It is irresponsible for HEW to state that the FDA regulatory program provides adequate assurances of uniformly acceptable quality for all currently marketed drugs. Given the large number of U. S. and foreign manufacturers and products and FDA's limited resources, the agency is simply not in a position to provide such assurances.

FDA itself has acknowledged that it cannot inspect every drug manufacturing establishment even once every other year. Indeed, recent FDA figures confirm that scores of drug plants have not been inspected in more than three years. For example, the FDA reported in 1974 that 141 establishments had not been inspected since 1970.[2/] And a March, 1973, GAO report to Congress stated that one-fourth of the drug firms studied had not been inspected within the required two-year period.[3/]

To be sure, the FDA plant inspection program is supplemented by batch certification for antibiotics, insulin and digoxin and by random sample analysis conducted at the National Center for Drug Analysis in St. Louis. But these programs are not sufficient to assure uniform product quality. For example, during 1973 FDA analyzed approximately 9,000 samples of drug products and projected an analysis of 15,000 samples in 1974.[4/] Yet this testing covers only a very small fraction of the hundreds of thousands of lots of available products. And, of course, these analyses are, for the most part, chemical tests, and therefore do not assure more than chemical equivalence at best.

In light of the FDA's inspection record and the severe limitations of its overall drug surveillance program, it is not surprising that the number of drug recalls for safety, potency and other problems remains consistently high. And these recalls persist despite the fact that in most cases the drugs are presumably formulated in