ATTACHMENT B
EXAMPLES OF TWO CENTERS' RR SURVEYS ISSUES THAT DIDN'T NEED IMMEDIATE TURN AROUND TIME (versus the example in the Justification Statement about the implanted cardiac defibrillator which would have required very fast approval from OMB)

CFSAN MILK SURVEY:

Justification:
Grade "A" milk processors must comply with their State's Grade "A" Milk Program, each of which is based on the United States Public Health Service (USPHS)/FDA Model Ordinance commonly known as the Pasteurized Milk Ordinance (see http://www.cfsan.fda.gov/~ear/pmo03toc.html). During quarterly inspections and validations, the State regulatory agency inspectors verify and document that the required minimum pasteurization time and temperatures are in compliance. FDA believes that most Grade "A" milk producers pasteurize at holding times and temperatures above the current minimum stated in the Pasteurized Milk Ordinance. However, FDA believes that there is a need to collect and assess the actual pasteurization holding time and temperature processes used. FDA requests OMB approval of the Rapid Response Survey titled, "Milk Pasteurization Time and Temperature Data Collection."

FDA will communicate the survey to the States through the instrument attached as Attachment A, which is comprised of a cover letter of instructions, a signature page and the survey instrument. Response to the survey is voluntary. The data will be collected by the State Grade "A" Milk Program Regulatory Inspectors during the routine quarterly inspections, the routine biannual pasteurization equipment validations or from records of the most recent pasteurization equipment validations. The information to be collected will include the actual pasteurization holding times, pasteurization temperatures, pounds of fluid milk produced in specific timeframes, and plant identification for each fluid milk product (for final consumer packaging) for each milk plant. The information will be used to support FDA's public health mission of oversight of Grade "A" milk and milk products.

CDRH NEGATIVE PRESSURE WOUND THERAPY DEVICE:

Justification:

1. Need for survey: The FDA has received reports of deaths and serious injuries with products that migrate into the home and other extended care facilities, specifically with negative wound therapy systems.

   The following bullets summarize reported device and patient problems with negative wound therapy systems:

   - Bleeding is the most serious adverse event which indicates 7 reported deaths and 17 injuries.
   - Treatment of these patients included a visit to the Emergency Room, hospitalization, additional surgical procedures and blood transfusions.
   - Extensive bleeding occurred at lower extremity vascular graft sites. Other events occurred during dressing change due to foam adhesion to the wound.

- Majority of events occurred either at home or in long term care facilities.

The FDA currently has insufficient information to gauge whether or not these types of issues are rare events or occur more frequently. With this data collection, the FDA seeks to understand the nature of the problem and attempt to determine if the problem is a widespread public health issue. Due to the level of concern at the FDA about these devices, a Center-wide Network Team has been established to examine this issue. The results of this data collection, in addition to other data sources, will assist the Network Team as it formulates next steps.