those for which the precise dosage is particularly critical and where a bioavailability problem would create a health hazard—and digoxin was certainly an example of that kind of drug; and also those formulations with previously documented bioavailability problems.

And last, we will also publish in the near future a notice concerning the procedures we will follow in calling for and reviewing data about the potential for bioavailability problems with other drugs; that is, those without previously well-documented bioavailability problems.

Mr. Chairman, in my opinion, the issue of bioequivalency is currently being overdrawn. As we have learned more about nonequivalency problems, it has become clearer that they are limited in number and are manageable. And, again, I think the digoxin story is a classic example of the problem.

If I may speak for a moment to our relationship with other Government agencies. Many Government agencies are involved in the procurement of drugs. An organization called the Intra-Governmental Professional Advisory Council on Drugs and Devices was established to provide these agencies with a forum for the timely interchange of medical-technical information, and, through cooperative efforts, to improve the quality of drugs furnished to the agencies. Types of information exchanged include specifications, standards, and those involving quality control and inspection. The FDA is a charter member of this council.

Working groups have been established within the council for in-depth exploration of appropriate subjects and areas. These groups meet every 4 to 6 months, which provides an opportunity for informal contact and exchange of information of mutual interest.

The FDA supplies the DPSC with copies of FDA daily action reports identifying all seizures, prosecutions, injunctions, and recalls involving drugs. Since September of 1973, we have also been supplying DPSC with unevaluated copies of all notices of observations, the form supplied to all drug firms by our inspectors at the end of inspections. These documents represent the individual inspector's raw and unreviewed observations.

Representatives of the Bureau of Drugs maintain frequent contact with the various Federal purchasing agencies and continually respond to inquiries, both written and by telephone, from DPSC, Defense Medical Material Board, Veterans Administration, GSA, and Public Health Service Stock Pile Management, concerning firms and products. These inquiries generally involve such matters as the adequacy of labeling, "new drug" status of drugs, FDA inspectional and laboratory results, and tests, procedures or other data in New Drug Applications that have been submitted to us.

In addition, when a drug is to be recalled from the market and we determine from distribution reports that the firm has supplied the drug to DPSC, VA, or other Government agency, we notify that agency of the recall. It is then the responsibility of that agency to insure appropriate recall of the drug under its control.

When we receive a report through our Drug Defect Reporting System, the DPSC is notified whenever the report originated from