

## **Justification for No Material/Nonsubstantive Change**

NHANES is a survey that is continuous. The unique aspect of NHANES is that the survey involves physical examinations in a mobile examination center (MEC). We operate in two year cycles—that is, some of the content changes every two years. Any content change in the MEC involves a lot of programming changes and testing of the software and protocol. We have to do the testing in the MEC that is being use continuously by the ongoing survey. Because we operate in this manner we included justification and burden hours in our OMB package for the 2007-8 survey cycle for pilot and methodological studies that needed to be conducted in 2007-8 for the 2009-10 survey planning.

We referenced the need to do this throughout the approved package. Here is what we said in the approved OMB package specifically related to the burden table:

“Maximum burden hours for ongoing process improvement and pilot testing are included” and “ Pilot tests or methodological studies to develop new NHANES components are also included in the line 6 burden.”

The NHANES Conditions of Approval stated the following:

“With respect to conducting any pilot or nonresponse studies, OMB should be provided with a formal request that describes the specific study design, need for the information, and response burden. OMB will respond within three weeks indicating approval, disapproval, or passback exchanges seeking further information. No pilot or nonresponse studies should be conducted without receipt of approval from OMB.”