including those from her own observations, those generated by the Trenton staff, and those from the statistical staff in CX 448 (Marcelli, Tr. 17388).

1115. Dr. Marcelli, a graduate industrial pharmacist at the time, was assigned to the 223 Test while working for Dr. Tainter as a Special Project Assistant for the Sterling Research Board. Dr. Marcelli had overall responsibility and supervision for all aspects of the study except the sample pickup. She was responsible for determining the attributes to be tested, conducting analysis of the data, and writing the report (Marcelli, Tr. 17401–02, 17404–05).

1116. It is respondent's position that the 223 Test was a properly conducted study and that its results are valid and reliable. Respondent contends that the study demonstrates that [**275**] Bayer Aspirin was pharmaceutically superior to other aspirin brands on the market, and that said study was, therefore, properly relied upon as a basis for claims of pharmaceutical superiority in the Blue Book campaign. Furthermore, respondent contends that, if an implied representation of therapeutic superiority is found in this case (contrary to its view), the 223 Test, in addition to other evidence, shows a reasonable basis for such representation.

1117. The samples of aspirin tested in the 223 Test were assembled as a result of a survey conducted in 1967 and a pickup of samples in 1968 (CX 448K-L; Alberts, Tr. 8952; Mattimore, Tr. 15336–38). In early 1967, the sales administration manager of respondent's Glenbrook Laboratories Division, Mr. Mattimore, was asked by his superior to conduct a survey to identify the various brands of aspirin which were available for sale in retail outlets in the United States. This was carried out by requesting every Glenbrook Laboratories salesman to report all brands of aspirin they encountered in a one-week period. The salesmen were provided with a form and instructed to record the name of every brand of 5-grain aspirin, and the name and address of the store in which it was found (Mattimore, Tr. 15336; CX 448K).

1118. Mr. Mattimore estimated that approximately 100 men went into approximately 3,350 stores, 35 per week per man. The salesmen were asked to go into units of all the major chains so that their coverage would reflect the brands in all outlets of such chains. In Mr. Mattimore's view, the survey reflected what was being sold in at least 70 or 80% of the stores in the United States at that time (Mattimore, Tr. 15336–38).

1119. In 1968, Mr. Mattimore was asked to obtain samples of the brands which had been identified in the survey. This was carried out in three stages—collection of samples of minor or regional brands, collection of samples of major brands, and collection of Bayer samples (Mattimore, Tr. 15338; CX 448K-L).

1120. In the first stage, in March 1968, the collection of samples of minor or regional brands, Mr. Mattimore assigned salesmen to pick up specific brands by going through the 1967 report forms and identifying salesmen who had reported such brands. Mr. Mattimore testified that this was the only practical way to proceed because store or private-label brands are commonly available only in particular outlets and that it was necessary to assign the task to the personnel who had located the brand initially. Otherwise, many of the brands identified the previous year would have been missed. Where a brand was clearly available in more than one location, *e.g.,* certain chain store brands, several salesmen were asked to provide samples (Mattimore, Tr. 15338–41). In the sample collection, each salesman was asked to pick up six samples of a particular brand, of different control numbers where possible (Mattimore, Tr. 15338–40). [**276**]

1121. In the second stage, salesmen were asked to pick up samples of Sterling's major competitors—Anacin, Excedrin, Bufferin, and brands which are known as nationally distributed 5–grain aspirins, including Squibb, McKesson, Norwich, and St. Joseph. Nationally distributed brands are those which are probably available in all 48 states which Sterling serviced (Mattimore, Tr. 15343). Since the objective was to get a national sample, Mr. Mattimore asked a sales representative in each of the Glenbrook 14 sales districts to obtain samples (Mattimore, Tr. 15343–44).

1122. In the third phase, Mr. Mattimore instructed salesmen to pick up samples of Bayer Aspirin, also on a national basis. This request was made to the 14 sales districts, following the same procedure as in obtaining samples of the combinations and the nationally distributed 5–grain aspirin tablets (Mattimore, Tr. 15344).

1123. When samples were received by Mr. Mattimore at his New York office, he checked them against his requests to the salesmen. Follow-ups were made if no samples were submitted for a brand, or if insufficient number of samples were received. In almost every instance, the explanation was that the representative could not locate the branded product (Mattimore, Tr. 15346). This was not surprising since there are changes in store and private-label brands (Alberts, Tr. 8953–54; Mattimore, Tr. 15348–49).

1124. The samples were generally shipped in a corrugated container, packaged with paper or some type of resilient material, sealed and shipped by mail. The Glenbrook salesmen from whom Mattimore requested samples had previous experience in picking up samples, a procedure followed with competitive products. It was Mr. Mattimore's view that in connection with the sample pick-up for this study the sales representatives did carry out his instructions properly (Mattimore, Tr. 15342–43, 15347).

1125. Mr. Mattimore testified that CX 448, pages K and L, called "Identification and Location of Brand and Acquisition of Samples," accurately describes the procedures which were followed in the 1967 survey and 1968 collection of samples (Mattimore, Tr. 15348–49).

1126. Mr. Mattimore testified that when the brand survey was conducted in 1967, and the samples were collected in 1968, neither Mr. Mattimore nor the sales representatives knew the specific purpose for which this was being done (Mattimore, Tr. 15344, 15374).

1127. In determining the characteristics to be tested in the 223 Study, Dr. Marcelli relied upon her own experience in the [277] Pharmacy Division, and also considered an earlier and less complete pharmaceutical study from the early 1960's, the results of which were available in a draft report, CX 445, "The Quality of Aspirin Tablets," by Jerome Winig and Gail Prince. On this basis, Dr. Marcelli prepared a list of characteristics which were considered important to pharmaceutical quality. The tentative list was checked with the Pharmacy Research Division of the Sterling Winthrop Division for their suggestions and confirmations. It was also discussed with Mr. Winig and Mr. Mannix at the Glenbrook Laboratories Trenton plant. Dr. Tainter approved the basic list in March 1968 (Marcelli, Tr. 17407–08).

1128. The 223 Test, CX 448, reports tests and observations of the following physical and chemical characteristics:

1. Aspirin content - USP requirements
2. Aspirin content - Bayer standard
3. Tablet weight - USP
4. Absence of capping
5. Disintegration time - USP method
6. Disintegration time - Bayer method
7. Free salicylic acid - USP limits
8. Free salicylic acid - Bayer requirements
9. Absence of off-color
10. Absence of acetic odor
11. Freedom from wicking or wadding
12. Frequency and severity of tablet miscount
13. Rate of tablet breakage
14. Clarity of package size
15. Clarity of aspirin concentration
16. Legibility of label copy
17. Presence and adequacy of indications for use
18. Adequacy and accuracy of dosage instructions
19. Presence of required caution
20. Presence of required warnings
21. Use of package insert

22. Provision of sealed package
23. Provision of safe, undamaged container
24. Presence of security-closed caps
25. Control number presence and legibility - carton
26. Control number presence and legibility - container
27. Chipping
28. Miscellaneous contents imperfections
29. Wadding presence and adequacy
30. Deficiencies in container appearance

Most of the attributes were either required under regulatory or compendial requirements or were regarded as desirable by Sterling at that time. Many of the latter were later [278] incorporated into regulatory or compendial requirements (Marcelli, Tr. 17411–12; CX 448I-J).

1129. RX 181A-E, a letter from Marcelli to Winig dated April 3, 1968, included a handwritten draft report form, including examples of the types of entries to be made on the basis of physical observation of the samples in New York and of the testing to be conducted at the quality control laboratory of the Trenton plant. RX 181 was written after consultation with Winig and Mannix. It was understood at that time that the laboratory testing was to follow the standard testing procedures used in the quality control laboratories (Winig, Tr. 13743; Mannix, Tr. 14609; Marcelli, Tr. 17409–10, 17585–88). Subsequent correspondence and discussion between Dr. Marcelli and Mr. Mannix concerned the format for presentation of results and the use of pass-fail standards (Mannix, Tr. 14621–22; Marcelli, Tr. 17409, 17585–86; RX 181F-G, K).

1130. In the 1960's and early 1970's, at the time the 223 Test was conducted (CX 448), the emphasis was on tablet disintegration rate. Today the emphasis is on dissolution rate and absorption-bioavailability (Danhof, Tr. 17067). At that time, there was no standard test for dissolution or bioavailability of aspirin tablets (Winig, Tr. 13756).

1131. CX 448P-U describes the various tests and observations carried out at the Trenton laboratory (Winig, Tr. 13739; Mannix, Tr. 14609–10; Marcelli, Tr. 17464–67; CX 448P-U).

1132. This work was done under the supervision of Mr. Edward Mannix, Director of Quality Control, at the plant. Mr. Jerome Winig, the plant manager, asked that the quality control laboratories undertake the work, at the request of the Sterling Medical Director, Dr. Tainter. As Director of Quality Control, Mr. Mannix was autonomous of the plant administration, reporting to quality control officials in the company. In the 223 Test, he was in charge of the testing. He set up the program, and participated in establishing the report format.

He assigned persons directly under his supervision to undertake the testing (Mannix, Tr. 14605–07; Winig, Tr. 14255; Marcelli, Tr. 17420–22).

1133. The test procedures used in the study were routine standard testing procedures, with which the laboratory staff were familiar. The personnel, equipment and procedures regularly used for testing chemical and pharmaceutical characteristics in the quality control laboratories were used in connection with this survey (Winig, Tr. 13738, 13743, 14261–62; Mannix, Tr. 14624–25, 14609; Marcelli, Tr. 17464–67; CX 429C).

1134. The tests conducted at the Trenton Laboratories were tablet count, color, odor, general appearance and disintegration. The tablet disintegration test was done by two different methods—the USP method and the Bayer method (Mannix, Tr. 14609–10; CX 448P-U). **[279]**

1135. The USP disintegration procedure used what is commonly termed the Vandercamp apparatus, described in the USP, using discs which move and hit the tablets as the apparatus is raised and lowered in the water medium. The Bayer basket technique involves a simple screen and stirring device and is used in the normal course of Bayer quality control. The Trenton plant's quality control staff was competent in both methods (Winig, Tr. 13740–42; Mannix, Tr. 14612–13).

1136. Analytic testing procedures in effect in the Trenton plant at the time are described in CX 429D-G, "Quality Control Specifications for Bayer Aspirin Tablets." These were the standard testing procedures used by the quality control group, and were taken from the plant monograph then in effect. They cover all the items dealt with in CX 448, except for color, odor, tablet count, and the USP disintegration method referred to above (Winig, Tr. 13742; Mannix, Tr. 14613–14; Marcelli, Tr. 17464–67).

1137. Testing began at the Trenton Laboratories for the CX 448 study in July 1968 and continued over a period of two years to August 1970 (Winig, Tr. 13737–38; Mannix, Tr. 14619; RX 181H, N-O).

1138. Two methods were used to transport the samples from Dr. Marcelli's custody in the New York office to the Trenton plant. Under one method, the samples were transported by the company's regular courier service to Secaucus, New Jersey, where there was a distribution center. There was routine transport between Trenton and Secaucus. The second method was through the mails. The mails were used when necessary (Mannix, Tr. 14628; Marcelli, Tr. 17444–46).

1139. After Mr. Mannix received the samples that were sent from Dr. Marcelli to the Trenton plant, he made assignments to various technicians to do the various tests according to their expertise and availability. The technicians were told that the work was in connec-

tion with a survey, and that they were to conduct it the same as they would an everyday procedure. No one told the technicians that the results of the study were to be used for advertising purposes. Testing of competitive products had been done previously on a routine basis (Winig, Tr. 13745; Mannix, Tr. 14622–24).

1140. At the time the testing was done, neither Mr. Winig nor Mr. Mannix had any understanding or information that the results were intended to be used for advertising purposes. It was their understanding that this was another survey of competitive products, like others that had routinely been done in the laboratories. The first information that Mr. Winig had of possible use or advertising was in the summer or fall of **[280]** 1971, at meetings to consider a new advertising campaign. Mr. Mannix was later informed of such consideration, and the resulting decision (Winig, Tr. 13736, 13752; Mannix, Tr. 14623–24).

1141. In conducting these laboratory procedures, following the usual procedures, the samples were not blinded. The purpose of the survey was to study commercial aspirin tablets in the form in which they were available to consumers, and this placed sharp limitations on blinding. Respondent's witnesses testified that since the survey employed routine, standardized tests, it was unnecessary to blind the samples and that blinding would have altered the physical composition of the tablets which is part of the evaluation (Rhodes, Tr. 11434–36, 11440–44; Banker, Tr. 12906; Fields, Tr. 16600–01).

1142. Mr. Mannix and his two supervisors were responsible for taking the data which constituted the test results from the notebooks and putting it into the reporting format to be sent to Dr. Marcelli. RX 181N-O is an example of the reporting format or reporting sheets sent from the laboratories in Trenton to the New York office (Mannix, Tr. 14625).

1143. In the collection of samples from the field, 14 Bayer samples were obtained and delivered to Dr. Marcelli. Seven of the Bayer field samples did not undergo laboratory examinations at Trenton because they were lost or destroyed in the course of transportation (Mannix, 14628–31; Marcelli, Tr. 17455–56; RX 181J; CX 429H).

1144. Efforts were made to find replacement samples for the lost Bayer samples of approximately the same age (or plant control number). These could not be found in retail establishments. Five replacements were found in Sterling facilities—four in "Free Goods 90 Park N.Y." which was a reference to aspirin which constituted part of an overshipment to a consumer or returned by a customer for credit, and one at the Sterling Winthrop Research Institute, Rensselaer. A total of 19 Bayer samples underwent physical observations in New York (Mannix, Tr. 14630; Marcelli, Tr. 17449–51).

1145. Laboratory tests were performed on the Bayer samples in August 1970. The samples tested at the laboratory were seven field samples and the five replacement samples (Mannix, Tr. 14631; Marcelli, Tr. 17454–55).

1146. In late January 1971, Dr. Marcelli undertook the analysis of the data resulting from the tests and performed the tabulation, analysis and writing of the report (CX 448). This work was done in January-March 1971. Dr. Marcelli had the advice and assistance of the Biometrics Section at the Sterling-Winthrop Research Institute, which is the expert biostatistical body at Sterling. The two handwritten tables in CX 430 were [281] prepared by the Biometrics Division. Dr. Marcelli had staff assistance in tabulating the data (Marcelli, Tr. 17478–81).

1147. Dr. Marcelli adopted a statistical cutoff for aspirin brands that were to be individually examined in the report, as the Biometrics Section indicated that comparisons should be confined to those brands where there was a minimum of six samples and at least four control lots in order to have a reasonable estimation of the distribution within the brand. All of the remaining brands were placed together in a single group labeled "Miscellaneous." At the time that this recommendation was made by the Biometrics Section, that section did not have access to any of the test results (Horner, Tr. 10762–63; Marcelli, Tr. 17482–85).

1148. It is Sterling's position that the overall conclusion arising from CX 448 is that Bayer Aspirin tablets were superior to all other plain 5–grain aspirin tablets represented in the study in terms of overall pharmaceutical quality. This was based upon analysis and evaluation of the data with respect to the 30 characteristics or categories reported on in the study. The 30 categories were divided into 26 primary categories and the 4 secondary categories. Bayer had 8 failures in 5 of the 30 performance categories, but no other brand with a reasonable representation equalled this record. The brand closest to Bayer in performance had twice as many failures. Only 3 of the Bayer failures fell into the 26 primary categories whereas with the other brands, 3 to 5 times as many failures fell into the primary categories (Marcelli, Tr. 17488; CX 448D-H; RPF 7.528).

1149. Dr. Marcelli reported that based on this 30 criteria employed in CX 448, Bayer was superior to 220 aspirin brands (CX 448D). Specifically, Bayer routinely yielded 324 mg aspirin per tablet with more lot-to-lot consistency than the other brands. One hundred fifty-seven competitors yielded at least one failure (CX 448D). For disintegration, Dr. Marcelli reported that Bayer consistently met a standard of beginning disintegration with 2 seconds and completing disintegration within 30 seconds, while 70 others failed to do so (CX 448D). For

FSA level, only one Bayer sample yielded FSA in excess of .035%, while 90% of competitive samples yielded such FSA values (CX 448E). Bayer showed a uniformly, pure white color while 9 major brands and approximately 20% of minor brands showed at least one off color sample (CX 448E).

1150. Dr. Marcelli also reported that Bayer showed perfect tablet count, but only four other major brands did so. One hundred seventy-eight minor brands showed tablet counts varying from the label claim (CX 448E, F). Bayer and 6 major brands manifested rare instances of broken tablets, while 50% of the minor brands registered broken tablets (CX 448F). Bayer and eight major brands manifested uniformly good label legibility. Most minor brands showed poor label legibility (CX 448F). On [282] packages of Bayer and five major brands, indications were clear. All minor brands registered deficiencies in the presentation of indications (CX 448F). She reported that only Bayer reliably included dosage recommendations, cautions and warnings on every sample (CX 448G). Only Bayer and St. Joseph provided package inserts (CX 448G). Among the major brands, only Bayer registered sealed units for every sample. Only a "handful" of minor brands provided such protection (CX 448G). Bayer routinely showed undamaged and safe containers, while other brands did not (CX 448G). Of the major brands, only Bayer manifested uniformly legible control numbers on cartons and bottles. Minor brands showed numerous failures, including omissions of these numbers (CX 448G). Bayer was free of extraneous dust and stray fragments, while 75% of the other brands manifested some deficiency detracting from the general appearance of the product of package (CX 448H).

1151. Dr. Marcelli concluded that Bayer alone showed failures in only 5 of the 30 categories, that those 26 parameters relating to efficacy, tolerance, stability, and safety, Bayer showed minor failures in 3 categories, and that no other brand with "reasonable representation" matched Bayer's record, and that competitive brands' failure rates ran three to five times Bayer's rate (CX 448H).

1152. Dr. Marcelli completed the report in March 1971, and distributed it to those on a list provided by Dr. Tainter. Her involvement ended with the submission of the report. Dr. Marcelli did not participate in any meetings later in 1971 that considered the report in the context of a proposed advertising campaign. She testified that she first heard of the possible use of the study for advertising purposes in late October or early November 1971, after she had left Sterling (Marcelli, Tr. 17532–33).

1153. In 1971, the 223 Test was considered by a group which included such company scientific experts as Dr. Blackmore, Director of Clinical Research at Sterling's Research Laboratory; Dr. Rosenberg,

Head of the Pharmacology Section of the Research Institute; Dr. Swarbrick, Head of the New Product Development Group and a former professor of Pharmaceutical Science (now Dean of the University of Southern California School of Pharmacy); Mr. Winig, Plant Manager at the Bayer Trenton plant and an expert in pharmaceutical and manufacturing standards in aspirin; Dr. Trout, Sterling Medical Director; and other medical personnel. A consensus was reached at those meetings that the 223 Test was valid and reliable and that it provided a basis for making a claim of superiority in pharmaceutical quality for Bayer Aspirin (Alberts, Tr. 9002–03; Winig, Tr. 13752; Trout, Tr. 16094).

1154. At the trial, respondent's expert witnesses, without exception, testified that because pharmaceutical quality is [283] related to therapeutic efficacy, physicochemical pharmaceutical tests, such as CX 448, provide a reasonable basis for conclusions regarding comparative therapeutic performance of aspirin products.

1155. Dr. Horner, respondent's expert biostatistician, testified that in assessing the clinical significance of differences in various parameters between aspirin brands, it is necessary to consider the net effect of all differences, rather than to isolate a single parameter. In this opinion, a critical issue is the assessment of overall pharmaceutical and therapeutic superiority, as opposed to making a series of independent decisions based on individual parameters (Horner, Tr. 10835).

1156. Dr. Feinstein testified that he reviewed the material in the "223 Test" (Feinstein, Tr. 16374). He described the study as containing the kind of evidence that he would resort to in making a decision as to which of the products would be better therapeutically (Feinstein, Tr. 16374, 16379).

1157. Dr. Rhodes, an expert in pharmaceutics, testified that, in his opinion, CX 448 is a valid pharmaceutical study, which demonstrates that when Bayer Aspirin was compared with a large number of other aspirin products available on the United States market, Bayer Aspirin was of better quality than those produced by its competitors. In his view, the 223 Test provides a reasonable scientific basis for the conclusion that Bayer Aspirin and Bayer Children's Aspirin have been tested against other brands of aspirin and found to be qualitatively superior to other brands. It would also be reasonable to draw a therapeutic conclusion based upon the therapeutic importance of the parameters measured in this study. In his opinion, a reasonable drug company in the late 1960's and early 1970's would have acted reasonably in selecting the parameters measured in the study in attempting to determine the pharmaceutical and therapeutic superiority of its aspirin over competitive brands of aspirin (Rhodes, Tr. 11425–26, 11434–43).

1158. It was the judgment of Dr. Banker, an expert in pharmaceutics, that the 223 Test was a comprehensive test which evaluated meaningful parameters of different brands of aspirin tablets. In Dr. Banker's view, the methodology is valid, and clearly established that Bayer was the most nearly optimized brand of aspirin tablets, and was pharmaceutically and therapeutically superior to the other brands evaluated. In his opinion, a reasonable drug company would have a right to rely on a study such as the 223 Test in making superiority claims for its aspirin and a reasonable hospital pharmacist or clinician would be justified in relying on such a study in selecting Bayer Aspirin over other brands of aspirin tablets for treatment of patients (Banker, Tr. 12779–81; Danhof, Tr. 16946–67). **[284]**

1159. Dr. Fields testified that the 223 Test was of value in selecting an aspirin brand to be used in the NIH Stroke Study because of the relationship between such characteristics and the therapeutic performance or side effects of an aspirin tablet. In the absence of controlled clinical studies, the 223 Test was considered to have a bearing upon determining which aspirin brand would produce the least variability, the most likelihood of bioavailability, and the least side effects. Among the physical and chemical characteristics considered were disintegration, amount of impurities, including free salicylic acid, and the stability of the tablet. According to Dr. Fields, the expert pharmacologists relied upon the 223 Test and other information in selecting Bayer Aspirin for use in the NIH Stroke Study (Fields, Tr. 16585–86, 16598–600, 16566, 16744–45).

1160. Dr. Scoville, a former FDA official, also testified that the 30 physical and chemical characteristics studied in the 223 Test were included in the type of material that is reviewed by the FDA, together with appropriate clinical data, in reaching judgments as to the safety and efficacy of a drug product and in determining whether to approve a drug for marketing or to seize or recall a drug product from the marketplace (Scoville, Tr. 14448–49).

1161. Dr. Falliers, an expert in allergy, testified that to the extent that the 223 Test demonstrated that Bayer Aspirin is pharmaceutically superior in the characteristics tested, it provided a reasonable basis to conclude that Bayer Aspirin is therapeutically superior (Falliers, Tr. 13320–21, 13326).

1162. The record shows that Sterling knew in August 1971, about five months after the completion of the 223 aspirin survey, that there were some 328 plain aspirin brands in the United States. Sterling knew in November 1971 that the number of competing aspirin brands was possibly as high as 442 (CX 363A; Alberts, Tr. 9045–47).

1163. The record shows that the reliability of the 223 Test and the validity of its findings are subject to serious doubts because of perva-

sive methodological deficiencies throughout the entire survey. Despite the elaborate and considerable research trappings which adorn the 223 Test, it is fair to conclude that its overall quality falls short of that generally required to substantiate unqualified claims of pharmaceutical or therapeutic superiority with respect to plain 5-grain aspirin brands. However, this does not detract anything from CX 448's utility as an ongoing internal quality monitoring tool, as its more modest predecessors had been (F. 1124, 1127, 1139, *supra*).

1164. It is well recognized that for a properly designed and well-controlled scientific study, a protocol must define in sufficient detail all of the important aspects of the study, including any plan for statistical evaluation (Moertel, Tr. [285] 6275, 6287; DeKornfeld, Tr. 8393, 8400; Horner, Tr. 10818–19, 10890–91, 10897). CX 448 does not contain any protocol (Rhodes, Tr. 11803). The draft report form contained in Dr. Marcelli's April 3, 1968 letter to Mr. Winig (RX 181A-E), although informative, cannot be characterized as a "protocol," and it does not include any description of contemplated statistical evaluation. In fact, no "protocol," in the conventional sense, was established for CX 448 (Marcelli, Tr. 17585–87). Mr. Mannix, who was responsible for overseeing the Trenton testing phase, testified that he had begun reporting test results to Dr. Marcelli before she had committed to paper what it was he was to be testing (Mannix, Tr. 14663).

1165. Test samples were collected by Sterling's field salesmen in 1968 (Mattimore, Tr. 5338–41, 15343). The record indicates that the sales representatives who collected the test samples received no written instructions concerning the manner of collection (Mattimore, Tr. 15370–79). The sales representatives simply received requests to pick up certain brands of aspirin (Mattimore, Tr. 15339). The witness called by respondent to provide evidence on the method and reliability of the collection state of this study did not remember whether or not written instructions ever existed concerning the collection of samples for major brands (Mattimore, Tr. 15374–79). No means exist to determine whether that portion of respondent's sales force involved in the collection effort had had any earlier training or experience in selecting samples (Mattimore, Tr. 15374–79) or how the sales representatives chose the retail outlets for the collected samples (Mattimore, Tr. 15378). The record does not show that any attempt was ever made to randomize any phase of the selection process.

1166. The sales representatives were not asked to report on the condition of the samples (Mattimore, Tr. 15372). They received no instructions regarding the manner of shipping the samples (Mattimore, Tr. 15372–74). Thus, no means exist to determine how much disparity there was among the samples in terms of physical appearance and storage conditions at the retail level. No way exists to deter-