The scalper is responsible for removing light trash, debris, and clumps. Then the destoner removes heavy articles, rocks, etc. After the destoner, the product is carried into the roaster by a bucket elevator. After roasting, the husks are removed and the nuts are transported along a conveyor to the blanchers. Next, the nuts are passed through a series of color sorters, and then to holding tanks.

From the holding tanks, the nuts are either passed on to the coarse grind process for a paste, the smooth grind process for the creamy butter, or the crunchy process. The nuts are transported from the storage bins into the ingredient room where the grind process occurs and the ingredients are added to the mixture. The peanut mixture is then piped to the packing area, where the product is placed into the appropriate containers by a mechanically operated conveyor system. The containers are labeled, passed through a metal detector, lot coded, and then packaged into cardboard cartons. The finished product is placed in a large warehouse until distribution. According to Mr. Matis, the finished product is shipped to various grocery warehouses and distribution sites.

CLOSING DISCUSSION

CONAGRA GROCERY PRODUCTS
101 S. Seabrook Dr.
Sylvester, GA 31791

3/21/01
JBG

At the conclusion of the inspection, a closing discussion was held with Mr. Matis and Mr. Ackley. I informed management that no deficiencies were found and a FDA-483, Inspectional Observations, would not be issued. With no further questions, I concluded the inspection.

Janet B. Gray, CSO
Savannah, GA RP

FOR COLLECTION OF SAMPLES ONLY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NO.
60 8th Street, NE
Atlanta, Georgia 30309
404 - 253 - 1161

TO:
2. NAME AND TITLE OF INDIVIDUAL: Mr Lavon Addy, Operations Manager
3. DATE: 5/23/01
4. FIRM NAME: Con Agra Grocery Products Company
5. HOUR: 1:20 p.m.
6. NUMBER AND STREET: 101 South Seabrook Drive P.O. Drawer 585
7. CITY AND STATE & ZIP CODE: Sylvester, Georgia 31791
8. PHONE # & AREA CODE: 229 - 776 - 8811

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
B. Douglas Brogdon

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
B. Douglas Brogdon / Investigator

[1]Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**
Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.
(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2]Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories
and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

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(f) "The Secretary may by regulation (1) require dealers and disbributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manuracturers to preserve such information.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
60 8th Street, NE
Atlanta, Georgia 30309
404-253-1161

2. NAME AND TITLE OF INDIVIDUAL
Mr Aaron Lavon Ackley, Ops Mgr

3. DATE
05/23/01

4. SAMPLE NUMBER

5. FIRM NAME
ConAgra Grocery Products Company

6. FIRM'S DEA NUMBER
N/A

7. NUMBER AND STREET
101 S. Seahrook Drive P.O. 585

8. CITY AND STATE *(Include Zip Code)*
Sylvester, Georgia 31791

9. SAMPLE COLLECTED *(Describe fully. List lot, serial, model numbers and other positive identification)*

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(NOTE: *If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.*)

Sample Consists of 12/18oz jars of Peter Pan Creamy Peanut Butter. Each plastic jar closed with yellow plastic lid were a paper label quoted in part "Peter Pan CREAMY PEANUT BUTTER NET WT 18OZ (1LB 2OZ) 510g INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPESEED), SALT. CONAGRA GROCERY PRODUCTS COMPANY P.O. BOX 57078, IRVINE, CA 92619 U.S.A. XXX 0 GRAMS TRANS FAT PER SERVING Nutrition Facts: XXX" jar lid bore Code "515H1".

Sample Consists of 12/18oz jars Peter Pan CRUNCHY PEANUT BUTTER NET WT 18OZ (1LB 2OZ) 510g INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPESEED), SALT. CONAGRA GROCERY PRODUCTS COMPANY P.O. BOX 57078, IRVINE, CA 92619 U.S.A. XXX 0 GRAMS TRANS FAT PER SERVING Nutrition Facts XXX" Lids bore code "515P1"

10. SAMPLES WERE
- [X] PROVIDED AT NO CHARGE
- [ ] PURCHASED
- [ ] BORROWED *(To be returned)*

11. AMOUNT RECEIVED FOR SAMPLE
N/C
- [ ] CASH
- [ ] BILLED
- [ ] VOUCHER
- [ ] CREDIT CARD

12. SIGNATURE *(Persons receiving payment for sample or person providing sample to FDA at no charge.)*
Aaron Ackley

13. COLLECTOR'S NAME *(Print or Type)*
B. Douglas Brogden

14. COLLECTOR'S TITLE *(Print or Type)*
Investigator

15. COLLECTOR'S SIGNATURE
B. Douglas Brogden

FORM FDA 484 (9/98) PREVIOUS EDITION IS OBSOLETE

RECEIPT FOR SAMPLES

PAGE 1 OF 1 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
U.S. Food & Drug Administration
60 8th Street, NE
Atlanta, GA. 30309 404-253-1164

2. NAME AND TITLE OF INDIVIDUAL	3. DATE	4. SAMPLE NUMBER
Mr Michael Mates, Quality Control Mgr	April 8, 2002	

5. FIRM NAME	6. FIRM'S DEA NUMBER
Conagra Foods	

7. NUMBER AND STREET	8. CITY AND STATE *(Include Zip Code)*
Seabrook Drive P.O. Box 585 Drawer	Sylvester, GA 31791-0585

9. SAMPLE COLLECTED *(Describe fully. List lot, serial, model numbers and other positive identification)*

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(NOTE *If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)*

Sample Consists of 12/17.6 OZ jars of Crunchy Peanut Butter labeled in part "Peter Pan PLUS PEANUT BUTTER WITH VITAMINS & MINERALS & Essential Vitamins & Minerals CRUNCHY XXX NET WT 17.6 OZ (1LB 1.6 OZ) 490g Nutrition Facts XXX INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPESEED), SALT, VITAMINS AND MINERALS (MAGNESIUM OXIDE, VITAMINE (ACETATE), IRON (FERRIC ORTHOPHOSPHATE), VITAMIN A (PALMITATE), ZINC (OXIDE), VITAMIN B6 (PYRIDOXINE HYDROCHLORIDE) COPPER (CUPRIC OXIDE), FOLIC ACID. ConAgra Foods P.O. BOX 57078, IRVINE, CA 92619-7078, USA. XXX " " Mfg code S2451"

Sample Consists of 12/18 OZ plastic jars of Peter Pan CREAMY PEANUT BUTTER labeled in part "S2481 XXX Peter Pan XXX CREAMY PEANUT BUTTER NET WT 18 OZ (1LB 2 OZ) 510g Nutrition Facts XXX INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPESEED), SALT. ConAgra Foods P.O. BOX 57078, IRVINE, CA 92619-7078 USA XXX

10. SAMPLES WERE	11. AMOUNT RECEIVED FOR SAMPLE	12. SIGNATURE *(Persons receiving payment for sample or person providing sample to FDA at no charge.)*
☒ PROVIDED AT NO CHARGE ☐ PURCHASED ☐ BORROWED *(To be returned)*	N/C ☐ CASH ☐ BILLED ☐ VOUCHER ☐ CREDIT CARD	Michael Mates

13. COLLECTOR'S NAME *(Print or Type)*	14. COLLECTOR'S TITLE *(Print or Type)*	15. COLLECTOR'S SIGNATURE
B. Douglas Brogden	Investigator	B. Douglas Brogden

FORM FDA 484 (5/98) PREVIOUS EDITION IS OBSOLETE **RECEIPT FOR SAMPLES** PAGE 1 OF 1 PAGES

FOR COLLECTION OF SAMPLE ONLY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
60 8th Street, NE
Atlanta, Georgia 30309
404-253-1169

Aaron

TO
2. NAME AND TITLE OF INDIVIDUAL
Mr. Lavon Ackley, Operations Manager

3. DATE
05/01/02

4. FIRM NAME
Conagra Foods

5. HOUR
11:50 a.m. / p.m.

6. NUMBER AND STREET
101 Seahorse Drive P.O. Box 585

7. CITY AND STATE & ZIP CODE
Sylvester, GA. 31791

8. PHONE # & AREA CODE
229-776-8811

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
B. Douglas Brogden

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
B. Douglas Brogden / Investigator

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories
and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

(f) "The Secretary may by regulation (1) require dealers and disbributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manuracturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manu- facturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election *(together with information identifying the notifier and the product)* to the manufacturer, and shall, when advised by the manufacturer or Secretary, of the need therefor for the pur- poses of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

Sec. 360 B.(a) It shall be unlawful-

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to *human beings*, and other measures, as in his judgement may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
60 8th Street, NE
Atlanta, Georgia 30309
404-253-1169

2. NAME AND TITLE OF INDIVIDUAL	3. DATE	4. SAMPLE NUMBER
Mr Aaron Lavon Ackley, Operations Mgr	May 1, 2002	1664400

5. FIRM NAME	6. FIRM'S DEA NUMBER
Conagra Foods	N/A

7. NUMBER AND STREET	8. CITY AND STATE *(Include Zip Code)*
P.O. Box 585 101 South Seabrook Drive	Sylvester, GA 31791

9. SAMPLE COLLECTED *(Describe fully. List lot, serial, model numbers and other positive identification)*

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(NOTE: *If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)*

Sample Consists of 4 Cases of 12/17.6 oz jars Labeled in part, " Peter Pan PEANUT BUTTER WITH VITAMINS & MINERALS xxx PLUS 8 Essential Vitamins & Minerals CRUNCHY NET WT 17.6 OZ (1lb 1.6oz) 499. Nutrition Facts xxx INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPESEED), SALT, VITAMINS AND MINERALS [MAGNESIUM (OXIDE), VITAMINE (ACETATE), IRON (FERRIC ORTHOPHOSPHATE), VITAMIN A (PALMITATE), ZINC (OXIDE), VITAMIN B6 (PYRIDOXINE HYDROCHLORIDE), COPPER, (CUPRIC OXIDE), FOLIC ACID.].
HUNT-WESSON, INC. P.O. BOX 4800, FULLERTON, CA 92834
XXY 52451 XXY "

10. SAMPLES WERE	11. AMOUNT RECEIVED FOR SAMPLE	12. SIGNATURE *(Persons receiving payment for sample or person providing sample to FDA at no charge.)*
☒ PROVIDED AT NO CHARGE ☐ PURCHASED ☐ BORROWED *(To be returned)*	N/C ☐ CASH ☐ BILLED ☐ VOUCHER ☐ CREDIT CARD	Lavon Ackley

13. COLLECTOR'S NAME *(Print or Type)*	14. COLLECTOR'S TITLE *(Print or Type)*	15. COLLECTOR'S SIGNATURE
B. Douglas Brogden	Investigator	B. Douglas Brogden

FORM FDA 484 (5/98) PREVIOUS EDITION IS OBSOLETE — **RECEIPT FOR SAMPLES** — PAGE 1 OF 1 PAGES

Section 704 (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Section 532(b) of The Federal Food, Drug and Cosmetic Act [21 USC 360 ii (b)] is quoted in part below:

"Section 532(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-

(1) * * * *
(2) * * * *
(3) * * * *
(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products"

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.
Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such an act nor shall compliance with such be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

Therefore, in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA form FDA 484, RECEIPT FOR SAMPLES, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

AFFIDAVIT

SAMPLE NO.

STATE OF: Georgia

COUNTY OF: Worth

Before me, B. Douglas Brogden, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 865 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Ms Aaron L. Achley in the county and State aforesaid, who, being duly sworn, deposes and says: I Am Aaron L. Achley, Operations Manager for Conagra Foods, 101 South Seabrook Drive, P. O. Box 585, Sylvester, GA 31791. In this position, I am familar with this firm's purchase, receipt, storage of the various raw materials including peanuts used in our manufacture of Peanut butter, Manufacturing, packing, and shipping of our Peanut butter lots and all records covering same.

This certifies that FDA investigator B. Douglas Brogden Collected a sample consisting of 4 Cases of 12/17.6oz jars of our Peter Pan Peanut Butter With Vitamins and Minerals ~~labeled~~ on May 1, 2002. The sample was collected from a lot Consisting of approximately 560 Cases of 12/17.6oz jars bearing our code S2451. Jars packed under code S2451 were labeled in part, "Peter Pan PEANUT BUTTER WITH VITAMINS E MINERALS xxx PLUS 8 Essential Vitamins & Minerals CRUNCHY NET WT 17.6oz (1lb 1.6oz) 499g Nutrition Facts xxx INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPE SEED) SALT, VITAMINS AND MINERALS [MAGNESIUM (OXIDE), VITAMIN E (ACETATE), IRON (FERRIC ORTHOPHOSPHATE), VITAMIN A (PALMITATE), ZINC (OXIDE), VITAMIN B6 (PYRIDOXINE HYDROCHLORIDE), COPPER (CUPRIC OXIDE), FOLIC ACID]. HUNT-WESSON, INC. P.O. BOX 4800, FULLERTON, CA 92834 xxx".

The lot sampled by the investigator was being held for sale when sampled. Additionally, Investigator Brogden had sampled this lot on or about April 8, 2002 when the lot Contained about 1344 Cases. He reported FDA's Southeast Regional Laboratory had analyzed the sample Collected on April 8, 2002 and had found 3.4 ppb Aflatoxins. Since the initial sample was considered by FDA to be Aflatoxin positive, ~~the~~ FDA's Southeast Regional Laboratory's guidelines required collection of the 48/17.6oz subpls Collected this date

AFFIANT'S SIGNATURE AND TITLE

Aaron Achley

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Conagra Foods, 101 S Seabrook Drive, P.O. Box 585, Sylvester, GA 31791

Subscribed and sworn to before me at Sylvester, GA 31791 (City and State)

this 1st day of May ~~19~~ 2002

B. Douglas Brogden

(Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30. 1940; Reorganization Plan No. 1 of 1953, effective April. 11, 1953; and P.L. 96-88 effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF: Georgia

COUNTY OF: Worth

Before me, B. Douglas Brogden, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 865 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Ms Aaron L. Ackley in the county and State aforesaid, who, being duly sworn, deposes and says:

Investigator Brogden requested copies of our manufacturing records, raw material receipt records, and records covering interstate shipment made from the sampled lot. Per corporate Policy, I am not Authorized to provide FDA with this information. If FDA feels it needs this information, a written request listing the information/records needed and the reason for requesting this information should be submitted to Ms Georgia Ingham, Associate General Counsel, Conagra Foods, 3353 Mitcheloon Drive, Irvine, CA. 92612.

The information contained in this statement is correct to the best of my belief and recollection.

The investigator was not charged for the sample collected this date, and delivered under our Miscellaneous Shipping Ticket 188585 dated 5/1/02

AFFIANT'S SIGNATURE AND TITLE

Aaron Ackley

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Conagra Foods, 101 South Seabrook Drive, P.O. Box 585, Sylvester, GA 31791

Subscribed and sworn to before me at Sylvester, GA 31791 (City and State)

this 1st day of May, 19 2002

B. Douglas Brogden

(Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30. 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

FOR COLLECTION OF SAMPLES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
60 8th Street, NE
Atlanta, Georgia 30309
404-253-1169

TO

2. NAME AND TITLE OF INDIVIDUAL
Mr. Michael J. Matis, Quality Control Manager

3. DATE
02/07/03

4. FIRM NAME
ConAgra Grocery Products Company

5. HOUR
11:15 a.m.
p.m.

6. NUMBER AND STREET
101 South Seabrook Drive P.O. Box 585

7. CITY AND STATE & ZIP CODE
Sylvester, Georgia 31791

8. PHONE # & AREA CODE
229-776-8811

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
B. Douglas Brogden

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
B. Douglas Brogden / Investigator

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**
Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.
(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories
and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

(f) "The Secretary may by regulation (1) require dealers and disbributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manuracturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manu- facturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election *(together with information identifying the notifier and the product)* to the manufacturer, and shall, when advised by the manufacturer or Secretary, of the need therefor for the pur- poses of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

Sec. 360 B.(a) It shall be unlawful-

(1) ***

(2) ***

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart, or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

***

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to *human beings*, and other measures, as in his judgement may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
60 8th Street, NE
Cetlanta, Georgia 30309
404 - 253 - 1169

2. NAME AND TITLE OF INDIVIDUAL	3. DATE	4. SAMPLE NUMBER
Mr Michael J. Matis, Q C. Manager	02/07/03	SEE BELOW

5. FIRM NAME	6. FIRM'S DEA NUMBER	7. FDA'S DEA NUMBER
Con Agra Grocery Products Co	N/A	N/A

8. NUMBER AND STREET	9. CITY AND STATE (Include Zip Code)
101 South Seabrook Drive	Sylvester, GA 31791

10. SAMPLES COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374 (c)] and / or Part F, Sub Part 3, Section 356(b) of The Public Health Service Act [42 U.S.C. 263d] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(NOTE: *If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.*)

196057: 10/40oz Plastic jars closed with yellow Screw lids Jars labeled in part, "Peter Pan PEANUT BUTTER CREAMY NET WT. 40 OZ (2lbs 8oz) 1.13Kg INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPESEED), SALT. HUNT-WESSON, INC P.O. BOX 4800, FULLERTON, CA 92834, U.S.A. PETER PAN IS A REGISTERED TRADEMARK OF CONAGRA BRANDS, INC XXX Nutrition Facts XXX" LOT 53037 XXX B.

196058: 12/18 oz plastic jars colored with Red plastic screw lids with lot # 53021 XXXX A Printed on lid. paper label affixed to jars quoted in part, "XXX Peter Pan PEANUT BUTTER CRUNCHY NET WT. 18 OZ. (1lb 2 OZ) 510g INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPESEED), SALT. Con Agra Foods P.O. Box 57078 IRVINE, CA 92819-7078, U.S.A. PETER PAN IS A REGISTERED TRADEMARK OF CONAGRA BRANDS, INC. XXX 0 GRAMS TRANS FAT PER SERVING Nutrition Facts XXX".

11. SAMPLES WERE	12. AMOUNT RECEIVED FOR SAMPLE	13. SIGNATURE (Person receiving payment for sample or person providing sample to FDA at no charge.)
☒ PROVIDED AT NO CHARGE ☐ PURCHASED ☐ BORROWED (To be returned)	N/C ☐ CASH ☐ BILLED ☐ VOUCHER ☐ CREDIT CARD	Michael J. Matis

14. COLLECTOR'S NAME (Print or Type)	15. COLLECTOR'S TITLE (Print or Type)	16. COLLECTOR'S SIGNATURE
B. Douglas Brogden	Investigator	B. Douglas Brogden

FORM FDA 484 (10/87) PREVIOUS EDITION MAY BE USED — RECEIPT FOR SAMPLES — PAGE 1 OF 1 PAGES

Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Part F, Sub Part 3, Section 356(b) of The Public Health Service Act [42 U.S.C. 263d] is quoted in part below:

"Section 356(b) In carrying out the purposes of subsection (a), the Secretary is authorized to

(1) ****
(2) ****
(3) ****
(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products."

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.

Nothing in Parts 1301-1308, 1311, 1312, or 1316 of this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he desires to do such act nor shall compliance with such Parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

An agreement between the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) provides that in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA form FDA 484, RECEIPT FOR SAMPLES, in lieu of DEA form 400, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

FOR COLLECTION OF FOLLOW-UP SAMPLE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
60 8th Street, NE
Atlanta, GA 30309
404-253-1169

TO

2. NAME AND TITLE OF INDIVIDUAL
Mr Michael J. Mates, Quality Control Manager

3. DATE
02/27/03

4. FIRM NAME
ConAgra Grocery Products Co.

5. HOUR
10:38 a.m. / p.m.

6. NUMBER AND STREET
101 S. Seabrook Drive, P.O. Box 585

7. CITY AND STATE & ZIP CODE
Sylvester, Georgia 31791

8. PHONE # & AREA CODE
229-776-8811

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
B. Douglas Brogden

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
B. Douglas Brogden/Investigator

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**
Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories
and ******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

(f) "The Secretary may by regulation (1) require dealers and disbributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manuracturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manu- facturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election *(together with information identifying the notifier and the product)* to the manufacturer, and shall, when advised by the manufacturer or Secretary, of the need therefor for the pur- poses of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

Sec. 360 B.(a) It shall be unlawful-

(1) ***

(2) ***

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

***

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to *human beings*, and other measures, as in his judgement may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
60 8th Street, NE
Atlanta, Georgia 30309
404-253-1169

2. NAME AND TITLE OF INDIVIDUAL	3. DATE	4. SAMPLE NUMBER
Mr. Michael J. Matis, QC. Mgr	02/27/03	196062

5. FIRM NAME	6. FIRM'S DEA NUMBER	7. FDA'S DEA NUMBER
ConAgra Grocery Products Co	N/A	N/A

8. NUMBER AND STREET	9. CITY AND STATE (Include Zip Code)
101 South Seaboard Drive	Sylvester, GA 31791

10. SAMPLES COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374 (c)] and / or Part F, Sub Part 3, Section 356(b) of The Public Health Service Act [42 U.S.C. 263d] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)

Sample consists of 4/12-18oz cases totaling 48/18 oz jars of Peter Pan Crunchy peanut Butter, individual jars were labeled in part, "Peter Pan CRUNCHY PEANUT BUTTER NET WT 18OZ (1LB 2 OZ) 510g INGREDIENTS: ROASTED PEANUTS, SUGAR, PARTIALLY HYDROGENATED VEGETABLE OILS (COTTONSEED AND RAPESEED), SALT. ConAgra Foods P.O. Box 57078, IRVINE, CA 92619-7078, U.S.A. XXX S3021XXFA XXX Nutrition Facts XXX".

Cases were labeled in part, "XXX Hunt-Wesson Inc. Fullerton, CA 92834 U.S.A. XXX 12 PLASTIC JARS 12/18OZ 27000-45002 45300-29912 21113021OOP A CRUNCHY Peter Pan Peanut Butter XXX"

11. SAMPLES WERE	12. AMOUNT RECEIVED FOR SAMPLE	13. SIGNATURE (Person receiving payment for sample or person providing sample to FDA at no charge.)
☒ PROVIDED AT NO CHARGE ☐ PURCHASED ☐ BORROWED (To be returned)	N/C ☐ CASH ☐ BILLED ☐ VOUCHER ☐ CREDIT CARD	Michael Matis

14. COLLECTOR'S NAME (Print or Type)	15. COLLECTOR'S TITLE (Print or Type)	16. COLLECTOR'S SIGNATURE
B. Douglas Braden	Investigator	B. Douglas Braden

FORM FDA 484 (10/87) PREVIOUS EDITION MAY BE USED. RECEIPT FOR SAMPLES PAGE 1 OF 1 PAGES

Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Part F, Sub Part 3, Section 356(b) of The Public Health Service Act [42 U.S.C. 263d] is quoted in part below:

"Section 356(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-

(1) ****
(2) ****
(3) ****
(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products."

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.

Nothing in Parts 1301-1308, 1311, 1312, or 1316 of this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions, or protocols, or under the law of the State in which he desires to do such act nor shall compliance with such Parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

An agreement between the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) provides that in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA form FDA-484, RECEIPT FOR SAMPLES, in lieu of DEA form 400, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

ATTACHMENT B

Copy of Cited Articles

Food and Drug Administration

SECOND EDITION

Published June 2006

Volume 1
Chapters 1-20

James T. O'Reilly
Member of the Bar,
Virginia and Ohio

THOMSON
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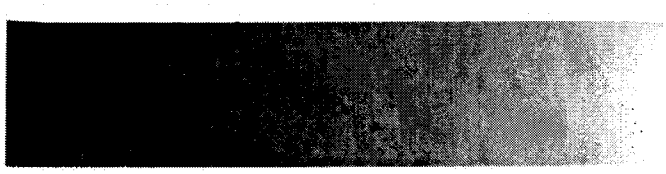

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§ 20:9 Inspection of records and documents

The Food and Drug Administration (FDA) does not have general authority to inspect all records of all firms subject to its control. The Food Drug & Cosmetic Act and the Public Health Service Act—the two statutory bases of FDA inspectional authority—are not complete grants of authority for the agency to examine records.[1] The Food Drug & Cosmetic Act delegations of inspection authority are granted as to "pertinent" items[2] and broader authority is given for prescription drugs, restricted medical devices, and infant formulas.[3] Records inspection is specifically authorized for those categories, but it is not unlimited power[4] and there is no corresponding reference for other products, such as drugs sold over the counter, cosmetics, food, food additives, or color additives.

Specific records authority exists for biological products under the biological establishment inspection powers of the Public Health Service Act.[5] The same statute empowers the FDA to include in its radiological products inspections the records of persons manufacturing or assembling such radiological products as X-rays and color television sets; however, the Act does not authorize inspections of the users of radiological products.[6]

Carriers of products regulated by the Act are required by § 703 to provide records of interstate shipment which the

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Winter Associates, Inc. v. Department of Health & Human Services, 497 F. Supp. 429 (D.D.C. 1980) (declaratory judgment denied to firm challenging inspection of clinical study records).

[Section 20:9]

[1]21 U.S.C.A. § 374; 42 U.S.C.A. §§ 262(c), 263i. Each statutory basis for inspection is subject to some limitations, explicit or implicit.

[2]21 U.S.C.A. § 374 grants authority "to inspect . . . all pertinent equipment, finished and unfinished materials; containers, and labeling" within the physical premises, as well as the premises themselves.

[3]21 U.S.C.A. §§ 374, 355, 360j(e), 350a.

[4]Matter of Medtronic, Inc., 500 F. Supp. 536 (D. Minn. 1980).

[5]42 U.S.C.A. § 262(c).

[6]21 U.S.C.A. § 360nn; *see* FDA, Investigation Operations Manual § 501.13 (1992).

FDA can copy.[7] If the records are not provided, the carrier may be penalized. If they are, the records cannot be used as evidence against the carrier in a prosecution by the FDA arising out of the transportation[8] of the goods. But this is a limited immunity for a limited class of persons.[9]

Apart from these directly inspectional authorities, the FDA also has certain substantive powers with ancillary inspectional provisions. Section 505 on new drug approval specifies that information required to be maintained as records of the new drug application (NDA) process shall be available to FDA inspectors to "copy and verify such records."[10] In the area of medical devices, Congress gave the FDA broad powers to require records to be kept and included the power to require firms to make reports and "provide such information as the Secretary may be regulation reasonably require" from the device firm.[11] This authority allows the FDA to specify what device information will be inspectable, based on its seeing a need for that information to assure the device's safety and effectiveness.[12] However, this authority depends on final regulations, and the FDA lost a dispute over restricted device inspections for lack of valid authority.[13]

The 1987 Prescription Drug Marketing Act also empowered the FDA to conduct extensive paperwork inspections regarding diversions of drug samples.[14] These are intense audits of the sales representative's activities to assure no diversion will occur.[15]

Apart from questions of strict statutory construction—and the statute would be construed strictly in favor of the defense in criminal prosecutions for refusal of records—is the broader

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[7]21 U.S.C.A. § 373.

[8]21 U.S.C.A. § 373 proviso; *see* U.S. v. Arnold's Pharmacy, Inc., 116 F. Supp. 310 (D.N.J. 1953).

[9]U.S. v. Gel Spice Co., Inc., 601 F. Supp. 1205 (E.D. N.Y. 1984).

[10]21 U.S.C.A. § 355(j)(2).

[11]21 U.S.C.A. § 360i.

[12]Matter of Medtronic, Inc., 500 F. Supp. 536 (D. Minn. 1980).

[13]Becton, Dickinson & Co v FDA, 448 F Supp 7 (NDNY), affd, 589 F2d 1175 (2d Cir 1978).

[14]21 U.S.C.A. § 353(d)(2)(C).

[15]FDA, Lipnicki, Summary of the FY-90 Drug Manufacturer PDMA Assignment (1989).

matter of statutory intent. Congress moved from the 1906 sample-collection power[16] into the 1938 inspectional power,[17] into the 1953 amendments,[18] and finally into the 1962[19] and 1976 grants[20] of specific records-inspection powers over prescription drugs and restricted devices. Congress chose not to expand the records power into records for foods,[21] or cosmetics,[22] or food or color additives, or most over-the-counter (OTC) drug[23] or unrestricted device categories.

The general construction of the Act to favor its health-protective goals tempts courts to construe inspectional provisions broadly; at the same time, however, a countervailing constitutional interest of the inspected firm opposes that inclination and favors an exclusive reading of the present Act.

Although the FDA lacks authority to demand certain records, its investigators are still instructed to ask for them.[24] However, a partial refusal or total refusal of inspection can only be charged where the FDA had clear statutory authority to demand that which was refused. FDA internal manu-

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[16]Act of June 30, 1906, ch 3915, § 4, 34 Stat 768.

[17]Act of June 25, 1938, ch 675, § 704, 52 Stat 1040.

[18]Act of Aug 7, 1953, ch 350, 67 Stat 476.

[19]Drug Amendments of 1962, Pub L No 87-781, § 201, 76 Stat 780.

[20]Medical Device Amendments of 1976, Pub L No 94-295, § 6, 90 Stat 539.

[21]Despite FDA's repeated desire that it do so, see HR Rep No 10358, 95th Cong, 1st Sess § 8 (1977); and Goodrich, *The Case for the Factory Inspection Amendment*, 17 Food Drug Cosm LJ 516 (1962). See the Food Good Manufacturing Practice (GMP) records inspection upheld, in National Confectioners Ass'n v. Califano, 569 F.2d 690 (D.C. Cir. 1978).

[22]Despite FDA's repeated desire that it do so. *See* Goodrich, *The Case for the Factory Inspection Amendment*, 17 Food Drug Cosm LJ 516 (1962); S 1681, 94th Cong, 1st Sess (1975); HR Rep No 1993, 95th Cong, 1st Sess (1977).

[23]FDA has also sought this authority for over-the-counter (OTC) drugs in S Rep No 2755, 95th Cong, 2d Sess § 175 (1978). As Goodrich, *The Case for the Factory Inspection Amendment*, 17 Food Drug Cosm LJ 516 (1962), noted in 1962, the burden remains on FDA to establish that any records request is "reasonable and within the scope of things relating to actual or potential violations of the Act," even if it falls within the inspection of records authority of the second sentence of § 704 or future expansions of that power.

[24]Swanson, *How to Handle an FDA Inspection—The Investigator's View*, 33 Food Drug Cosm LJ 109 (1978); *see* FDA Investigation Operations Manual § 501.1. (1992).

als admit that a records refusal will not be classed as a "refusal of inspection" where the agency lacked a clear statutory power of access to the requested record.[25] Counsel should be alert for end-run maneuvers; instead of prosecuting the firm for its refusal, the FDA is more likely to use broad boilerplate language including records inspection in ex parte requests for search warrants.[26] If the firm recognizes the ploy and moves to stay the execution of the warrant, it should simultaneously move to quash the overbroad warrant and to suppress any records obtained under the warrant for which the Act does not provide statutory access authority. A serious confrontation between firm and investigator over records access should be brought to the attention of the firm's counsel immediately so that a warrant defense strategy can be prepared.[27]

What is the value of records inspection over mere physical observation by the investigator? First, a firm's internal expressions about problems make damning evidence in any court case where a safety or efficacy problem is being prosecuted under the Act's standard of individual liability. If the violation is known to the firm and is not sufficiently corrected, the FDA could build its case upon the documentary admissions of the firm's officials.[28] As the criminal prosecu-

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[25]FDA Investigation Operations Manual ch 514 (1992), "It is not a 'refusal' for management to refuse to provide formula information, lists of shipments, codes, etc. except where the law specifically requires them to furnish this."

[26]*Compare* Becton, Dickinson & Co. v. Food and Drug Administration, 448 F. Supp. 776 (N.D. N.Y. 1978), order aff'd, 589 F.2d 1175 (2d Cir. 1978), in which the warrant's validity was questioned and subsequently the warrant was quashed, with a prosecution case for refusal which was thrown out by the court, United States v Iwen, No 77-CR-47, Food Drug Cosm L Rep (CCH) ¶ 38,119 (ED Wis 1977).

[27]In at least one case, after counsel encouraged the firm to refuse the inspection of an allegedly restricted device, the FDA responded by naming the counsel as an individual codefendant in an injunction action. United States v Sherwood Medical Indus, Civ No 77-0890-CV-W-2, pending (WD Mo 1977).

[28]Note that the FDA could not obtain those documents by subpoena since the agency lacks subpoena power, and would have to prepare a criminal case and get the Justice Department to arrange for grand jury subpoenas *duces tecum ad testificandum*.

tion in the *U.S. v. Park*,[29] case demonstrates, the existence of records may be a vital link between the criminal charge and the *responsible official* of the inspected firm. It is agency policy not to warn firms about the use to which records can be put in enforcement cases.[30]

The FDA's means of collection are important. Internal manuals warn FDA investigators that certain inspections "may require the obtaining of voluminous copies of records in order to document evidence of deviation. All of these become part of the government's case should it go to litigation."[31] Investigators are urged to produce "impressive" exhibits, and none are so impressive as written admissions of known breaches of regulations or product-specific approval requirements.[32] Records inspection is vital to many extensions of FDA enforcement efforts into new and stronger fields. The matter of records inspection deserves careful advance attention from regulated firms.

Special categories of records deserve special consideration. First, trade secrets and proprietary information, such as line speeds or product quantitative formulas, should be kept well out of reach unless the firm is aware of a statutory obligation to share them with the FDA (or unless the FDA has them already, e.g., in an NDA filing).[33] If the records of the trade secret are shared with the FDA, the record should be marked *confidential—trade secret*, the firm's counsel should be notified, and the inspector's notes should state that the

[29]U.S. v. Park, 499 F.2d 839 (4th Cir. 1974), judgment rev'd, 421 U.S. 658, 95 S. Ct. 1903, 44 L. Ed. 2d 489 (1975), involved letters to and from the grocery firm which Park headed regarding its sanitation problems, which were important, according to the Supreme Court, to the establishment of individual liability based on responsibility of the top official for the violation.

[30]Former FDA Acting Chief Counsel S. H. McNamara said after leaving FDA: "Don't expect the inspector to warn you that you need not provide something he asks for. A good inspector is like a good salesman; he will push . . .. It is not improper for him to ask. It is your responsibility to know the limits on an inspector's rights." McNamara, How to Survive an FDA Inspection, 10 Cosm Toiletries & Fragrances Assn Cosm J 3, 5 (1978).

[31]FDA Investigation Operations Manual ch 527 (1992).

[32]FDA Investigation Operations Manual ch 522 (1992).

[33]*See* Ch 22 for an extensive discussion of confidentiality.

particular information was claimed to be confidential.[34] As discussed elsewhere, the FDA's desire to take photographs should be uniformly opposed, as a matter of policy and right, so that visible secrets are not revealed.[35]

Secondly, medical privacy is an important value.[36] Medical records of patients should be protected wherever possible by deleting individual identifiers from files delivered to the agency. This was a primary issue of congressional concern in the medical device records section of the Act, and special rules apply to patient identity in device-related inspections.[37] Clinical practices inspections may seek access to the patient records, but the firm should hold the investigator to the promises of confidentiality expressed in the FDA's own documents.[38] In a rare case, patient identity records will be demanded because, in the words of the head of the FDA's clinical monitoring program: "Every now and then we run into a clinician who insists on testing an investigational new drug on fictitious patients; others are more daring, they prefer to use deceased patients, probably because they generally exhibit fewer adverse reactions to the drug and they don't usually bring malpractice suits."[39] The FDA has authority to examine the NDA records.[40]

In those cases, the patient identity goes to the central purpose of the inspection, and disclosure may be justifiable. However, patient privacy calls for caution in permitting records inspection of patient-identifiable records except in very unusual circumstances. These privacy considerations should

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[34]FDA Investigation Operations Manual § 516.1 (1992); *see* O'Keefe, *Legal Issues in Food Establishment Inspections*, 33 Food Drug Cosm LJ 121, 133 (1978).

[35]*See* § 20:4; and O'Keefe, *Legal Issues in Food Establishment Inspections*, 33 Food Drug Cosm LJ 129–30 (1978).

[36]U.S. v. Device More or Less Labeled Theramatic, 641 F.2d 1289 (9th Cir. 1981).

[37]21 U.S.C.A. § 360i(a)(4).

[38]Regulations on clinical practices will be found at 21 C.F.R. pts 52, 54.

[39]FDA, E. L. Brisson, FDA's Bioresearch Monitoring Program 3 (Dec 14, 1977) (Address to Food and Drug Law Institute 3).

[40]Leo Winter Associates, Inc. v. Department of Health & Human Services, 497 F. Supp. 429 (D.D.C. 1980).

not be jeopardized by allowing routine government access to sensitive medical information in patient files.[41]

A final set of records deserving special consideration are those relating to developmental, nonmarketed products. The FDA may penalize a firm indirectly for standing in defense of its rights to refuse records inspection.[42] Where a new product may someday be the subject of food additive petitions, but at the time of inspection is not yet subject to the FDA, the agency may threaten reprisals for noncooperation.[43] The indirect penalty is a future refusal to consider the results of the tests being conducted by the firm when they are submitted to the FDA some years or months after that inspection.[44] This may affect the persons who conducted the test or their institution and its testing review board. Legal decisions about developmental projects are close judgment calls, and merit special attention for their potential effects on the firm's future business.

Finally, as a practical matter, firms which submit to inspection of their records must decide whether to permit photocopying or to make inspectors hand copy the information. The Act is silent on this matter, and permission for copying without photocopying is literally unobjectionable as a compliance with § 505's *copying* rule.[45] Of course, since the FDA lacks subpoena power, its hand copies might be its only evidence, unless grand jury subpoenas are available. But the longer the investigator stays at the firm to hand copy records, the more likely the firm is to face problems

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[41]O'Reilly, *Medical Privacy and Medical Research*, 12 U Dayton L Rev 243 (1986).

[42]*See* Leo Winter Associates, Inc. v. Department of Health & Human Services, 497 F. Supp. 429 (D.D.C. 1980); Ross, FDA Inspections: The Limits of Authority, 8 Pharm Tech 58 (Mar 1984).

[43]Ross, FDA Inspections: The Limits of Authority, 8 Pharm Tech 58 (Mar 1984):

> We may not accept safety studies performed by a foreign laboratory in support of American products if that laboratory refuses to permit an inspection of its facilities. We believe that we must adopt this position in fairness to the domestic laboratories and to discourage any trends to shift the conduct of safety testing to overseas laboratories.

The major reprisal is disqualification, see 21 C.F.R. § 58.202(a), 43 Fed Reg 60019 (Dec 22, 1978).

[44]21 C.F.R. § 58.202(a).

[45]21 U.S.C.A. § 355(j)(2).

How to Handle an FDA Inspection— The Investigator's View

By JAMES W. SWANSON

Mr. Swanson Is a Food and Drug Administration Regional Director.

THERE YOU SIT in your office at the plant. It's nine o'clock and the morning hasn't gone too badly so far. Not too badly, that is, if you discount the fact that half the night clean-up crew didn't show up; one of the can lines went berserk, and presented all the empty cans to the filler upside down, and you already had a telephone call from a newspaper reporter regarding a consumer complaint of a railroad spike in a can of green beans.

But your moment of respite is short-lived as a call comes for you on the intercom: "Mr. Peterson there's a gentleman here to see you; he says his name is Swanson and he's from the Federal Food Company— What was that, sir? — Oh — Mr. Peterson he says it's the Federal Food and Drug Administration. He's here to make an inspection."

I assume for some of you, this is a rather familiar scenario. The reasons for your aggravation may be different; the type of plant may be different; and the names would be changed to protect the innocent; but, it's not at all an unfamiliar scene. The Mr. Peterson of our little tragedy is now allowed to slowly beat his head on the desk and moan, "Oh, why me? Why today? Oh why can't he come back next week after I have this place cleaned up?" Oh "Why me," indeed! That question, and the other two, can be answered by briefly describing a process and two policies of the Food and Drug Administration (FDA).

Planning an Inspection

The process leading to Mr. Peterson's dilemma began almost three years before that fateful day. The development of a schedule of work for the FDA field districts is preceded by an intricate process of long-range planning, priority setting, budget submissions, and resubmissions, and resubmissions; program development and refinement, resource allocations according to program priority, and, finally, the issuance to the districts of a fiscal year workplan that directs that certain work be done. We are not yet, however, to the point of having Mr. Peterson's plant selected for inspection. This is done in the field at the district level. Here, the bureau programs are translated from total numbers and man-hours by type of industry to lists of names of specific firms projected for coverage during that particular planning cycle.

Now, what would make a district supervisory investigator select Mr. Peterson's plant for inspection on this particular occasion? The answer is simple—"It depends." It depends on several factors.

(1) The main selection criteria involves potential for health risk to the public. If your firm is producing a product which could become a health hazard to the public if not properly processed, we will be much more likely to schedule you for an inspection. Given no other problem, we'll be around at least every year. Low Acid Canned Foods, for example, belong in this category.

(2) Secondly, we will be scheduling firms that have established a poor track record, firms with a history of borderline sanitary conditions, shaky quality control systems, or a series of consumer complaints. These will get our attention promptly and repeatedly until something changes.

(3) And, of course, there is subjective judgment also applied to this process. The supervisory investigators are aware of the general conditions in the various industries, such as: a rodent population explosion in a locality, insect invasions of fields of raw produce and the pesticides used to control them, weather conditions, or labor disputes. These can all affect the condition of your plant and products and we may well come to see how much.

(4) Lastly, firms that have a good track record generally, go on the back burner for a while. We'll get to you, but not very often.

So, to try to shorten up a long story, that's generally how we get a plant scheduled for inspection. But why today? Why, to quote Mr. Peterson, didn't we let him know we were coming? Well, that's where one of the policies comes in. It has been our policy as long

as I can remember, that unannounced inspections are the best procedure for us to follow. We have found that over the years, unannounced inspections give us a much truer picture of what is going on in a plant than if we had made an appointment two or three weeks in advance. We much prefer to observe the operation of a food plant as it would normally be on any day. Being somewhat suspicious by nature, we have a feeling that conditions might be somewhat altered if we made an appointment. Not that anyone in this room would find the need to make a change in their operations strictly because the FDA inspector was coming, but there are some who would.

Unspoken Rules

And that brings us to the other policy covering Mr. Peterson's question, "Why don't you come back next week when I have this place cleaned up?" The answer lies in one of our unspoken rules of planning the work. That is, try to inspect a firm when they are potentially at their worst. We like to get into warehouses after the cold weather has driven the rodents inside. We like to get into canning plants when they are glutted with an overwhelming flow of raw materials. We like to get into firms that have a potential for microbiological problems when it is boiling hot outside. This, I know, creates problems. The poor plant manager is beset with dragons on all sides and, lo and behold, comes another one to add to his woes. We know it is disruptive; we know it is inconvenient. However, it is highly probable that any time we make an inspection of one of your plants, you would consider it to be inconvenient. But, we maintain that if we find that you are able to produce a good product under good control under the worst of conditions, we can be much more confident that you can produce a good product when things are less hectic. Let's face it—we just don't get around that often, unless it is for some specific reason. And, since it is your responsibility to comply with the law, you should be able to do so, even under the worst of conditions.

Meeting the Investigator

Now we understand more about why the investigator is at Mr. Peterson's plant and now comes a rather critical part of the inspection. That is, meeting the investigator and getting started. There are several real good tips that I can give you which will insure that you have an amicable relationship with the investigator.

First, and probably the cardinal rule which you should not violate; keep him waiting, at least a half an hour, but be sure there is nothing to read in the waiting room except four-year-old issues of trade periodicals.

Item number two, give him a challenge. Make statements like "You'll not find anything wrong with our plant, why waste your time here?" Or, "My shop is in great shape—you really want to see my competitor six blocks down the street."

Invariable rule number three. Insist that a specific person accompany the investigator throughout the inspection and then: A) make sure that the person is not available for at least an hour; and B) that that person cannot answer any question unless he first checks with higher authority.

And, finally, be sure to discuss, in general terms of course, how much your firm pays in federal taxes, and relate that somehow to the investigator's salary.

Now that you have established a good relationship with the investigator, it is time for him to begin the regulatory inspection of your plant.

For those of you taking notes, I hasten to point out that the preceding was all tongue-in-check and was meant to convey a different message than the words actually stated. I have been an inspector a long time. Every one of these things has happened to me over and over again, and, frequently all together in the same plant. You do not have to welcome an investigator to your plant with open arms, but I advise you that it is probably unwise to make him feel that he is in enemy territory. The investigator is a real, live person. Depending upon the size of your plant and the experience he has had in your particular industry, he is probably as wary of you as you are of him. So, treat the investigator like a human being! You may even be rewarded by finding out that he is one.

Throughout the inspection, you'll notice one thing about our investigators—they ask a lot of questions. It's not that they are unknowledgeable about your industry—it's just the old forest and tree syndrome. After all, you live in that forest and you know where those trees are every day. Now, our people have been in many of the same kinds of forests but the trees are placed in different locations in each different forest they get into, even though the species remain the same. Therefore, in order to get an accurate lay of the land, they ask questions.

The Law and Company Policy

Some of these questions, and maybe all of them, will send you scurrying for your manual entitled "What to do when the investigator comes" (or words to that effect). In this manual, you'll find that many of the questions asked by the FDA investigator are listed as no-no's. The manual will tell you that the answers to these questions are not required by law and are certainly prohibited by company policy. Why in the world would a person be as presumptive as this investigator to ask such questions that fly in the face of both the law and company policy? Well, it's because we told him to. The investigator has a good number of questions that he is going to ask you; questions about your volume of business, amount of interstate commerce, product formulations, lists of consignees, code breakdown, and the like. Now, the majority of questions of this caliber are probably not in the category of those where the law requires an answer. However, you can expect that the investigator will ask the questions. If you wish, a polite refusal might be in order; but we would much prefer that you cooperate.

Photography

Photography is an entirely separate matter. It is our view, and it is our instruction to our investigators, that photography is part of an inspection and will be used if the investigator deems it necessary. Our people are told not to ask permission to take photographs in a plant. They are instructed to be equipped to do so, if the occasion arises during the inspection where photographs would be of value to the understanding of an inspection. Presently, if you as plant management object to the use of the camera in your plant, the investigator is supposed to reason with you over your objections to taking photographs. Such reasoning includes the philosophy that a picture is worth a thousand words: meaning that it is a much more accurate depiction of the condition than are the written words which will be used by the investigator to describe the same condition. You will have to recognize that the investigator is a fact finder. He reports what he sees and these reports are reviewed by others for decisions. The reviewers, obviously, have not been in your plant and must rely on the findings reported by the investigator. These, then, should be as factual and accurate as possible for the best understanding of the existing conditions. Photographs are very useful in understanding the facts.

If you still object after the reasoning process is over, the investigator might well point out a couple of recent court cases that have sustained the use of photography in inspections. If this doesn't turn the trick, the investigator is instructed to put his equipment away and continue with the inspection without use of the camera. He will, however, report this as a refusal in his report and, one of these days, we will wind up in court again on the issue of refusal to permit inspection, to see if we can not get this finally resolved. In the meantime, the investigator is instructed to use the camera where he thinks it is needed.

The Final Discussion

When the inspection is over and the time comes to sit down and have a critique of what occurred, we find that all too often the plant management feels that they have already spent enough time, and want to get the process over with as quickly as possible. This is a mistake. It is during the final discussion, after an inspection, when the issues can come out and be thoroughly understood by both parties, the management and the investigator. The investigator's job is to discuss with you his findings; to explain the comments that he has made on his observation sheet, the form FD 483, and to see to it that he is not misunderstood. Remember, he may not be familiar with your unique terminology and later you may be puzzled by a statement made on the 483.

This does not mean that you cannot disagree with the investigator's findings or his statements made about them. By all means, if you disagree, speak up. But as we instruct our investigators to be as tactful and courteous as possible, we would like to expect as much from you. I can recall being in a plant back east, many years ago, where, after carefully explaining to the plant manager an observation I had made, he started his response with: "Look, you dumb Swede, you really loused up on that!" These discussions are not easy. In fact, they are frequently difficult. After all, the plant manager is faced with someone who is being critical of his operation, and the investigator knows he is in a somewhat hostile environment as well. These are conditions that can rapidly create misunderstandings, sharp disagreements and animosity.

Although I cannot guarantee that an investigator will not lose his cool once in a while, they most certainly are instructed not to, and most certainly make every attempt to keep the situation under control. Disagreements will arise. Our people are instructed to listen to such

disagreements and, unless they are resolved on the spot, report them as part of their inspection report. Above all, our people are instructed not to get into arguments with the plant personnel over different perceptions of the same situation. This is, obviously, non-productive and does not serve to create a climate where the true facts can come out.

Conclusion

One last thought. Our investigators are trained to be just that, investigators. They are finders of fact and most of them are good at it. They are not, however, plant design and construction engineers. They are not vermin control experts. They are not process control experts. They are investigators. During the final discussion you have with them about their findings, they will recommend what they see needs to be done. They will not recommend how to do it. That is your responsibility. So, if Mr. Peterson is a bit frustrated by the fact that the investigator will not tell him how to keep railroad spikes out of the canned green beans, and will only stoically maintain that he should, we will all forgive him. **[The End]**

FALSE ADVERTISING CHARGED IN "NO HUNGER" BREAD SEIZURE

Alleging that advertising claims for "No Hunger" bread mix are illegal and grossly deceptive, U. S. marshals seized more than 20,000 cartons of the product in Cleveland on March 2. According to a complaint filed by the Food and Drug Administration, medical claims made in newspaper advertisements for the mail-order product are unsubstantiated by scientific evidence and are violative of both the food and drug sections of the Federal Food, Drug, and Cosmetic Act. The ads claim that the bread will aid in weight reduction, induce "regularity," and improve the circulation. However, the Agency stated, the bread is simply a form of whole wheat bread with added fruit oil.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 42,202

A Trade Association View of the FDA Food Inspection Programs

By LAURIE BURG

Ms. Burg Is Staff Counsel for Scientific Affairs at Grocery Manufacturers of America, Inc.

I HAVE BEEN ASKED to give you the "trade association" view of factory inspections. This is an interesting assignment considering that many may think the industry and associaton views are synonymous. Let me take a moment at the outset to explain what I believe the trade association view is, and to put the Grocery Manufacturers of America (GMA), and my role there, into perspective.

Trade associations are organizations of individual companies which seek to accomplish as a group what they find difficult or impossible to accomplish alone. What makes GMA a particularly interesting trade association is that its membership consists of the manufacturers of the entire range of products which are marketed through retail grocery outlets.

Since it is GMA's policy to involve a cross-section of the membership in the internal debate over public policy issues, the development of well-balanced positions is usually a nightmare for the GMA staff. But for the very same reason, once they are formed, GMA positions usually carry quite a bit of clout.

I believe trade associations perform a uniquely valuable service. We provide a middle ground between Washington's peculiar brand of reality and the reality of the food plant out in the tangible world. Most importantly, GMA's internal policy formation process serves to exclude extremist points of view and focuses our efforts on what is actually achievable.

It is from this unique middle ground that I will view factory inspections as a part of overall quality assurance.

GMA Technical Committee

To give you some idea of my frame of reference, my beat at GMA is regulatory rather than legislative and primarily involves working with the FDA. Although I work on a variety of corporate and legal matters other than food issues, I spend the bulk of my time serving as counsel to GMA's Technical Committee for Food Protection. This is a group of top notch technical people who are responsible at high management levels within their companies for product development, production, and quality assurance and control.

Because of their expertise, the GMA Technical Committee members have been active throughout the 1970s in developing and implementing high industry standards for quality assurance. Wherever possible, the Committee has encouraged self-regulation and enforcement in cooperative efforts with the FDA.

For example, GMA has published industry-wide Voluntary Recall Guidelines, Voluntary Transportation Guidelines, and Voluntary Sanitation Guidelines. The latter was implemented through a series of training seminars. GMA similarly supported the FDA's Cooperative Quality Assurance program with training workshops and educational materials.

The Technical Committee has also been involved with the FDA's development of good manufacturing practices. GMA's comments on the FDA's current proposal support the concept of good manufacturing practices (GMPs). But because the Technical Committee members deal regularly with factory inspections, they know that the GMPs must be refined. While the GMPs should set appropriate standards for quality control, they should not be needlessly detailed in areas which bear no direct relationship to product adulteration. Such details only serve to increase the already high level of misunderstanding between plant managers and inspectors.

One of the nicest things the Technical Committee does is help prepare its fledgling attorneys for talks before august bodies such as this. Today's panel presents me with an opportunity to communicate some of the membership's real life problems with the FDA inspections. In line with my trade association perspective, I will focus not on the extreme, but on the practical and the achievable.

Inspection Problems

I spent a great deal of time on the phone with Technical Committee members over the past few months, asking them about their experiences with the FDA inspections. Their complaints boiled down to a few basic reasonable problems. But in reflecting on their reactions, I couldn't help but think about the last time I was pulled over to the side of the road by a policeman for one of those random, road-block, on-the-spot automobile compliance checks.

I knew that the gentleman with the holster and badge was just doing his job, and that his purpose was to assure that my vehicle was not a public hazard. I also knew that he was perfectly entitled to peer into every part of my automobile. But no matter how reasonable I tried to feel, his mere presence made me immediately and irrationally defensive. When he whipped out a form and started writing, I became downright nervous. The fact that he had the power to take my car off the road made me resentful. To top it off, his authority to render me wheelless must have made him just a little bit overconfident.

This is the position the FDA inspectors and plant managers find themselves in as the inspection begins. Unfortunately, instead of recognizing this, both sides often react in a way which only makes matters worse. What is too often forgotten is that both the company and the FDA have precisely the same goal in mind: to assure the production of safe, wholesome food.

The fact is, America's food supply today is the safest, most wholesome and most abundant in the world. Naturally, industry has an economic incentive, aside from its obvious responsibility to consumers, to prevent product adulteration. A single production mishap could put billions of dollars' worth of product development and advertising on the line.

Inspection Process

But the inspection process is also a significant factor in maintaining the high quality of American food products. GMA members recognize this. And while I can't say they enjoy the FDA inspections, our members do admit that a thorough, professional inspection can be useful. A fresh, outside view can sometimes improve a company's existing self-inspection procedure or QA program.

The FDA could also benefit from the inspection process. GMA members are quite willing to help train new FDA inspectors. As one Technical Committee member said to me, "no one knows a food plant

better than someone who's been in it for twenty years." A well-trained inspection team ultimately serves both industry and the FDA in their common goal.

Since the FDA inspections are a fact of life, both the inspector and the industry representative should do their best not only to make the process as thorough and professional as possible, but also to benefit from it.

For its part, industry should accept the fact that the FDA will inspect their plants from time to time and should be prepared to cope with a certain amount of bureaucratic detail. Companies cannot reasonably expect all inspectors to be perfect. Some will be unreasonable, just as some plant managers will be unreasonable.

But it would be helpful if the FDA would recognize the initial confrontational tension between its inspectors and companies and modify its inspections policy to discourage behavior which only makes an uncomfortable situation worse. As matters stand, the FDA's Inspector Operations Manual trains inspectors not to be direct, but to actively seek information to which they are not clearly entitled. In doing so, the FDA places the burden of ensuring due process under a criminal statute on the party being inspected.

The plant manager responds by concentrating his efforts on catching the inspector in improprieties rather than on displaying his or her plant, which—after all—is the purpose of the inspection. With each additional request, the plant manager becomes increasingly defensive, which in turn makes the inspector more suspicious, and causes him to make additional requests. This atmosphere of mistrust accelerates throughout the inspection and usually results in a standoff. In the end, neither the FDA nor industry benefits.

What is worse, the entire process is recorded in infinite regulatory detail which both parties must then process through their respective bureaucracies. What is finally committed to paper becomes the subject of a Freedom of Information Act scramble which both the FDA and industry dread.

It is no wonder that the significance of plant inspections has been lost in the increasing mistrust between the parties. From my perspective as a trade association lawyer, it seems that a few basic policy changes on the FDA's part, along with some attitudinal adjustments on industry's part, could go a long way toward turning this trend around and making inspections more productive for all concerned.

In the remainder of my time, I would like to look briefly at five such areas where change would be constructive: records inspection, photographs, inspectional purpose, trade secret problems, and the Form 483.

Records Inspection

The battle over the inspection of industry records is an old one, the details of which I don't need to tell you. What makes it a bitter battle is the fact that the FDA is well aware of the fact that the Food, Drug, and Cosmetic Act does *not* authorize inspectors to see any company records other than those of inbound shipments.

Yet, the FDA inspectors routinely persist in seeking access to such vital company records as formula files, personnel files, complaint files, sales data files, and production volume files. In fact, the Inspector Operations Manual goes into great detail regarding the proper way to record information obtained from company records.

What is more, inspectors routinely request records access orally rather than in writing. By doing so, the FDA is obviously trying to avoid the protection provided by Section 703 of the Act which shields information obtained by written request from use in criminal prosecutions. As inspectors are carefully taught, the voluntary relinquishment of such information waives the statutory immunity.

By sanctioning such a policy, the FDA is tampering with the most basic due process guarantees. The fact that some companies permit access to their records is not sufficient justification for the infringement of the rights of companies which do not. The matter of records access is one of the few on which Congress has spoken plainly. GMA goes on record once again today asking the FDA to listen.

Photographs

The permissibility of photographs during inspections is not so clearly resolved. The FDA and industry each have their own interpretation of the *Acri*[1] case. It is crystal clear to the Agency that *Acri* authorizes the taking of photographs, while it is just as clear to industry that it does not. The matter has been repeatedly discussed in this and other forums, with most authorities concluding that the question will remain unresolved until it is further litigated.

Nonetheless, the FDA's Inspector Operations Manual sets out an elaborate and argumentative scheme designed to overcome industry

[1] *U. S. v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (D. C. Iowa 1976).

objections to photographs. The inspector is instructed not to ask permission to use a camera, but simply to use it. In the face of an objection from management, the inspector is to explain that photographs may be taken as part of an inspection and why they are necessary.

If management objects again, the inspector is to cite the *Acri* case. If the name of the case does not sway the company management, the inspector must then ". . . advise them that you will report this to your district as a refusal to permit part of the inspection." If this threat doesn't work, and "management is still adamant" in its refusal, the inspector is permitted to "put away the camera".

The FDA's policy on photographs is a prime example of the way in which the flames of mistrust between the regulators and the regulated industry are fanned. It would be unreasonable to expect that the FDA would not seek to take photographs pursuant to its own interpretation of the law. Company policy, in many cases, permits photographs.

But the elaborate argument set out in the Inspector Operations Manual will not instantly change the policy of a company which does *not* permit photographs. At best, it will intimidate an unknowledgeable individual into permitting them.

The issue of the permissibility of photographs cannot be resolved at the plant level. The FDA should therefore respect individual company policy once it is asserted and instruct its inspectors not to engage in legal arguments for which neither they nor the plant manager are qualified.

Inspectional Purpose

As one Technical Committee member told me, there are a hundred ways to walk through a food plant: you walk through one way if you're looking for the answer to a specific question, another way if you're looking at the overall operation, and an entirely different way if your tour is intended to train someone who knows nothing about your process. It would benefit both the company being inspected, and the FDA, if the inspector informed the plant manager when he arrives, if not before, of the specific purpose of his visit.

This is especially true when the inspector is responding to a complaint. The company is just as anxious as the FDA to rectify complaints, if not more so. Certainly the consequences are more serious for the company than for the Agency. The identification of the com-

plaint would enable the company to rectify it immediately without impairing the inspector's ability to conduct a full investigation if he chooses to do so.

Knowing the purpose of the visit is no less important when a new inspector is utilizing the inspection as a training exercise. In fact, both the FDA and the company could benefit from some advance notice. The company could then be sure that a knowledgeable individual is available to the inspection team to orient them to the product and process and to answer questions.

Questions are a crucially important part of education and should be encouraged whenever possible. But it is wasteful and unfair to occupy a busy plant official for several extra days during the course of a regular inspection answering detailed questions which are being asked for another purpose.

The Agency could benefit more by entering into an open, cooperative training program with industry. In fact, there are long term benefits in such an approach for all concerned. Companies are generally quite proud of their operations and are more than willing to show them off. The FDA should take advantage of this instead of backing the plant official into a training role and subjecting him at the same time to the rigors of a formal inspection.

Trade Secret Problems

It's no secret that the burdens engendered by the Freedom of Information Act (FOIA) far outweigh the Act's usefulness as a tool of public access to government. The FDA is forced to allocate a significant portion of its budget to filling these requests, while industry is forced by the FDA policy to make them.

It is not a secret that the food industry is extraordinarily sensitive to the release, under FOIA requests, of what it considers to be trade secret information. In an industry where complete ingredient labeling is required, the only proprietary information left to a company is the details of its manufacturing process. Industry and the Agency regularly clash on this issue. The FDA believes that most processes are basically the same, and that industry is overly sensitive.

It may be that the two sides will never see eye to eye on the definition of a real trade secret. But industry's sensitivity is really quite easy to accommodate.

One simple solution would be to provide a company with a copy of the Establishment Inspection Report (EIR) before it is permitted to be released to the general public. But whether or not the Agency adopts such a policy, it would be a simple matter to increase the level of inspectors' sensitivity to the issue. Inspectors should be encouraged to be aware of trade secret information during the inspection and they should be trained to include only clearly non-proprietary information. The inspector should also mark those portions of the EIR which, in his opinion, should be withheld from disclosure by the FOIA clerk.

At the very least, the FDA should not dismiss so casually a subject which it knows is of extreme importance to those it regulates.

Form 483s

The 483, or the "I observed", report is the statutorily mandated instrument which sums up the results of the inspection. It is used to list violations of Section 402A(3) and (4) of the Act. Because of the official nature and focus of the document, it generates a great deal of follow-up effort within the company and the FDA as well. The 483 should therefore be as specific as possible. We have a few suggestions along that line:

First, the inspector should keep a sense of perspective in listing violations. One 483 was recently returned to a member company with the notation that two dead rats were found in the plant. The 483 did not note, however, that the rats had been found in traps set for that purpose.

Second, the appropriate section of the Code of Federal Regulations should be included on the 483 wherever possible. This would help to refine the form to include only actual violations.

Third, if a violation has been corrected before the inspection concludes, the correction should be noted on the 483 along with the violation.

Finally, the inspector should familiarize him or herself with all special arrangements between the Agency and the company before conducting the inspection. In many cases, the 483s list conditions which are not actually violative because of special regulatory interpretations. But once something is listed on the 483, the company is required to battle the FDA bureaucracy in order to clarify the matter.

While none of these suggestions are particularly shocking, their implementation may go some distance toward improving the relationship between the inspectors and the inspected.

Summary

I would like to close with a rendition of what I feel, from the trade association perspective, are the facts of life.

Policemen will continue, as long as there are drivers, roads, and government, to pull drivers over to the side of the road. They will continue to peer into automobiles in ways that the drivers find unreasonable. The policeman is likely to continue the search until he has found something to write down on the forms his superiors require him to fill out. And, if policemen are lucky people, they will enjoy their jobs and make zealous efforts to perform their duties well.

And drivers? Well, they will listen to a lot of speeches by people who will tell them to relax about the whole thing. And if they know someone who knows the Chief of Police, they will try to get some insight into his public-minded motives in order to accept it all a little better. But no matter how sincere the purpose, drivers will in all probability continue not to like being pulled over very much. They will continue to bristle a bit during the process, and, in fact, the happier and more zealous the policeman, the more the drivers will bristle.

If the FDA and the regulated industry could take an honest look at this situation, and accommodate it with a few changes in their attitudes and approaches to inspections, I believe both sides could benefit more from the process.

Industry should not set company policies which prevent the FDA from obtaining information to which it is entitled. Plant personnel should be helpful to inspectors, should be open about displaying their production processes, and should share their expertise with new inspectors whenever possible.

The FDA should take another look at the way in which it trains inspectors to seek access to records and photographs and should respect company policy when it is in accordance with the law. Inspectors could be more open about what they are trying to accomplish during the inspection, and more sensitive to the issue of trade secret information and the workload created by Form 483.

But most importantly, individuals who work for the FDA and for the companies it regulates must bear in mind that they are not operating at cross-purposes, but rather are seeking to achieve a mutual goal. It is therefore important for both parties to eliminate attitudes and tactics which detract from the achievement of that goal. They should seek instead to encourage a positive, working relationship. **[The End]**

An FDA Inspection: Preparing for the Inevitable

By ARTHUR W. HANSEN

Mr. Hansen is Director of Consumer and Environmental Protection at the Del Monte Corporation.

IF YOU ARE IN THE FOOD BUSINESS, an FDA inspection is indeed inevitable. An FDA inspection should not be cause for alarm—provided you are properly prepared at all times. Prior preparation is the first key for assuring that you will come through an inspection successfully. The second key is response or follow through.

Only effective prior preparation and effective response can provide management with reasonable assurance that an FDA inspection will not result in legal action against the firm or its products. We must never forget that violations of the Federal Food, Drug, and Cosmetic Act (FDC Act) can undermine the reputation of a food company, causing a loss of consumer confidence and, subsequently, a loss of business. Preparation for an FDA inspection can be divided into two parts:

1. People Preparation
2. Facilities Preparation

People Preparation

People preparation must start with the highest level of management and proceed on through to the lowest level of management in a production facility. At the beginning, company management must decide what its basic policy will be toward an FDA inspection. Will it be a very strict policy of allowing an inspector only to inspect and to receive such information as mandated by the Food, Drug, and Cosmetic Act and its regulations? Will it be a policy of complete openness and cooperation to the point of allowing an inspector complete freedom to inspect and to receive any information he wants? Or will it be a policy somewhere between those two extremes?

I believe most companies have a policy that is somewhere between those extremes. Certainly each company must consider all of the facts

and decide what policy best serves their interests. There are people in industry who are tempted to give the inspector total freedom and to allow him access to any and all files and records in the belief that this will best protect them from getting into trouble with the FDA. Your legal counsel, however, will probably warn you that this approach may place your company in unnecessary jeopardy.

In my company, our policy is to maintain a cooperative and friendly attitude towards any inspector, and there are certain records and information which we give even though we are not legally required to do so. We also have limitations and, in all cases, we make every effort to clearly define what may or may not be freely given to an inspector.

This brings me to one of the most important principles—you must be certain that all employees who may be involved with an inspection know and fully understand whatever ground rules the company has established. Merely having them set forth in an instruction manual is not good enough. A plant manager should not have to consult a manual while an inspector is on his premises. This is awkward and burdensome to both parties. We have experienced difficulties where a plant manager didn't know and understand company policy. A continuous effort must be made to keep plant management fully informed about your company's current policies regarding FDA inspections. If you don't, you will soon find that through changes in personnel you will have someone who "didn't get the message". A strong training program is particularly important in a multi-plant operation to assure uniformity in the application of company policy.

We believe a company training program should stress that employees dealing with FDA inspections:

1. Know and understand company policy and ground rules.
2. Know his rights and responsibilities.
3. Know the inspector's rights and responsibilities.

We believe a plant manager with those three principles under his belt can best serve the interest of his company and the FDA.

Obviously a training program must impart a thorough knowledge of the regulatory requirements which must be adhered to in a food production plant such as the Good Manufacturing Practices regulations. In addition, the training program will include the more detailed and often more restrictive requirements set by the company, not merely to meet regulatory requirements, but to meet the standard of quality and performance established by the company for business reasons.

It may be interesting to note that we occasionally test the effectiveness of our training by putting on a mock inspection where the role of the FDA inspector is played by one of our own employees. The results have been most interesting. In one case, our own "FDA inspector" was so clever he obtained from an experienced plant manager several significant items of information not to be released according to company policy. I will not reveal his identity to the FDA!

Facilities Preparation

Now I would like to discuss the other kind of preparation—facilities preparation. This must really begin when a plant, a new production line, or a specific piece of equipment is designed. Preparation must continue through to the day-by-day, hour-by-hour operation of the plant, the production line, or the specific piece of equipment.

This is not the time or place to go into the details of engineering design. I do want to emphasize, however, the importance of having someone involved in the design stage who is thoroughly versed in plant sanitation requirements and capabilities. All good things to engineers, they often have other priorities in mind, and if someone with sanitation knowledge and experience isn't looking over their shoulders, you may get a plant or equipment with built-in regulatory problems.

Fortunately, we see an increasing use of stainless steel and other types of non-corrosive and easy to clean materials. We also see more use of built-in cleaning systems that make it possible for plant management to maintain a higher level of sanitation with fewer people and without serious loss of production time. You must constantly guard against the design of production lines and equipment with overhead structures and motors that could have been reduced or eliminated with the use of better design techniques. Such overhead structures are a common and very old source of product contamination and, consequently, regulatory problems.

The finest plant and equipment in the world won't operate and keep clean by itself. You must have a detailed program that will assure the production of safe, wholesome products in conformity with all regulations. What level of quality you want above that is up to your individual company. You must have a program which identifies and monitors all critical control points. You must also have an auditing program to assure your company that each facility is, in fact, functioning as you want it to function. You cannot put a good program in place and assume it will continue to function effectively. Your

programs for controlling processing safety, sanitation, and other aspects of your operation are run by people, and that is why you must have an ongoing training and auditing program.

I will describe some aspects of our procedure for managing FDA inspections, and then also discuss the vitally important response or follow through after an FDA inspection. I'm not saying our system is perfect, but it has been effective for us and is similar to many other companies' procedures.

The Plant Manager's Role

We have an FDA inspector accompanied at all times during an inspection by the plant manager or, if he is not available, then the assistant manager or the general foreman. We believe that the plant manager can provide the best assistance to an inspector because of his knowledge of the plant operations and the company. Also, the plant managers are responsible for the operation of the plant, and if there are any problems, he should be the first to know and is in the best position to institute any corrective action that may be necessary.

If an inspector wants records or information not allowed to be given by company policy, the plant manager so informs the inspector. If the inspector does not want to accept the refusal, our manager is not to argue with the inspector but simply tell him that he does not have authority to deviate from company policy. He may also tell him that if he puts his request in writing, it will be forwarded to higher management for a decision.

If it is an unusual or difficult request, it may be referred to our Corporate headquarters. In that case, I would receive the request and would recommend a response if necessary after consultation with the executive in charge of that area of our operations. Our managers are instructed that whenever practical, they should immediately correct any deficiencies noted by the inspector. At the conclusion of an inspection, the manager should carefully review the results of the inspection to insure there is no misinformation or misunderstanding in the inspector's report.

The plant manager then prepares his own report of the inspection, including what corrective action he has taken or plans to implement. This report, along with any documents left by the FDA, is sent in duplicate to my office in the Corporate headquarters. These reports are reviewed and one copy forwarded to the executive in charge along with any recommendations for further action that may be warranted. This represents the heart of our response procedure. Every inspection

report is reviewed by management at the division level and at the Corporate headquarters. This provides assurance that prompt and adequate corrective action is implemented.

When a letter is sent by FDA to the Corporate President, such as a Notice of Adverse Findings, I have been designated to respond for the President and to provide him a copy of the response. Such letters usually come long after the corrective action has been implemented. However, I always check again with the plant involved to be absolutely certain that what we tell FDA we have done is completely factual. If we disagree with any aspect of the inspection report covered by a letter from FDA, we also take that opportunity to explain our position.

In all our contacts with the FDA, we follow the principle that the fewer you have contacting the FDA, the better your communication will be. Obviously our plant management must deal directly with the FDA during an inspection, but beyond that point, virtually all liaison with the FDA is centered with me and one other individual in my department. By following this practice, we can always know precisely what business we have ongoing with the FDA and can be assured that it is being handled in complete accord with the corporation's best interest. This practice also provides the FDA with the most prompt and effective response possible from the corporation. Let me emphasize again in coping with an FDA inspection, there is no substitute for a prompt and effective response. If you doubt this, read the *Park* case!

Product Recall

Finally, I would like to briefly discuss what hopefully is not inevitable—a product recall. Being able to quickly and effectively recall a product may in some instances be necessary to protect public health and, perhaps, in all instances necessary to protect your company's health. Your Corporate officers bear the ultimate responsibility and could be subject to criminal prosecution if hazardous or illegal products are on the market place. The FDA has published guidelines covering three classes of recalls plus market withdrawals and stock recoveries. These are defined as follows:

Class I Recalls

A Class I Recall is a situation in which there is a reasonable probability that the use of or exposure to a violated product will cause serious adverse health consequences or death.

Class II Recalls

A Class II Recall is the situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse

health consequences or where the probability of serious adverse health consequences is remote.

Class III Recalls

A Class III Recall is the situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

Market Withdrawals

Market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, such as normal stock rotation practices, routine equipment adjustments and repairs, etc.

Stock Recovery

A stock recovery means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, such as the product which is located on premises owned by or under the control of the firm where no portion of the lot had been released for sale or use.

The FDA will determine the health hazards, if any, associated with products being recalled. They will also determine whether the recall is a Class I, II, or III. This will determine to a large degree how a company must proceed with a recall. Specifically, that will dictate the depth of a recall, that is, consumer level, retail level, or wholesale level. It will dictate what type of publicity is required and, finally, what kind of effectiveness checks will be necessary in the end.

No food company should operate without a recall plan. In fact, if you are a packer of low acid canned foods, you are required by regulation to have such a plan on file. This plan must be written and must be practiced until you are confident that your company has the ability to effectively recall a product should it ever be necessary. This is a situation that can't be "played by ear". You must have an effective plan ahead of any need and a designated staff to carry it out. Even then, the experience of many companies indicates that recall plans seldom function perfectly.

I would like to make one final point. If you do a first-class job of preparing for and responding to the inevitable—an FDA inspection —you will minimize the probability of having to conduct a product recall. This proves a point we sometimes are hard pressed to believe— the FDA's inspectional activities really are in our own best interest. I really believe that—but not all of the time. **[The End]**

The FDA Inspection: What You Need to Know to Protect Your Company

By STEPHEN H. McNAMARA

Mr. McNamara Is Vice President for Legal Affairs and General Counsel of the Cosmetic, Toiletry and Fragrance Association, Inc.

THIS PAPER DISCUSSES the Food and Drug Administration (FDA) inspection. It explains the extent of FDA's authority to conduct inspections of cosmetic and cosmetic drug manufacturers, and it also provides suggestions for manufacturers concerning how most effectively to cope with the FDA inspection.

FDA inspections have a serious regulatory purpose. The inspector comes, usually, to determine whether the inspected company is complying with the requirements of the Federal Food, Drug, and Cosmetic Act (FDC Act) and FDA regulations. He is *not* a "friend" who comes to "help". Your company must regard him as a policeman gathering evidence, evidence that ultimately may be used against the company. Almost every FDA-initiated recall, civil seizure action, injunction action, and criminal prosecution has as its basis data acquired by an FDA inspector during an inspection. Accordingly, it is critically important that you have a good understanding of FDA's rights and your company's rights during an inspection, and that you act accordingly to protect your company.

Every FDA-regulated company should have a standard operating procedure, a written plan, for coping with the FDA inspection. The plan should explain for affected personnel (1) FDA's rights, (2) the company's rights, and (3) company policies and practices to be followed during the FDA inspection. This paper is intended to help you to develop such a plan for your company, or to review

and refine your existing inspection procedures. A useful way to approach this subject is to discuss a hypothetical FDA inspection, from start to finish.

(1) Receiving the Inspector

Before beginning an inspection, the FDA inspector is required by the FDC Act to present credentials identifying himself and a written notice of inspection (Form FD-482) to the owner, operator, or agent in charge of the establishment to be inspected.[1] Your company's inspection plan should designate the person to receive and accompany the inspector. "Back-up" personnel should also be identified. These persons should be trained so that they understand thoroughly the extent of FDA's rights, your company's rights, and your company's policies with respect to the various matters likely to arise during an inspection.

Upon receiving the inspector, your company representative ("you", hereafter for convenience) should begin immediately to compile a comprehensive record of the inspection. This record should open with the notice of inspection provided by the inspector. Examine his credentials, to be certain they conform to the signature on the notice of inspection. Record the full name of each inspector. If, later, FDA should institute an enforcement action based upon the inspection, you will want to know the identity of each FDA inspector, for depositions or other pre-trial discovery.

(2) What About Insisting Upon a Warrant?

The FDC Act provides that FDA inspectors are authorized . . .

". . . to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and . . . to inspect . . ."[2]

The FDC Act makes no mention of requiring a warrant from a United States district judge or magistrate to authorize the inspection. Furthermore, the FDC Act provides that "refusal to permit entry or inspection" is a criminal offense.[3] Accordingly, most companies permit an FDA inspection without attempting to insist upon the presentation of a warrant.

However, in 1978 the United States Supreme Court, in *Marshall v. Barlow's, Inc.*, ruled that it is unconstitutional for inspectors of the

[1] §704(a) of the FDC Act, 21 U. S. C. 374(a).
[2] *Id.*
[3] § 301(f) of the FDC Act, 21 U. S. C. 331(f).

Occupational Safety and Health Administration (OSHA) to conduct an inspection without a warrant unless the inspected company consents to the inspection.[4] In this decision, the Supreme Court stated that "warrantless searches are generally unreasonable" and that "this rule applies to commercial premises as well as homes."

Nevertheless, the Supreme Court stated that warrantless inspections *are* permitted in the exceptional circumstance of certain "pervasively" or "closely" regulated industries "long subject to close supervision and inspection." The Court identified the "liquor" and "firearms" industries as examples of the exceptional industries in which warrantless inspections are permitted without the consent of an inspected firm.

FDA asserts that companies subject to regulation under the FDC Act come within the exception in *Marshall v. Barlow's, Inc.* permitting unconsented warrantless inspections of pervasively regulated industries, in that companies regulated under the FDC Act have long been subjected to close federal regulation. However, the United States district courts have ruled "both ways" on the issue of whether an unconsented and warrantless inspection under the FDC Act is constitutional in light of the *Barlow's* decision.[5] Since FDA can probably obtain an inspection warrant anyway, by telling a United States district judge or magistrate that the Agency has not inspected your company for a while and that they want to see what you're doing, most companies decide to permit an inspection without attempting to insist upon a warrant.

FDA does *not* routinely obtain a warrant before attempting to conduct an inspection. If an FDA inspector should arrive at your company armed with a warrant, this would be a most unusual and suspicious circumstance, requiring prompt and careful attention. If the warrant should provide for photographs, for access to manufacturing records, or for other FDA activity you otherwise would refuse to permit, it is especially important to react immediately; you may find it necessary to comply with the warrant until you can reach the official who issued the document.

(3) Before the Inspection Begins

Before the inspector begins his inspection, ask him why he is there and attempt to determine what he intends to review. It some-

[4] *Marshall v. Barlow's, Inc.*, 436 U.S. 307 (1978).

[5] Compare *United States v. Roux Laboratories, Inc.*, 456 F. Supp. 973 (D.C. M.D. Florida 1978) (ruling FDA may not conduct an inspection without a warrant if the company does not consent) with *United States v. New England Grocers Supply Co.*, 488 F. Supp. 230 (D.C. Mass. 1980) (ruling that neither a warrant nor consent was required for an FDA inspection of a grocery warehouse).

times happens, for example, that he is interested only in a particular subject, and that you can provide desired information without "opening the door" for him to wander generally through your establishment. In such a case, you may want to get the information for him and let him depart as quickly as possible.

Also, before allowing an inspection to commence, you should tell the inspector of your company's policies that will control the inspection. For example, you may want to tell the inspector that company policy prohibits taking cameras into the plant and that he must leave his camera in his car or in your office, that any questions or requests for information are to be directed only to you and not to other company employees, etc. (In sections (7)-(9) below, this paper reviews several such policies that you should consider adopting.)

(4) Conduct of the Inspection—FDA's Limited Rights

Suppose the inspector states that his purpose is to conduct a routine surveillance inspection of your establishment: What is the extent of his inspection authority?

The FDC Act provides FDA authority "to inspect, at *reasonable times* and within *reasonable limits* and in a *reasonable manner,* such factory, warehouse, establishment, or vehicle and all pertinent *equipment, finished and unfinished materials, containers,* and *labeling* therein." [Emphasis added.][6]

Note particularly what the Act does *not* state. It does *not* mention, for example, any FDA access to master formula records, batch production records, results of analyses, or complaint files. You are *not* required to show such records to the FDA inspector. (*Caveat:* The Act *does* authorize inspection of such records in the case of prescription drugs or restricted devices, but *not* in the case of cosmetics or non-prescription drugs.)[7]

Technically, the law does not require even that you talk to the inspector. However, when an inspector asks reasonable questions about the type of products you manufacture, your manufacturing procedures, etc., you probably will want to respond. After all, you may save yourself a lot of time. It is time out of your productive day during which you accompany an inspector. If he has to stand in your plant for two weeks to determine the kinds of products you manufacture, he may decide to do just that, when you could avoid such an extended FDA presence simply by answering reasonable questions.

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[6] § 704(a) of the FDC Act, 21 U. S. C. 374(a).

[7] *Id.*

(5) Taking of Samples

The FDC Act provides that the inspector is authorized to collect samples.[8] During an inspection FDA inspectors routinely take samples of finished and unfinished materials and of labeling, and companies generally permit the taking of *reasonable* samples of this type. The courts have recognized that this is an appropriate inspection function.[9] You may insist that the inspector pay for the fair value of samples taken, but most companies do not bother.

(6) "Holding" a Suspect Product

While he may take samples of materials in your establishment, the FDA inspector does *not* have the authority to detain or embargo materials that he believes to be in violation of the FDC Act. The inspector may request that you voluntarily hold a cosmetic or cosmetic drug that he believes to be adulterated or misbranded, but he cannot require that you do so.

"Seizure" of an article in your establishment pursuant to the FDC Act requires the institution of a civil proceeding in a United States district court. In general, before an article can be "seized" under the FDC Act, the following chain of events must occur: The FDA district office recommends to FDA headquarters that a civil seizure be instituted, and if FDA headquarters agrees, the FDA chief counsel writes to the local United States attorney, *requesting* the initiation of a civil seizure action. Assuming the United States attorney agrees (as he usually does), he files a complaint for forfeiture in the local United States district court, and then the United States marshall serves upon the article a "warrant for arrest". Service of this warrant upon the article accomplishes seizure. Thereafter, there will be a hearing before the court to determine, on the merits, whether the article is adulterated or misbranded and should be condemned as alleged by FDA. However, FDA may ask *state* health officials to detain goods until a federal civil seizure action is accomplished. State officials may exercise authority under state law to embargo goods pending FDA action.[10]

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[8] §§ 702(b), 704(c) and (d) of the FDC Act, 21 U. S. C. 372(b), 374(c) and (d).

[9] *United States v. 75 Cases . . . Peanut Butter*, 146 F. 2d 124 (CA-4, 1944), cert. den. 325 U. S. 856 (1945); *United States v. El Rancho Adolphus Products*, 140 F. Supp. 645 (D.C. M.D. Pa. 1956), affd. 243 F. 2d 367 (CA-3, 1957), cert. den. 353 U. S. 976 (1957); *United States v. Roux Laboratories, Inc., supra.*

[10] See, e.g., *United States v. An Article of Food . . . 345/50-Pound Bags*, 622 F. 2d 768, 769 nt. 1 (CA-5, 1980).

(7) Conduct of the Inspection—Protecting Your Company's Rights

Let's now consider several policies or procedures you can adopt to control the conduct of the FDA inspection, in order to protect your company's rights and interests:

• You should accompany the FDA inspector *at all times.* Do *not* allow him to proceed unattended by the company representative.

• Advise the inspector that any questions or requests for data are to be directed *only* to the company's designated representative.

The FDC Act authorizes only "reasonable" inspections, and, surely, it is not reasonable to permit someone who is not an employee to roam unattended through your establishment asking questions of whomever he pleases. Such activity could be disruptive of production and perhaps even dangerous to someone unfamiliar with your plan.

• Employees other than the company representative should be instructed not to speak to the inspector. They should not volunteer conversation, and if asked a question by the inspector, they should respond that it is company policy not to discuss their work with visitors and that any questions should be directed to the company representative designated to accompany the inspector.

• Keep a detailed record of *everything* the inspector says or does. This information may become important in the future, especially if FDA should undertake regulatory action based upon the inspection.

• Whenever the FDA inspector takes a sample of anything, you also should take a sample of the same article, to be maintained as a part of your company's record of the inspection. For example, if FDA samples a particular lot of finished product, or a particular label, you want to be certain that you have an identical companion sample in your records, readily available for reference if FDA subsequently asks questions or undertakes regulatory action.

• Do not sign or initial "affidavits" or other documents. FDA inspectors frequently enter information that they believe to be important on a form entitled "Affidavit" (Form FD-463a) and then ask a company representative to sign or initial the form, thereby acknowledging the accuracy of the statement. There is no obligation for you to sign or initial any such affidavit, and there is no good reason to do so. Any admissions in the statement could be used against your company in court.

Many companies have a standard policy that their employees are not authorized to sign or initial any documents for the FDA inspector.

If the inspector asks for written acknowledgment with respect to a particular matter, ask the inspector to submit a *written* request for the information to your company, for review and consideration by management and company counsel. In practice, this usually will be the end of the matter because FDA inspectors appear to be loath to request anything in writing.

• Corrections during the inspection. If the FDA inspector calls your attention to a violation of law that is easily correctable, most companies would try promptly to correct the situation during the course of the inspection.

• Do not volunteer information. It may be reasonable to provide certain information in response to questions from the inspector, but there is no reason to suggest new avenues of interest that otherwise might not be investigated.

• Always be honest in everything you say to the inspector. For example, it is one thing to tell an inspector that he has no statutory right to demand production of certain information, and to decline to provide it. It is a quite different matter to give the inspector a potentially devious, or dishonest, response. The former should be understood and respected. The latter just invites trouble.

• Finally, be polite. You may need to be firm in asserting your company policies or in protecting your rights in some other respect, but you should always remain courteous. Personal animosity cannot help you.

(8) Photographs

FDA asserts that it has the right to take photographs, and the inspector probably will argue with you if you tell him not to bring his camera into the plant. The FDA Inspection Operations Manual (IOM) includes a section instructing the inspector to insist that he has a right to take photographs, and to cite a particular judicial decision if a company refuses to permit photography.[11] However, a statement appearing earlier in the Manual, which the inspector is unlikely to mention, explains why FDA really wants those photographs: The IOM tells the inspector that "Good photographs are one of the most effective and useful forms of evidence of violations."[12]

The judicial decision that the inspector will cite to you if you refuse to permit photographs, *United States v. Acri Wholesale Grocery*

[11] FDA Inspection Operations Manual Sub Chapter 520, Section 523.1 "In-Plant Photographs" (TN 79-22; 10-19-79).

[12] FDA Inspection Operations Manual Sub Chapter 520, Section 523 "Photographs-Photocopies" (TN 79-22; 10-19-79).

Co., actually stands for the proposition that *if* a company permits FDA to take photographs without objection, the photographs may be used in evidence against the company in a judicial enforcement action such as a criminal prosecution.[18] Neither that case nor any other FDA case has penalized a company that refused to permit photographs during an FDA inspection.

It appears that most companies that are knowledgeable about their rights under the FDC Act do *not* permit photographs during an inspection. The Cosmetic, Toiletry and Fragrance Association (CTFA) commends that policy to its member companies. Photographs may overemphasize a particular detail in a misleading way, or may reveal trade secret manufacturing procedures that you do not want to release outside of your control. If you are firm about it, the FDA inspector will put away his camera and proceed with the inspection.

(9) Access to Company Records—Generally

You are *not* required to provide access to manufacturing records (master formula records, batch production records, analytical data, complaint files, etc.). The FDA inspector may make repeated efforts to examine and copy such records, but (unless, as discussed in Section (4) above, the records concern prescription drugs or restricted devices) he is *not* entitled to require you to let him see or copy any of your manufacturing records.

There is, however, a "middle ground" approach you may wish to consider for responding to requests for such records. If, for example, the FDA inspector states that he wants to see your master formula records and batch production records to verify that you include in your products the ingredients listed on the labels, you may elect to follow a selective "look but don't copy" policy. That is, in order that he may verify that your company does put the ingredients in its products that it lists on the labels, you may want to let the inspector very briefly see a few pertinent records from your files, but *not* permit him to copy the information. This approach has the advantage of allowing the inspector to confirm that you follow appropriate procedures in a responsible manner, without releasing from your control documents that may include trade secret information.

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[18] *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (D.C. S.D. Iowa 1976).

(10) Shipping Records

There is a limited exception to the general rule that FDA is not entitled to require production of manufacturing records for cosmetics and non-prescription drug products: The FDC Act provides that persons receiving FDA-regulated articles in interstate commerce or holding such articles so received, shall, upon *written* request, permit the FDA inspector . . .

"at reasonable times, to have access to and to copy all records *showing the movement in interstate commerce* of any food, drug, device, or cosmetic, *or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof.*" [Emphasis added.][14]

Accordingly, if FDA so requests *in writing,* you must provide access to records concerning interstate shipment.

However, the Act provides that evidence obtained in this manner may not be used against you in a criminal prosecution (although it may be used in a civil seizure action or injunction). If the inspector does request such information, it is important that you insist that the request be made in writing before providing the documents, so that you assure yourself of the protection afforded by the statute with respect to any resulting criminal prosecution.

(11) FDA Inspection Tactics re Company Records

Be especially alert with respect to FDA inspection tactics concerning company records. When faced with a refusal by a cosmetic manufacturer to provide manufacturing records, on the grounds that FDA is not entitled to demand production of such records for cosmetic products, FDA inspectors have been reported to shift tactics and to assert that a particular product is a *drug* and that they want to see the manufacturing records for the designated product.

It is extremely important for you to remember that, insofar as FDA's rights to demand involuntary production of your manufacturing records are concerned, the distinction between "cosmetic" and non-prescription "drug" is a distinction without a difference.[15] Generally, FDA does *not* have the right to compel production of manufacturing records *either* for a cosmetic *or* for a non-prescription drug.

You may need to be especially careful to protect yourself here. FDA's *drug* Good Manufacturing Practices (GMP) regulations have

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[14] § 703 of the FDC Act, 21 U. S. C. 373.

[15] In many *other* respects the distinction *is* significant. See, e.g., McNamara "When Is a Cosmetic Also a Drug—What You Need to Know, and Why", 35 CCH Food Drug Cosmetic Law Journal 467 (August 1980).

been written in a misleading manner to suggest to the unwary reader that he has an obligation to permit inspection and copying of manufacturing records for all drug products. Indeed, the drug GMP regulations state as follows:

"All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred."[16]

Be careful!! The "key" word in this regulation is "authorized". FDA is *not* "authorized" to require production of manufacturing records for non-prescription drugs. Indeed, FDA's *preamble* to the drug GMP regulations explicitly concedes as much. In the preamble, the FDA Commissioner states that "Congress did not include in the scope of the inspection authority . . . authority to inspect records regarding the manufacture of OTC ("over-the-counter" or non-prescription) drug products . . ."[17] Furthermore, FDA's Inspection Operations Manual tells the same story: "In general Section 704 of the Act [i.e., the section of the FDC Act authorizing FDA inspections] does not provide mandatory access to: Formula files . . . Complaint files."[18] Don't be fooled by an inspector's assertion of "drug" status! Remember, you must know your rights to be protected. When the FDA inspector asks for such records, he does not advise you that you are not required to provide them.

(12) The "Exit Interview"

At the completion of the inspection, the FDA inspector will meet with the "owner, operator, or agent in charge". At this time, the FDA inspector provides an FDA form entitled "Inspectional Observations" (Form FD-483), listing observations the inspector believes are violations.[19]

It is prudent to discuss with the inspector this list of observations. If you do not understand an item, ask about it. If you do not agree with a particular observation, explain your position. If you have cor-

[16] 21 CFR 211.180(c).

[17] 43 *F. R.* 45066 (September 29, 1978).

[18] FDA Inspection Operations Manual Sub Chapter 500, Section 501.1 "Authority to Enter and Inspect" (TN 79-22; 10-19-79).

[19] § 704(b) of the FDC Act, 21 U.S.C. 374(b), provides that "Upon completion of any such inspection . . . and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

usually will destroy any notes he may have made during the inspection. The EIR thus becomes FDA's primary record of the inspector's visit to your firm, and it will be reviewed by FDA compliance officers looking for violations of law. (If product samples were taken, they may be examined in an FDA laboratory. Also, labeling taken by the inspector may be examined at FDA offices.)

You will, of course, be interested to know what the inspector has said about your establishment in his EIR, and you may obtain a copy of the EIR when FDA has closed its file on your inspection.[20] If FDA refuses to release a copy of the EIR concerning your inspection, the Agency still has an "open" file on the matter, i.e, the Agency is still considering whether to institute some form of regulatory action.

One reason to request a copy of the EIR is that EIRs are subject to release under the Freedom of Information Act to any member of the public, including your competitors. Accordingly, you may want to review the EIR to determine whether FDA has inadvertently failed to purge the document of trade secret information before release. If you find FDA releasing an EIR that reveals trade secret information concerning your establishment, you should object to the Agency immediately.

(15) FDA Analyses

If FDA performs analytical work on a sample of an ingredient or finished product taken during the inspection, you are entitled to a copy of the results of analysis upon request.[21] Note that you should be able to obtain such reports of analyses without waiting until FDA "closes the file" concerning the inspection.[22] Thus you may be able to obtain analytical results before you can obtain the EIR. (If FDA performs analytical work, you generally can also obtain from FDA a portion of the sample subjected to analysis, so that you may perform analytical work on the same sample tested by FDA.)[23]

(16) Conclusion

If FDA should conclude that an inspection has revealed significant violations of the FDC Act or of FDA regulations, the Agency may initiate regulatory action (e.g., request a recall, recommend a civil seizure action, etc.). It is precisely because of the serious enforcement actions that can arise out of an inspection that it is so important

[20] 21 CFR 20.64, 20.101.
[21] 21 CFR 20.105(c).
[22] *Id.*
[23] § 702(b) of the FDC Act, 21 U. S. C. 372 (b); 21 CFR 2.10(c).

rected an observation during the course of the inspection, tell the inspector. Ask the inspector to make any appropriate changes in the list of observations at this time. Also, if you intend to correct certain observations, explain this. Even if the inspector does not amend his list of observations, he should include your comments in his report of the inspection (the Establishment Inspection Report (EIR), discussed in Section (14) below). Such comments may affect the way he and his superiors at FDA evaluate the inspection. You want to satisfy FDA that you are taking all reasonable steps to manufacture safe and accurately labeled products.

Also during the exit interview, the FDA inspector will provide a "Receipt for Samples" (Form FD-484) for all samples taken during the course of the inspection (unless he has already provided such documentation when the samples were taken). At this time you should confirm that you have taken companion samples of all articles sampled by the inspector.

• *Caveat:* If during an exit interview you promise the inspector to make certain corrections, be certain to do as you have promised. The next time an FDA inspector visits your plant, he will determine and report whether promised corrections have been made.

(13) After the Inspection

Promptly after the inspection, appropriate company personnel should meet to discuss the inspection. Was your company in compliance with the requirements of law? If not, what corrective steps should be taken? Were the inspector's "Inspectional Observations" accurate? If you disagreed with the inspector's observations during the exit interview, did he make appropriate changes in his observations? If the inspector noted violations, were they of such significance that some type of follow-up regulatory action might be expected from the Agency? Who in corporate management should be advised of the inspection and its outcome? Depending upon the nature of the "Inspectional Observations" and the exit interview, after the inspection you may want to send FDA a written response to the observations, thereby making certain that the FDA record includes a considered statement of your views.

(14) The "EIR"

After departing, the FDA inspector returns to his resident post or to the FDA district office and prepares a detailed Establishment Inspection Report (EIR). After the EIR is completed, the inspector

for you to understand and to exercise you rights during an inspection, and to keep detailed records of each inspection.

Never forget the potentially serious nature of any FDA inspection. In order to protect your company's rights and interests, you should establish standard operating procedures for your company for the conduct of FDA inspections, and affected company personnel should be thoroughly trained to follow these procedures. This paper should help you to provide an effective inspection plan for your company.

[The End]

CHANGES IN INSPECTION RULES FOR NONCLINICAL STUDIES SOUGHT

The quality assurance inspection system required by the good laboratory practice regulations for nonclinical laboratory studies is inefficient and excessive, according to the Pharmaceutical Manufacturers Association. In a recent petition submitted to the Food and Drug Administration, the nonprofit group urged that routine operations be excluded from study-specific inspections, provided that the operations are inspected on a regular basis by a quality assurance unit.

Rigidly scheduled inspections of routine and repetitive operations are excessively time-consuming and burdensome, PMA argued, and the adherence to detailed standard operating procedures coupled with adequate personnel training and review of documentation obviate the need for many routine inspections. A PMA poll of firms revealed that only a very small percentage of inspections resulted in significant findings.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 41,004

TEMAZEPAM ADDED TO CONTROLLED SUBSTANCES SCHEDULE IV

Based on the recommendation of the Secretary of Health and Human Services, the Drug Enforcement Administration has placed the controlled substance tempazepam in Schedule IV. According to DEA, temazepam has a currently accepted medical use in treatment in the U. S., and the drug has a lower potential for abuse than do drugs listed in Schedule III. The proposed placement of temazepam in Schedule IV was supported by the American Society of Hospital Pharmacists.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 40,993 and 80,864
