

previously expressed that the time and funds required to obtain and list the specific source of each sample would not be justified. It is our considered opinion that such information is exceedingly important. Conditions of storage including temperature and humidity can have an important bearing on the potency of many drug products. Information concerning the source of samples can be provided to this office or directly to the firms involved.

Pursuant to the comment in your letter of March 15, I shall again advise our member companies involved, which have not already done so, to request the method of analysis for the specific alleged violative samples in question.

It will be greatly appreciated if prompt attention can be given to any inquiries directed to you or your staff by our member firms with respect to sample sources and methods of analysis. This information will assist us in completing our review of the overall survey which to us is a project of major significance.

Sincerely yours,

C. JOSEPH STETLER.

1966 FDA drug potency study comparative analysis

	P.M.A.	Non-P.M.A.
I. Total number of firms in study.....	84	162
II. Total number of products examined.....	1,933	2,640
(a) Generic.....	531	2,050
(b) Brand.....	1,402	590
III. Number of violative samples.....	119	257
IV. Average number of products per firm.....	23.0	16.3
V. Number of firms with generic and brand violations.....	5	29
Percentage of firms with generic and brand violations.....	5.9	17.9
VI. Number of firms with violations (generic or brand).....	49	78
Percentage of firms with violations (generic or brand).....	58.3	48.1
VII. Number of firms without violations.....	35	48
Percentage of firms without violations.....	41.6	51.8
VIII. Generic products:		
(a) Number of firms with generic products in study.....	53	134
(b) Number of generic products in study.....	531	2,050
(c) Average number of products per firm.....	10	15.3
(d) Percentage of generic products in total sample $\frac{IIa}{II}$	27.4	77.6
(e) Number of products sampled among violative firms.....	241	1,706
(f) Percentage violative samples among violative firms studied $\frac{g}{e}$	10.7	10.6
(g) Number of violative samples.....	25	175
(h) Percentage violative samples of generic products in total sample $\frac{g}{b}$	4.9	8.5
(i) Number of firms with violative samples.....	13	66
(j) Percentage of violative firms $\frac{i}{a}$	24.5	49.2
(k) Number of firms without violations.....	40	68
(l) Percentage of firms without violations $\frac{k}{a}$	75.4	50.7
IX. Brand name products:		
(a) Number of firms with brand name products in study.....	77	106
(b) Number of brand name products in study.....	1,402	590
(c) Average number of products per firm.....	17.9	5.5
(d) Percentage of brand products in total sample $\frac{IIb}{II}$	72.4	22.3
(e) Number of products sampled among violative firms.....	1,120	372
(f) Percentage violative samples among violative firms studied $\frac{g}{e}$	8.3	22.0
(g) Number of violative samples.....	94	82
(h) Percentage violative samples of brand products in total sample $\frac{g}{b}$	6.7	13.8
(i) Number of firms with violative samples.....	41	42
(j) Percentage of violative firms $\frac{i}{a}$	53.2	39.6
(k) Number of firms without violations.....	36	64
(l) Percentage of firms without violations.....	46.7	60.3