DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arvind B. Dhruv Ph. D., President and CEO

FIRM NAME	STREET ADDRESS
Guardian Drug Co. Inc.	2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dayton, NJ 08810-1508	Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectio nal observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate standards and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically:

A. Your current analytical test methods for all finished drug products including (b) (4) and APIs do not include verification of the accuracy for standard and sample preparations during the assay testing (Test Procedures; TP-1-666 and TP-4-1020, respectively). The HPLC analysis for assay is conducted without preparing a second check standard and additional sample in the analysis.

For example,

(b) (4) stability assay results range from (b) (4) (b) (4) month time point, respectively) and (b) (4) (Lo (b) (4) Controlled Room Temperature (CRT), (b) (4) month time point, respectively).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Edmund F Mrak, Investigator Ko U Min, Investigator	X Edmund F Mrak Invest gator Signed By: Edmund F. Mrak Jr -S Date Signed: 02-17-2022 12:11:16	DATE ISSUED 2/17/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind B. Dhruv Ph. D., President and CEO	
FIRM NAME Guardian Drug Co. Inc.	STREET ADDRESS 2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1508	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

You did not control variation in performance of the assay method through determination of accuracy in standard and sample preparation.

Additionally, unexplained variations in sample results when more than one preparation was evaluated for drug products was observed; the accuracy of standard and/or sample was not evaluated for these preparations either.

For example,

OOS# 20-001 for Diphenhydramine HCl Assay Lot# 633-5354, Specification (b) (4) % was attributed to "Unknown analytical error"; the following data generated during your investigation expresses unexplained variability.

Sample Type	Injection 1	Injection 2
Original Analysis	92.17%	89.70%
Original Solution Original Vial	91.23%	91.44%
Original Solution New Vial	90.74%	91.45%
Retest by Original Analyst Prep 1	102.06%	102.63%
Retest by Original Analyst Prep 2	102.05%	102.55%
Retest by Original Analyst Prep 3	102.39%	102.26%

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator Ko U Min, Investigator	X Edmund F Mrak Invest gator Signed By: Edmund F. Mrak Jr -S Date Signed: 02-17-2022 12:11:16	2/17/2022

Only the passing retest results were reported after testing by the original analyst and the second analyst, and your investigation did not explain the ~10% difference observed from the original solution and the retest solutions that were prepared by the same analyst; the accuracy of the standard preparation was not evaluated for the original or for the retest.

B. Your procedure LAB-EQP-050 "Procedure for Operation and Calibration of (b) (4) (b) (4) " Revision 2, Effective 12/01/2016 for the (b) (4) (equipment ID#RD-37) does not require a system suitability/verification prior to conducting sample analysis. The current procedure only lists direction to measure the specific optical rotation of the sample without demonstrating system suitability prior to data acquisition. There is no assurance that the equipment can accurately assess specific optical rotation of APIs including (b) (4) Phenylephrine HCl, and Brompheniramine Maleate.

C. There is no assurance that the Karl Fisher (KF) Moisture Analyzer (equipment ID#QC-99) operates as intended and can accurately assess water content for the release testing of APIs for use in finished product manufacturing including (b) (4) Ibuprofen USP, and Dextromethorphan Hydrobromide USP.

1. Your SOP LAB-EQP-080 "Procedure for Operation and Calibration of (b) (4) Titrator Model (b) (4)" Revision 0, Effective 03/10/2021 does not require an accuracy check once the (b) (4) verification is determined.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind B. Dhruv Ph. D., President and CEO	
FIRM NAME Guardian Drug Co. Inc.	STREET ADDRESS 2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1508	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

2. You disabled the raw data function on the (b) (4) method from the instrument; the data printouts do not include method parameters and the raw data (Composite solution concentration, titrant volume consumed, duration, and drift) required to verify if the analyses are conducted within the instrument calibrated parameters.

3. The accuracy of the (b) (4) volume dispensing is not demonstrated during the (b) (4) calibration. The (b) (4) volume accuracy check was not performed in the most recent calibration, performed on 02/01/2022, for (b) (4) instrument ID#QC-99. The (b) (4) volume accuracy for (b) (4) instrument ID# QC-66, which was used prior to (b) (4) instrument ID#QC-99, was also not performed for 2019 and 2020.

D. Your procedure LAB-EQP-021 "To provide a procedure for the operation and calibration of the (b) (4) Model (b) (4) pH meter" Revision 9, Effective date 12/01/2014 for pH meters including ID# QC-07 used to measure pH during Assay and determination of Acid Neutralizing Capacity of Alkums (OTC antacid tablet finished product) is deficient in that:

1. pH probe thermometers are not calibrated as part of calibration procedure nor are they verified at the time of use to ensure that they are reading the correct temperature when the pH is taken.

2. For the (b) (4) calibration, the offset and the temperature are not checked, monitored, or recorded.

3. No usage logbook is assigned for pH meter ID#QC-07.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator Ko U Min, Investigator	X Edmund F Mrak Invest gator Signed By: Edmund F. Mrak Jr -S Date Signed: 02-17-2022 12:11:16	2/17/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind B. Dhruv Ph. D., President and CEO	
FIRM NAME Guardian Drug Co. Inc.	STREET ADDRESS 2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1508	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

E. You lack scientific justification for expiration dates assigned to laboratory chemicals. Your SOP LAB-GEN-007 "Chemicals, Reagents, Indicators and Solutions" Revision 6, Effective date 01/09/2017 section 1.3.2 states "In the absence of manufacturer's expiration date, all chemicals shall be assigned expiration date of (b) (4) from date of receipt" and you do not differentiate whether the chemicals, reagents, indicators, and solutions are opened and partially used vs. unopened and new.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically:

A. Assay of Guaifenesin API Lot (b) (4) resulted in an out of specification (OOS) result of 96.27% and an OOS investigation was not initiated. Instead, you initiated Laboratory Unplanned Deviation 20/11 on 04/22/2020 to probe the assay injection variation between two injections (96.27% for injection 1 and 99.91% for injection 2, Specification (b) (4) %) of a single prep of Guaifenesin API Lot# (b) (4). Your response was limited to re-injection of the original sample and the result was reported. Your investigation concluded that the variation between injection 1 and 2 was "due to injection artifacts". The HPLC run included samples prepared from 4 Lots RCA# (b) (4) and (b) (4) and only Lot (b) (4) exhibited variation. You did not extend your investigation to the other three (3) lots within the run to ensure that the "injection artifact" did not affect the sample results.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator Ko U Min, Investigator	X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 02-17-2022 12:11:16	2/17/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind B. Dhruv Ph. D., President and CEO	
FIRM NAME Guardian Drug Co. Inc.	STREET ADDRESS 2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1508	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

B. Your Laboratory Unplanned Deviation 20/06 initiated on 02/19/2020 for the failure of dissolution analysis of Guaifenesin ER Tablets 600mg Lot#233-5584 did not isolate the root cause of variation. You determined the root cause to be "Common cause variation and also setting of dissolution specifications" without substantiation and the batch was rejected. You reported that the sample failed L3 however, you did not initiate an OOS investigation.

C. Your Laboratory Incident Report (LIR) 21/08 initiated on 12/10/2021 for the failure of dissolution analysis of Guaifenesin ER Tablets 600mg for Lot#233-8711 for L3 testing did not isolate the root cause of variation. The LIR 21/08 investigation also stated that the root cause was "due to common cause variation isolated to Batch 233-8711" and batch was rejected, however no OOS investigation was initiated.

D. Your Laboratory Out of Specification (OOS) Investigation #20-004 initiated on 02/25/2020 for failure of assay of Guaifenesin API Lot (b) (4) did not consider potential impact on all samples in the HPLC run. The HPLC run on 02/24/2020 included two samples Lot (b) (4) and failed the system suitability criteria with % RSD 1.6% (Specification NMT (b) (4) %); no lab event or deviation was initiated. On 02/25/2020, you conducted a re-injection (re-run) of the original sample prep of both lots (b) (4) on the original instrument (ID# RD-21) and column generating an OOS result of 96.24% for Lot RCA(b) (4) The results of the original run and the re-run are included in the table below:

Guaifenesin API Assay (Specification (b) (4) on dried basis)		
Sample	(b) (4)	(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Edmund F Mrak, Investigator Ko U Min, Investigator	X Edmund F Mrak Invest gator Signed By: Edmund F. Mrak Jr -S Date Signed: 02-17-2022 12:11:16	DATE ISSUED 2/17/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Arvind B. Dhruv Ph. D., President and CEO

FIRM NAME	STREET ADDRESS
Guardian Drug Co. Inc.	2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dayton, NJ 08810-1508	Drug Manufacturer

Lot				
Runs	Original Run (02/24/2020)	Re-injection (02/25/2020)	Original Run (02/24/2020)	Re-injection (02/25/2020)
% RSD (NMT (b) (4) %)	1.6%	0.5%	1.6%	0.5%
Injection 1	98.92%	99.41%	99.60%	96.24%
Injection 2	99.08%	98.20%	100.64%	99.15%
Assay on dried basis (Average)	99.5%	99.3% (Reported)	100.6%	96.7%, 99.6% (Individual & Not Reported)

You initiated OOS #20-004 for Lot (b) (4) failed Injection 1. Your investigation included the re-testing (new sample prep) by the original analyst and reported those results. Your investigation did not isolate the root cause of original failure and did not consider potential impact on result for Lot (b) (4). Your OOS investigation concluded that the OOS result was due to an "isolated system error".

E. Your Laboratory OOS# 21-020 initiated on 11/11/2021 to probe the failure of Bismuth Subsalicylate Assay for Regular Strength Gastro Bismuth Liquid Stability Lots (b) (4) months CRT) 95.5% and (b) (4) months CRT) 87.8% (Specification (b) (4) %) determined "laboratory error attributed to error in mixing of sample before taking it for sample preparation". Your investigative re-

testing by two analysts produced results that were outside of your acceptance criteria as per SOP# 5.16 "Handling of Out-of-Specification Test Results", Revision 12, Effective 05/11/2021, Step 5.7.2 (ii) states that the retest results will be considered if "(b) (4) ". Your investigation did not evaluate the percent difference in average assay results between analysts for retest of (b) (4) and Lot# (b) (4) (b) (4) calculated as 4.6% and 4.5%, respectively.

OBSERVATION 3

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically:

You lack adequate controls to ensure that production batch records for drug intermediates are reviewed and approved by the quality unit before such intermediates are forward processed in the next manufacturing stage. Furthermore, you released and distributed finished drug product before the production batch records for its intermediates were reviewed and approved by the quality unit. For example:

Six OTC antacid tablet finished product lots including Alkums Ultra Strength and Regular Strength in various flavors manufactured using drug intermediate Calcium Carbonate (b) (4) lots: 341-417627, 341-417801, and 341-417822 were released and shipped for distribution prior to granulation batch record review and approval by the quality unit.

OBSERVATION 4

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind B. Dhruv Ph. D., President and CEO	
FIRM NAME Guardian Drug Co. Inc.	STREET ADDRESS 2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1508	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

The preparation of your master production and control records was not described in a written procedure.

Specifically:

You lack adequate controls over drug product batch in-process QA records to ensure that they cannot be reproduced and that all in-process control records issued are accounted for before batch disposition. For example:

Your In-Process Record, REV:0, Effective Date: 01/14/2022 provides the required number of In-Process QA (IPQA) forms for Product Code 233 as 18. Review of the compression batch record for Guaifenesin Extended Release Tablets 600 mg, Product Code: 233, Lot No.: 8701 revealed that there were 20 In-Process QA Checks, Form: IPQA-G233-R2 in the record and there were no written comments to explain the origin of the additional IPQA forms.

OBSERVATION 5

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically:

A. Your cleaning methods for the granulation equipment train including the (b) (4) (Equipment ID # MFG-014), (b) (4) (Equipment ID # MFG-017), (b) (4) (Equipment ID # MFG-012), and (b) (4) Mixer (Equipment ID # MFG-041) used for manufacture of drug products including Guaifenesin Extended Release Tablets 600 mg, Product Code: 233 and Gastro Bismuth Tablets,

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind B. Dhruv Ph. D., President and CEO	
FIRM NAME Guardian Drug Co. Inc.	STREET ADDRESS 2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1508	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

Bismuth Subsalicylate 262 mg, Product Code: 122 are not validated in accordance with your internal procedure SOP 5.07, REV: 10, Effective Date: 11/08/2018, Cleaning Validation which requires successful performance of three cleaning cycles before the cleaning method can be considered validated. You reported that you have only documented successful performance of two cleaning validation protocols CVP-15/01, Report Approved: 06/15/2015 and CVP-18/01, Report Approved: 02/20/2018 for Guaifenesin granulation and you continue to use the equipment for granulation of drug products and clean in accordance with unvalidated procedures.

B. You have not validated the effectiveness of your equipment cleaning methods for the granulation equipment train including the (b) (4) (Equipment ID # MFG-014), (b) (4) (Equipment ID # MFG-017), (b) (4) (Equipment ID # MFG-012), and (b) (4) Mixer (Equipment ID # MFG-041) used for manufacture of drug products including Guaifenesin Extended Release Tablets 600 mg, Product Code: 233 and Gastro Bismuth Tablets, Bismuth Subsalicylate 262 mg, Product Code: 122 to remove or reduce microbial contaminants to a level sufficient to prevent objectional microbiological contamination of your drug products manufactured in the equipment train.

C. You have not established dirty and clean hold times for the granulation equipment train including the (b) (4) (Equipment ID # MFG-014), (b) (4) (Equipment ID # MFG-017), (b) (4) (Equipment ID # MFG-012), and (b) (4) Mixer (Equipment ID # MFG-041) used for manufacture of drug products including Guaifenesin Extended Release Tablets 600 mg, Product Code: 233 and Gastro Bismuth Tablets, Bismuth Subsalicylate 262 mg, Product Code: 122. Furthermore, your cleaning validation studies reported for cleaning validation protocols CVP-15/01, Report Approved: 06/15/2015 and CVP-18/01, Report Approved: 02/20/2018 for Guaifenesin granulation did not include challenge conditions expected to support effectiveness of cleaning methods after any proposed dirty and clean hold time limits.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator Ko U Min, Investigator	X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 02-17-2022 12:11:16	2/17/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind B. Dhruv Ph. D., President and CEO	
FIRM NAME Guardian Drug Co. Inc.	STREET ADDRESS 2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1508	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

OBSERVATION 6

There was a failure to handle and store drug product containers and closures at all times in a manner to prevent contamination.

Specifically:

Your liquid packaging Line (b)(used to fill and package drug products including Product Code: 552, Children's TUSSNEX DM Liquid exposes the direct product contact bottle caps (closures) to the packaging area environment and (b) (4) which was found in disrepair. The (b) (4) used to hold and feed bottle caps to the packaging line did not have a protective cover. Frayed tape observed on the (b) (4) in contact with bottle caps challenges cleaning and may shed particulate contamination into the drug product.

OBSERVATION 7

Employees engaged in the manufacture, processing and packing of a drug product lack the training required to perform their assigned functions.

Specifically:

There are no records documenting On the Job training (OJT) for the QA Inspector/Associate and Operators. All of the training records consist of SOP read and understood with either "Satisfactory" and "Understood" evaluation and a group led training. Your SOP 4.02 "Procedure for Training of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator Ko U Min, Investigator	X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 02-17-2022 12:11:16	2/17/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	1/26/2022-2/17/2022* FEI NUMBER 2245306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Arvind B. Dhruv Ph. D., President and CEO	
FIRM NAME Guardian Drug Co. Inc.	STREET ADDRESS 2 Charles Ct
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1508	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

Employees" Revision 9, Effective 01/28/2016 does not define "Satisfactory" evaluation or include assessments to demonstrate the effectiveness of read and understand SOP training. For example, QA In-Process checks are performed by QA Inspectors/Associates for Guaifenesin Extended Release Tablets 600mg for description, weight, thickness, hardness, and friability however, no OJT training records are available for any employees that perform these tasks to demonstrate their proficiency.

***DATES OF INSPECTION**

1/26/2022(Wed), 1/27/2022(Thu), 2/01/2022(Tue), 2/02/2022(Wed), 2/03/2022(Thu), 2/04/2022(Fri), 2/17/2022(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator Ko U Min, Investigator	X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 02-17-2022 12:11:16	2/17/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, 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. A copy of such report shall be sent promptly to the Secretary."