eliminated the so-called "NDA backlog"—the FDA's Bureau of Medicine approved 83 drugs for marketing; approximately 2 dozen of these are considered to be new chemical entities.

The discrepancies in this figure and the one I mentioned earlier, Senator Nelson, is that of the 24, 10 of them were different dosage forms of the same chemical entity, but under the rules, they have to get a new NDA for each form.

Senator NELSON. If the new drug is approved and there are a dozen other drugs on the market that perform the same function as far as you can tell, the company in its advertising can't claim that it has anything, can it?

Dr. GODDARD. Not unless they can substantiate that claim. In fact, that happens sometimes, Senator. A drug, let's say, for example, a tranquilizer produced by 28 different firms, may be advocated in the advertising for minor psychiatric illnesses, tension states, anxiety—we might find almost anything that tranquilizers are good for. Another company may come along and do some entirely different research which shows that children who have, let us say, enuresis, benefit by the use of tranquilizers. That would be the only firm that could make a claim of enuresis relief in that advertising, despite the fact that the other 28 in the market have the same chemical compound. That is another irrationality.

During this same fiscal year, Senator Nelson, we received a number of other NDA's and found them not approvable. Five times as many NDA's were found to be not approvable as were found to be approvable. If, however, two groups of applications, those for pentaerythritol tetranitrate—PETN's—and dipyrones—which represent special problems—are excluded from consideration and further discussion, three times as many applications were found to be not approvable as were found to be approvable. The majority of those rejected were found to be deficient in several aspects. Forty-five percent of these unapprovable NDA's did not have enough animal safety data—generally, considerably more animal data are required for commercial marketing than for clinical trial. Seventy-two percent of the unapprovable NDA's did not show adequate clinical safety when used in humans; 76 percent were lacking in clinical efficacy; component and composition data were not adequate in 30 percent and 41 percent of the NDA's returned, respectively. In 71 percent of these NDA's the application did not stipulate manufacturing controls which we felt would assure a quality drug product. Samples submitted were unacceptable in 46 percent of those returned. And in 53 percent of these NDA's we refused to allow proposed labeling.

We can anticipate a claim by PMA that these refusals were based on our medical bureau's subjective judgments—with which they disagree.

We are prepared to present any of these NDA's to the scientific community for its evaluation of our actions if PMA will obtain agreements from its members to release the files.

Mr. GORDON. Would you be prepared to conclude that the work submitted to support the NDA's is pretty sloppy?

Dr. GODDARD. What I would say is that it is the present level of submission is not an acceptable level and we intend to take steps to correct these deficiencies.