DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

the agency's thinking to sponsors of clinical trials in the business community and the academic research community about their obligations under FDAAA. The [illegible] when finalized, will [illegible] year.

Let me turn to your specific questions.

1) Do the findings of the new study outlined above [illegible] compliance with reporting requirements [illegible] section 801 of FDAAA? Please summarize [illegible]

NIH's internal compliance data.

The FDA conducted a preliminary [illegible] and identified a number of factors that influence the [illegible] authors on a public Web site [illegible] of applicable clinical trials that are not known within the established timeframe, [illegible] sponsors outlined in FDAAA. For example, [illegible] provides for a potential delay in submitting the results for [illegible] up to three years after the completion date [illegible] ing on ClinicalTrials.gov. These factors illustrate the complexity of accurately measuring compliance [illegible]

[illegible] statutory changes [illegible]

[illegible] equip[illegible]ed to comply with the requirements, and the [illegible]DA will be able [illegible] enforce [illegible] ufelh mote[illegible]ly. At this juncture, it would be premature to conclude t[illegible] statutory chan[illegible]

the agency's thinking to sponsors of clinical trials in the life sciences community and the academic

parties

results

of FDAAA? Please summarize

compliance with reporting requirements by section

NIH's internal compliance data.

ta used by Prayle (made available by the

The FDA conducted a preliminary review of the

ave

not

under FDAAA.

2) Does NIH have adequate resources and authority to oversee reporting requirements?

NIH has sufficient resources and authority to implement the reporting requirements.

3) *Does NIH believe additional*

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland

D.C. 20515

Dear Representative Markey:

Thank you for your February [illegible] regarding the January 3 issue of the [illegible] *Medical Journal (BMJ)* on compliance with mandatory reporting of results to Clinical Trials.gov. Y[illegible] interest[illegible] important. identical letter is being sent to R[illegible]

there is no question that [illegible]

and results components of the [illegible] Act. Since [illegible] (FDA) to [illegible]

the NPRM currently in de[illegible] uncertainty about

Francis S. Collins, M.D., Ph.
Director