

5. Did F.D.A. indicate to your firm the source(s) of its sample(s) of your product(s) (acceptable or violative)? If your answer is yes, list the product(s) and their source(s) on a separate sheet.

Yes ----- 8
No ----- 36

6. Did F.D.A. indicate *when* the sample(s) of your product(s) were picked up? If your answer is yes, indicate the date(s) on a product-by-product basis on a separate sheet.

Yes ----- 8
No ----- 36

7. Is your firm able to identify either the source(s) of the sample(s) of your product(s) or the date(s) of sampling? If your answer is yes, indicate source(s) and date(s) on a product-by-product basis on a separate sheet. Do not include information on source(s) or date(s) provided by F.D.A.

Yes ----- 18
No ----- 24

8. Did F.D.A. specifically identify the lot or control number(s) of your product(s) (acceptable or violative)? If your answer is yes, indicate the lot or control number(s) on a product-by-product basis on a separate sheet.

Yes ----- 39
No ----- 7

9. Is your firm able to identify the lot or control number(s) of your product(s) (acceptable or violative) cited in the attached list? If so, please identify by lot or control number on a product-by-product basis on a separate sheet.

10. Please list your products in the attached list which *have not* been identified by lot or control number by either F.D.A. or your firm. Use separate sheet.

11. Does your firm have any reason to question the validity of F.D.A. methods or the statistical analysis of the results as the latter is related to sampling error or limits of variations? If your answer is yes, please qualify.

Yes ----- 36
No ----- 5

12. Has your firm undertaken an analysis of the product(s) (acceptable or violative) cited in the attached list which you have been able to positively identify? If so, indicate results in terms of percent active ingredient as related to potency declaration in labeling or U.S.P. and N.F. standards on a product-by-product basis on a separate sheet.

Yes ----- 42
No ----- 3

13. Does your firm plan to, or will you be willing to, undertake such an analysis of the product(s) which can be positively identified?

Yes ----- 38
No ----- 2

NOTE.—These two firms had done so prior to receipt of the questionnaire.

14. Has F.D.A. initiated any action or follow-up on the violative products of your firm?

	Yes	No
Additional samples -----	20	19
Reinspection of plant -----	12	24
Recall -----	2	32
Seizure -----	1	32
Citation -----	1	32
Other -----	4	26

15. Please add any additional comment, suggestion, or explanation which will assist us in the conduct of the project.

Company -----
Signed -----

Please return to Mr. C. Joseph Stetler, Pharmaceutical Manufacturers Association, 1155 Fifteenth Street, N.W., Washington, D.C., 20005, by February 24, 1967.