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SUMMARY

This complaint/recall inspection of Chobani Idaho Inc. manufacturing ninety two various flavor and container sizes of Greek Yogurt products was conducted by an ad hoc FACTS assignment #8718055. There had not been a previous inspection conducted by FDA as the plant had initiated operations in November of 2012. Production processes were discussed and review of the corrective measures taken by the firm to correct the causes of the complaints and the recall were completed. This firm is licensed and routinely inspected by the Idaho State Department of Agriculture Bureau of Dairying (ISDA).

At the start of this inspection the firm was producing various Greek Yogurt flavors on lines #(b) (4) (b) (4) Equipment utilized for the processing and packaging of all products was evaluated. Credentials were presented and Form FDA 482 was issued to Mr. Mark J. Flagg, Director of Operations, on September 05, 2013 and to Mr. Hector Yzquierdo, Director of Manufacturing, (Mr. Yzquierdo does not have a middle initial) on September 16, 2013 the most responsible individual at

the plant on those days of the investigation/inspection. Mr. Mike Wiggs and Ms. Brook Legineche of ISDA were also involved in accompanying this investigation/inspection.

An exit interview was conducted on 09/18/2013 with Mr. Yzquierdo, Mr. Flagg, (b)(6),(b)(7)(C) (b)(6),(b)(7)(C), Assistant Quality Control Manager, and Mr. Halil Ulukaya, Chief Manufacturing Officer, (Mr. Ulukaya does not have a middle initial) representing Chobani, and with Ms. Legineche representing ISDA. This inspection found minor GMP deficiencies and a Form FDA 483 was not issued. A recap of the information utilized in the record review of the complaint/recall corrections along with observations in the processing area was discussed. Mr. Flagg indicated that corrections would be made as quickly as possible. No samples were collected and no refusals were encountered.

ADMINISTRATIVE DATA

Inspected firm:	Chobani Idaho
Location:	3450 Kimberly Rd Twin Falls, ID 83301
Phone:	(208) 732-1700
FAX:	No Fax number available
Mailing address:	Same as location
Dates of inspection:	9/5/2013, 9/6/2013, 9/16/2013, 9/17/2013, 9/18/2013
Days in the facility:	5
Participants:	Lester O. Boian, Regional Milk Specialist John W. Banks, Investigator

HISTORY

Chobani Idaho Inc. was incorporated in the state of Idaho early in 2012. It is a subsidiary of Chobani, which has its corporate office at, 147 State Highway 320 Norwich, New York 13815. Chobani Idaho Inc. has a sister plant, Chobani New York Plant 669 County Road 25 New Berlin, New York 13411. The firm has not had a previous FDA inspection and is not under a current injunction or any warning letter correspondence from the state of Idaho or FDA. Leading up to this inspection, on August 30, 2013 Chobani had initiated a "market withdrawal" of the products from Chobani Idaho Inc. production from all the warehouse and retail establishments they supply because of product quality issues. Chobani was able to contact and remove product from ninety five percent (95%) of all the distributers and retailers of their products. With concern of the general public holding product, Chobani voluntarily issued a nationwide recall of all Chobani yogurt products produced in Chobani Idaho Inc. plant with best buy code dates from September 11, 2013 to October 07, 2013. This recall created the need for this current assignment to investigate the activities Chobani Idaho Inc. is utilizing to address the issues with their production.

INTERSTATE COMMERCE

Chobani Idaho Inc. production is approximately (b)(4)% interstate commerce. In general the product is moved from the firm's finished product cooler storage and is transported to a distributer's cooler storage, two of the larger customers are (b) (4) . Chobani Idaho Inc. does not control any of the sales operation as sales are conducted from the Corporate Office Sales Group and the firm does not have records of the distribution or to the companies the product is supplied.

JURISDICTION

Chobani Idaho Inc. manufactures Greek Yogurt only, with the exception of selling raw or pasteurized cream, in variety of flavors and flavor combinations all with the Chobani label. (See Exhibit #1) No labels were collected.

These products are all under the Grade A Interstate Milk Shippers (IMS) program and are routinely inspected by Idaho State Department of Agriculture Dairy Bureau every three (3) months and the pasteurization equipment is evaluated every three (3) months with timing of the pasteurizers every six (6) months. The FDA standardized State Rating Officer completes a IMS listing rating of the firm every two (2) years and the FDA Regional Milk Specialist will complete a Federal check rating every three (3) years.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Plant Personnel: Mark J. Flagg – Director of Operations

Mr. Flagg is responsible for all phases of the operation of the plant. All departments report to him and would make all he final decisions on day to day operations. He is the individual that would report directly to corporate on issues with the plant.

Hector Yzquierdo – Director of Manufacturing

Mr. Yzquierdo is the second in command to Mr. Flagg and has his responsibilities when Mr. Flagg is not at the plant.

Kristy M. Kliedl – Quality Control Manager

(b)(6),(b)(7)(C) - Assistant Quality Control Manager

(b)(6),(b)(7)(C) – C.C. Processing

These plant personnel were available for the inspection and supplied the records and other information requested. These personnel can be reached through the plant address and telephone number.

The plant personnel had to establish permission from the corporate office to allow review of records at the firm. Though permission was granted for the review of information, only a very few pieces of information were allowed to be copied and removed from the firm. Chobani Corporate was not willing to allow the information out of their control with concerns of the Freedom of Information Act.

Corporate personnel: Halil Ulukaya – Chief Manufacturing Officer
669 Country Road 25
New Berlin, New York 13411

Mr. Ulukaya has the corporate level responsibility over the Chobani Idaho Inc. plant and the Chobani New York plant manufacturing and is the direct connection for Mr. Flagg to Chobani Inc. Corporation.

Laura M. Zervic – Assistant General Counsel, Branding and Regulatory Affairs
Chobani Global Holdings
147 State Highway 320
Norwich, New York 13815

Ms. Zervic is the liaison to the Seattle District office in the developing of the national recall and the follow up of any actions for the recall.

Catherine A. King – General Counsel
147 State Highway 320
Norwich, New York 13815

MANUFACTURING/DESIGN OPERATIONS

Chobani Idaho Inc. produces only Greek yogurt in a variety of flavors and package sizes. See exhibit #1 for a listing of the flavors and sizes produced.

The firm receives approximately (b) (4) ((b) (4)) pounds of raw milk per day directly from grade "A" IMS listed dairy farms in Idaho. Fruit and fruit flavoring is received from (b) (4) (b) (4) . (These companies were supplied verbally and the addresses were not given.) Each of these companies can supply any of the fruit and/or fruit flavors for Chobani Greek Yogurt products and are received at the plant in aseptic filled (b) (4) containers (totes) accompanied by a Certificate of Analysis (COA) indicating aseptic processing and filling of the fruit or fruit flavors. Both Chobani Idaho Inc. and Chobani New York Plant receive their fruit and fruit flavoring supplies from these companies in this manner.

Yogurt production process: Raw milk is separated (b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)

(b) (4) . The yogurt is then streamed to the fillers and from the fillers to the caser and palletizer. Once palletized the yogurt is (b) (4) chilled for (b) (4) depending upon the packaging. Most yogurt cups will be in the (b) (4) for (b) (4) . (b) (4) the pallets are moved to the finished product cooler until transported.

Cream process: The cream from the milk separators is pumped to the raw cream storage tanks. Cream can either be pasteurized and sold as pasteurized cream or sold as raw or heat treated cream. Cream can be (b) (4) (b) (4) .

Primary Equipment: (Number of units – Description)

(b) - Milk High Temperature Short Time (HTST) pasteurization units (Including (b) (4))
(b) (4) – Cream HTST unit
(b) (– Cold milk separator
(b) - Raw cream silos
(b) (– Pasteurized cream tanks
(b) (4) - Yogurt separators
(b) (4 – Maturation tanks
(b) (– (b) (4) tanks (b) (4))
(b) (4 – (b) (4) blending systems
(b) (4) – Fillers (b) (4) ps)
(b) (4) raw milk silos

Chobani Idaho Inc. is still in the construction stages and will be adding additional equipment as they commission additional product lines

MANUFACTURING CODES

Chobani Idaho Inc. has a best buy date of sixty (60) days from the date of production on all of their Greek yogurt products. Ink jet coding can be found on the lid, foil seal or the side of the container. Coding is in two lines with the first line containing: Product name, Best buy date (day/month). The second line contains: (b) (4) (b) (4) (#16-012).

COMPLAINTS

This inspection of Chobani Idaho Inc. is an ad hoc FACTS assignment #8718055 directly related to the national recall on September 05, 2013 issued by Choban. The objective in this assignment was to review the causes creating the need for the recall, installations of corrections made, on-going

procedures to maintain corrections, if the scope of the recall is sufficient, and product testing utilized by the firm.

In July the routine Grade A sampling and testing samples taken by the Idaho Department of Agriculture (ISDA) from the Chobani Idaho Inc. production were visually noted, by the laboratory technician, that surface defects were present and additional testing was conducted noting a yeast like growth developing in the yogurt samples. ISDA followed-up with Chobani Idaho Inc. and the firm reviewed their keeping quality samples and found some samples beginning to show signs of swelling. The firm at this point believed it was a yeast problem and began an equipment cleaning regimentation but found the problem was being reduced but not stopped, so samples were sent (b) (4) (b) (4) , where a mold growth of Mucor *circinelloides* was plated.

The firm then began a complete cleaning of the entire production facility starting with the air supply replacing all hepa filters, cleaning all of the filter banks and duct work throughout the facility. Each production room was cleaned from the ceiling to the floor including all the outside surfaces of equipment and the floor drains. Processing equipment was cleaned in place (CIP) cleaned then disassembled and checked for cleanliness, visual and swabbing. If not clean, the equipment was hand cleaned and the CIP cycle adjusted, then the equipment was reassembled and CIP cleaned again. The cleaning process began with the raw side of production and progressed through the packaging and cooling areas. In an e-mail from (b) (4) technician, to Mr. Flagg on March 08, 2013, (b) (4) had found (b) (4) that were not yet in use, within the (b) (4) area.

All of the valves in the (b) (4) in the area were completely dismantled and thoroughly cleaned, then reassembled and CIP cycles were evaluated and changed as needed. All (b) (4) (b) (4) were completely commissioned for CIP so all (b) (4) are included in the CIP cleaning cycles. These (b) (4) are important in the product flow as (b) (4) (b) (4) . With this clean-up and change in the system, the firm felt they were ready to continue full production in the facility on 08/12/2013.

The Idaho State Department of Agriculture (ISDA) continues to monitor the firm's production and will be completing the IMS routine inspection of the facility which includes disassembling and inspecting equipment for cleanliness. The routine three month pasteurization equipment evaluation and testing will be completed by ISDA in September and October as they come due for testing.

Records were reviewed on the cleaning regimentation of the firm. Title of records was "Action Items for Corrections". The records were by department and contained the item to be cleaned and inspected, person responsible for the activity completion, completion date and the status of the item; whether completed, needing continuous monitoring, or etc. Records demonstrated an exacting coverage of the equipment and facility, with some of the items being on a continuous monitoring to make sure the item continued to properly clean. Cleaning records from 8/12/2013 to 8/20/2013 were carefully analyzed for any deviations from the protocol and all the records were found satisfactory.

CIP charts were reviewed and though there were a few anomalies found in the charts; length of time, temperature, flow and chemical conductivity were established on each CIP chart reviewed to meet the requirement of the equipment cleaned.

Chobani Idaho Inc. requested assistance form outside companies as they began the thorough cleaning of the facility. (b) (4), was requested to have all of the construction personnel enter the building as the production workers are required, dressing in plant clothing and boots, going through the hand sanitation, and utilizing hair covering. All other entrances into the facility except the main entrance were closed. (b) (4) (b) (4) the firm's chemical provider, with help from (b) (4) the equipment installer, was requested to evaluated the flow volumes, chemical strengths, length of CIP cycles and other values of the CIP systems to improve the overall CIP cleaning of the production system. There were still (b) (4) technicians at the firm at the close out of the Investigation/Inspection maintaining a review of the cleaning cycles for improvements.

The firm routinely does sampling and testing of all the production lines every (b) (4) pulling (b) (4) samples to conduct coliform tests, and (b) (4) stress tests. Samples are identified as to production line, time the sample was take. Coliform testing has been changed (b) (4) (b) (4). Any positive result on coliform creates a hold on that lot of product. A review of the lot proceeds for (b) (4) (b) (4) hours by the Quality Control management and release or destruction of the product is decided upon by the Quality Control Manager.

The stress testing is completed by (b) (4) (b) (4). At the end of the periods each sample is checked for container condition, product consistency, surface defects, smell and flavor.

Environmental sampling is being conducted each (b) (4) with locations in all areas of the facility to validate the effectiveness of the cleaning program. Swabbing is completed on the floor areas, floor drains and around equipment. Air plates are placed in different areas to check the air flow in the rooms and the effectiveness of the hepa air supply system. The scope is aimed at (b) (4) (b) (4) and additional swabbing is done on schedule plus or as corrective action is required due to a presumptive positive or a suspect area of contamination. Quality control technicians are responsible for completing the swabbing and sending swabs out for testing. The outside laboratory testing the environmental sample is (b) (4) (b) (4) (b) (4). A step by step protocol has been established by Chobani for the technicians to follow when swabbing. The protocol was reviewed along with testing records from (b) (4). The protocol was very precise and regimented; Chobani was not willing to allow a copy of the protocol to leave the facility. All the reports reviewed from the environmental testing were found negative, "not found".

Chobani Corporate send several groups of the keeping quality samples from the beginning, middle and end of the recall period, best buy date September 11, 2013 to October 7, 2013, to (b) (4) (b) (4) to test for (b) (4),

(b) (4). Chobani Corporate has informed the firm that all of the samples were negative by phone, but records have not been supplied to the firm so there were no records to review.

Chobani Idaho Inc. production sampling testing records were reviewed from 08/01/2013 through 08/15/2013 on all production lines. Testing results showed sporadic low level counts in a few lines up to 08/04/2013 where Lester O. Boian found there were counts showing for both yeast and mold in a majority of the lines from (b) (4) through the next (b) (4) sampling and testing that afternoon. In discussion with management, Mr. Yzquierdo stated that was the concern that caused the discovery of the (b) (4) in the (b) (4) room. The sample testing records indicated that after August 08, 2013 there were only two samples noted by John W. Banks that had counts of concern. (b) (4) yogurt sample taken at (b) (4), production date of 8/10/2013 (best buy date 10/9/2013), had yeast count of (b) (4) and mold count of less (b) (4) (b) (4) sample taken at (b) (4) (same production date) had yeast count of (b) (4) and less than (b) (4) mold, sample at (b) (4) had yeast count of (b) (4) and mold less than (b) (4) and sample at (b) (4) had yeast count of (b) (4) and less than (b) (4) mold.

Following the review of the sampling records, the keeping quality samples were reviewed in the sample cooler. The review of the two varieties from the records with counts, the (b) (4) keeping quality samples were not found, and from the plant production records it was discovered that the production was very small and the samples may have already been used. The (b) (4) (b) (4) keeping quality samples were visually noted without defects. The review of the containers up to the August 8th production date showed signs of bulging in a majority of the samples, but after August 8th production (best buy date of October 7th) to the present day, September 16th, only (b) (4) (b) (4) samples were showing signs of bulging. (b) (4) yogurt samples best buy dated 10/8/2013 were slightly bulged on the top from line (b) (4) and from line (b) (4). And (b) (4) 6 oz yogurt samples best buy date 10/8/2013 were slightly bulging at the top from line (b) (4) and line (b) (4). (b)(6),(b)(7)(C) commented that he would make sure that Quality Control would conduct a review of the production those two products, and the two products noted in the record review.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

There was no previous inspection by FDA of this facility so there are no previous objectionable conditions to review. No form FDA 483 was issued for this inspection.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

From the inspection conducted by Lester O. Boian on 09/05/2013 the following notes were made:

Inside of filler on line #1 overhead piping and filler head contained product residue on outer surface. (Improve hand cleaning of filler outer surfaces)
Mr. Yzquierdo immediately directed an employee to hand clean the filler prior to use, and it was completed during the inspection.

Filler on line #2 had condensate forming on the overhead piping. No dripping noted (Improve the air flow inside the filler to eliminate condensate)
Mr. Flagg notified the engineering staff and they were investigating the hepa air flow into the filler. Mr. Flagg indicated they would notify ISDA when completed. (Lester O. Boian reviewed the filler on 09/17/13 and found it satisfactory)

Connector hoses from the fruit totes to the (b) (4) were kinked and some lying on the floor. (Initiate station positioning of the totes to limit length of connector hoses to be short as possible to help in eliminating kinking and touching the floor)
Mr. Flagg indicated that he would get with the engineers within a week and begin developing a means to direct the placing of the fruit/fruit flavor totes in a approximate location each time they are positioned at the (b) (4) sites. ((b) (5) (b) (5))

Product surfaces of equipment available for inspection were found satisfactory.

Discussions were conducted with the personnel noted in the Responsibility section above. Due to the nature of this ad hoc FACTS assignment inspection, the general discussion was centered on the discovery of the information that is noted in the Complaints / Product Defects section above.

ADDITIONAL INFORMATION

There is no additional information beyond what was provide above.

SAMPLES COLLECTED

No samples were collected.

VOLUNTARY CORRECTIONS

Mark Flagg, Director of Operations, stated that all of the staff at Chobani Idaho Inc. was concerned about the defects that have plagued their yogurt products. They are dedicated to correct anything that comes up and will make quick corrections on the plant objectionable observations noted above.

EXHIBITS COLLECTED

Exhibit #1 (Pages 1-4) – Chobani Inc. Voluntary Recall Notice
Exhibit #2 – Corporate and New York plant address
Exhibit #3 – Laura Zervic address
Exhibit #4 (Pages 1-9) – Chobani (b) (4) Line(b)(4) Filler Clean Sheet

ATTACHMENTS

Attachment #1 – Form FDA 482 date 09/05/2013
Attachment #2 – Form FDA 482 dated 09/16/2013

FMD - 145

Mr. Halil Ulukaya
Chief Manufacturing Officer
669 Country Road 25
New Berlin, New York 13411

Establishment Inspection Report	FEI:	**3009726115**
Chobani Idaho Inc.	EI Start:	09/05/2013
Twin Falls, Idaho 93301	EI End:	09/18/2013

Lester O. Boian, Regional Milk Specialist

John W. Banks, Investigator

Attachment #1
Chobani Idaho Inc
FEI #3009926115
09/05/2013 FB

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
Food and Drug Administration
Seattle District Office
20215 26th Ave Suite #210
Bothell, Washington 98021
phone: (425) 302-0340
FAX (425) 302-0404

TO

2. NAME AND TITLE OF INDIVIDUAL: Mr. Mark J. Flagg
3. DATE: 09/05/2013
4. FIRM NAME: Chobani Idaho Inc
5. HOUR: 9:05 a.m. / p.m.
6. NUMBER AND STREET: 3450 Kimberly Road East
7. CITY AND STATE & ZIP CODE: Twin Falls, Idaho
8. PHONE NO. & AREA CODE: (208) 732-1700

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]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
Les Boian	Les Boian Regional Milk Specialist

[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, tobacco products, 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, tobacco products, 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 person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products 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, restricted devices, or tobacco products 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

(Continued on Reverse)

Attachment #2
Chobani Idaho Inc
FEI # 3009726115
09/16/2013 #8

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
Seattle District office
22215 26th Avenue SE Suite 210
Bothell, WA 98021
phone- (425) 302-0340 Fax (425) 302-0440

TO

2. NAME AND TITLE OF INDIVIDUAL
Hector Izquierdo - Director of Manufacturing.

3. DATE
09/16/2013

4. FIRM NAME
Chobani Idaho Inc

5. HOUR
a.m.

6. NUMBER AND STREET
3450 Kimberly Road East

5. HOUR
3:15 p.m.

7. CITY AND STATE & ZIP CODE
Twin Falls, Idaho 83301

8. PHONE NO. & AREA CODE
(208) 732-1700

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For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
Les Bolan	Les Bolan Regional Milk Specialist
[signature]	John W. Binns Jr.

[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, tobacco products, 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, tobacco products, 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 person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products 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, restricted devices, or tobacco products 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

(Continued on Reverse)