DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MD 21702-5012

REPLY TO
ATTENTION OF

OCT 10 2006

Office of the Commander

Division of Dockets Management (HFA-205)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

A Presentation to Public Hearing regarding Guidelines on Emergency Research Conducted without Informed Consent under FDA's Emergency Research Rule.
Docket No. 2006D-0331

On behalf of the U.S. Army Medical Research and Materiel Command, I welcome the guidance proposed by the Agency to further explain the procedures to be followed when an exception from the informed consent requirement for emergency research is requested.

As an organization committed to developing products to provide America's military Forces with the best emergency and intensive care possible, I recognize that the research community at large is in need of clear, practical guidance in order to protect all potential participants in research.

Furthermore, I understand that the burden of morbidity and mortality from trauma on the American population is great with trauma as a leading cause of death responsible for over 160,000 deaths in the U.S. annually. These sobering statistics underscore the reality that the products currently available do not adequately address the Nation's trauma treatment needs. New technologies ***must*** be evaluated using scientifically sound methods in relevant patient populations.

With this clear guidance, sponsors and researchers can prepare meaningful research protocols that appropriately address the critical priorities of informing the community and protecting potential research participants. Additionally, Institutional Review Boards will better understand their responsibilities in reviewing protocols seeking exemptions from informed consent regulatory requirements.

Sincerely,

Eric B. Schoomaker, M.D., Ph.D.
Major General, US Army
Commanding General