- We recall reviewing an FDA regulation that provided for a "lookback" period to screen the blood supply for Hepatitis C (Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection ("Lookback"). Is this ICR associated with that rule? Yes, that rule was approved on 10/5/2007 under 0910-0610 (aka 0910-0460) .

- Please explain why FDA is merging 0910-0460 and 0910-0116. As applicable, we try to consolidate packages with similar regulations, e.g. 21 CFR part 606. In this case, 0116 already had the HIV lookback regulations. When the HCV lookback final rule was published, it revised some of the regulations in that package, e.g, §§ 610. 46 and 610.47. Therefore, we consolidated these two packages since the regulations overlapped. Also, there is no record of an OMB control number 0910-0460: please clarify and provide a brief summary of what 0910-0460 was for. In a 2/2001 OMB Notice of Action for the HCV lookback proposed rule, it stated to reference 0910-0460 for any future submission. When we submitted the HCV lookback final rule package, we referenced 0460 on the Supporting Statement. However, OMB assigned a new number 0910-0610 when it approved that package. We inadvertently used the 0460 OMB number in #15 that we referenced on the Supporting Statement rather than the newly assigned 0610 OMB number.

- What was the "one time burden" estimated in 0910-0460 of 456,280 hours? The "one-time burden" in 0460 was comprised of 284,080 hours of reporting burden for §§ 610.48(b)(3)(ii) and (iii), (b)(4), and (c)(4). It was also comprised of 172,200 hours of recordkeeping burden for §§ 606.100(b)(19), (b)(1)(viii), and 610.48(c)(3). This "one-time burden" for these regulations was for the establishment of written procedures and doing a restrospective review of historical HCV testing records. These regulations are referenced in Tables 2 and 4 , respectively of the 0460 Supporting Statement. These Tables and discussion are in #12 of the 0460 at Supporting Statement. If the current total for 0460 is 495,309.5 hours and the one time burden is 456,280 hours, what accounts for the remaining hours? As stated in #12 of the 0460 Supporting Statement, the remaining 39,029.5 hours was for the ongoing annual burden for collecting establishments to comply with the regulations for HIV and HCV lookback (see Tables 1 and 3 in the 0460 Supporting Statement). Please specify which burdens in table 1 and 2 of the supporting statement are attributable to 0116 and which are attributable to 0460. Please see attached document. We have highlighted the applicable regulations for each package in the attached document. The yellow highlights represent the regs from the previous 0116 package. The blue highlights represent the regs from the 0460 package. However, as referenced above, a couple of the regulations in the previous 0116 package were revised by the HCV final rule and are therefore designated as from the 0460 package.

<<0116ss10-23-08CLEAN.doc>>

- Please provide a more detailed explanation for why the burden estimates are changing in #15. For example, the response discusses the revised estimate for the total annual records under 606.160. Please indicate where in the supporting statement this revised estimate is discussed. On what basis are the estimates being revised? The explanation only seems to state that the estimate for 606.160 is being reduced by 150,000 and the one-time burden in 0910-0460 is being eliminated. At most, this accounts for only 606,280 hours. The recordkeeping estimate for §§ 606.160 and 606.165 are generally discussed in #12 for 0016. The estimate that the majority of the recordkeepers collect 99% of the blood supply up from 98% was revised based on a review of the estimates by our Office of Blood Research and Review. As stated in #15, there was an overall decrease of ~633,000 hours from the combined 0116 and 0460 packages. As already stated, approximately 606,000 hours was from the elimination of the one-time burden and reduction in § 606.160. The remaining decrease of ~ 27,000 hours can largely be attributed to a decrease of ~ 16,500 hours under § 606.165 and ~ 7,000 hours under § 630.6(a) (for a total

decrease of ~ 23,500). The decrease for §§ 606.165 and 630.6(a) are also due to the impact of revising the estimate from 98% to 99%. The reporting estimate for § 630.6(a) is also discussed #12 for 0116. The remainder (~ 3,500 hours) does not appear be attributable to any one particular regulation.

- Please provide more detail as to why the number of responses is increasing by 2.48 million.
  The number of responses didn't increase by 2.48 million. In the 2005 ICR submission, the wrong number of responses was uploaded. This ICR corrects that error.