

V. Professional information—Continued

D. Control laboratory:

(Determine by checking on a specific product supplied by the hospital Pharmacist)

- | | Yes | No |
|---|-------|-------|
| 1. Does the company utilize outside control facilities? | ----- | ----- |
| 2. Does company have a quality control laboratory | ----- | ----- |
| a. List number of employees | ----- | ----- |
| b. Percentage of professional employees: | ----- | ----- |
| c. List name, education, and experience of head of the Control Laboratory: | ----- | ----- |
| d. List qualifications of all other professional employees (i.e. B.Sc. Pharmacy, B.Sc. Chemistry, etc.) (Use back of page if necessary) | ----- | ----- |
| 3. Does the control laboratory receive or collect samples and regulate the release of materials from: | | |
| a. Receiving Department (Raw Materials) | ----- | ----- |
| b. Manufacturing Department | ----- | ----- |
| In-Process goods | ----- | ----- |
| Finished Preparations | ----- | ----- |
| 4. Does the control laboratory have the final authority to reject items which do not comply with specifications? If so, are these items | | |
| a. Reprocessed? (By authority of -----) | ----- | ----- |
| b. Repacked? (By authority of -----) | ----- | ----- |
| c. Discarded? (By authority of -----) | ----- | ----- |
| 5. Are stability data on finished items awaiting shipment periodically collected and reviewed by the control laboratory? | ----- | ----- |
| 6. If tests are performed by an outside laboratory, does the company have a policy to spotcheck tests? | ----- | ----- |
| 7. If analytical control is performed by company itself, does the head of control laboratory check his use of "Dummy" products? | ----- | ----- |
| 8. List name and title of person interviewed: | ----- | ----- |

VI. Inspector's Comments:

A. Do inspector's recommend this company as a supplier of competitive Pharmaceutical products for use by J.M.C.H. Yes -----
No -----B. In the inspector's opinion, is a return visit indicated? Yes -----
No -----

[SIGNATURE] -----

(Name)

(Title)

(Date)

EXHIBIT 3

[From the Montefiore Hospital and Medical Center Pharmacy Bulletin, vol. 5, April 1967]

INVESTIGATIONAL DRUGS

Investigational drugs at Montefiore Hospital can be divided into two groups. The first group consists of drugs which are approved by the Food and Drug Administration (FDA) for the use intended by the investigator and which are on the market but which are not in the hospital formulary. Before using such a drug, it is only necessary to complete the Request and Approval for Investi-