APPENDIX "A"

SUPPLEMENTARY SUBMISSION TO THE HOUSE OF COMMONS SPECIAL COMMITTEE ON DRUG COSTS AND PRICES BY THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA, FEBRUARY 1967

As the Committee is no doubt aware, various witnesses who closed out the hearings gave testimony on several critical issues that is in conflict with evidence presented by Dr. Irwin Hilliard, the Canadian Medical Association, the Canadian Pharmaceutical Association, the Patent and Trademark Institute, and PMAC. Accordingly, we respectfully request that the Committee receive and give consideration to this supplementary submission in lieu of a further formal appearance by PMAC.

In his testimony, Mr. David Henry, director of investigation and research under the Combines Investigation Act, proposed that drug prices could be lowered by means of licensing imports. His proposal depends on the assumption that FDD can guarantee the safety and efficacy of all imported drugs. As Mr. Henry himself stated, if the FDD cannot provide this guarantee, "then the exercise comes to an end." The Directorate, of course, was never constituted to perform such a mommoth task. Dr. C. A. Morrell, testifying before the Committee on Drug Safety when he was FDD Director-General, said rightly that you cannot put "government-approved" on a drug.

His successor, Dr. Chapman, told your Committee in his last appearance that it is essential to inspect all imported drugs for purity and quality. But surely it is equally imperative, as has been pointed out by both Dr. Hilliard and the chief of FDD's pharmaceutical chemistry division, Dr. L. Levi, that safety should be considered in terms of efficacy. This, of course, applies not only to imported drugs but also to the question of compulsory licensing of secondary domestic manufacturers. Unless a secondary manufacturer can prove to FDD the clinical equivalency of his product, then he cannot rely on the medical information developed and provided by the originator through experience with his own preparation.

The problem of therapeutic equivalency is still an area of great complexity and limited knowledge, as evidenced in the recent announcement by the United States' Food and Drug Administration of a major research program with an initial expenditure of $5 million. In the public interest, we therefore urge the Committee to step warily in making any new recommendations that would create fresh problems in this area, at the same time repeating our wholehearted endorsement of the Hilliard Committee proposals which should be vigorously applied through new legislation or regulations.

Mr. Henry and Dr. Henry Steele, the associate professor of economics from Houston University who appeared on behalf of the Alberta government, have