Thus, careful reanalyses of the products of 40 PMA member firms, alleged to be violative, show that only one percent did not meet standard potency limits.

Responses to Questions #2 and #3 are also highly significant.

Only six firms have reported being notified by FDA of alleged violations involving their products in the seven months following completion of the survey in June, 1966. Thirteen companies were suddenly notified in January, 1967, just a few days prior to public release by FDA of the more detailed survey results on January 31.

Responses to other questions reveal that FDA failed to advise 36 firms of the sources of the samples found to be violative. This is important, because it did not afford the firms an opportunity to check whether, for example, unusual storage conditions may have accounted for the potency violations alleged. Similarly, 36 firms were not told when the samples were obtained.

Twenty-three firms state that they have reason to believe there were more samples of their products obtained by FDA during the survey than were accounted for by FDA as either acceptable or violative when the results were finally published. For example, one company received a report on 79 samples (including four alleged violations found baseless on reanalyses), and has had no information on 36 additional samples obtained from the company by FDA at the same time.

FDA SURVEY OF DRUG POTENCY QUESTIONNAIRE 1966

(This is a copy of a questionnaire sent Feb. 10, 1967, by PMA to the presidents of 49 of its member firms alleged by FDA to have one or more violative products on the market. Replies for each question, supplemented with later information received from the firms, are shown.)

To be answered as completely as possible and returned to P.M.A. no later than Friday, February 24, 1967. Address replies to C. Joseph Stetler. Use additional sheets, if necessary.

1. Did your firm receive any information from the F.D.A. or from an F.D.A. inspector that samples of your products cited in the enclosed list (acceptable or violative) were to be the subject of this study?

Yes	8
No	36

2. Did your firm receive any private communication from the F.D.A. or from an F.D.A. inspector concerning the results of their analysis of your products (acceptable or violative)?

	Acceptable	*Violation*
Yes	1	22
No	33	20

3. When was your firm advised of either (1) or (2) above?

1. Date*
   - April 1966–7
   - August 1966–1
2. Date*
   - July 1966–1
   - August 1966–1
   - September 1966–1
   - October 1966–1
   - November 1966–1
   - December 1966–1
   - January 1967–13
   - February 1967–1
   - No date submitted—2

*Violative only.

4. Does your firm have any reason to believe that a larger sample of your product(s) than is cited in the attached list was obtained by F.D.A. for purposes of the study? If your answer is yes, list the product(s) and number of excess samples (by lot or control number, if possible) on a separate sheet. You may wish to use a composite sheet for answers to questions 4, 5, 6, 7, 8, 9, 10, 11.

Yes	23
No	20