DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 22, 2004

The Honorable Tom Davis
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Chairman:

I am writing in response to your October 13, 2004 letter regarding the problems that have arisen relating to Chiron Corporation's influenza vaccine, Fluvirin, for this flu season. I was pleased to provide testimony before your Committee on October 8, 2004, and I want to assure you that FDA is working diligently to respond to your request and to assure you that it is a high priority.

As you know, we are working hard to assure the safety and health of Americans as the flu season approaches. In coordination with the Department of Health and Human Services (HHS), we have been actively exploring all viable options to secure additional dosages of safe and effective flu vaccine that will provide more Americans protection against the flu. As a result of these efforts, I can report that we have been able to increase the available supply of flu vaccines for the U.S. population to 61 million doses for this flu season.

Coupled with that initiative, we have been contacting manufacturers worldwide in an effort to identify increased supplies of antiviral medications that will provide further protection and treatment for Americans during this flu season and are making progress in this area as well. Finally, we have already been working with our partners in the United Kingdom, as well as with Chiron, to complete our review of the problems encountered at their production facility in order to expeditiously determine what steps would be required to bring that facility into compliance. I'm sure you will agree that all of these efforts are of the highest priority and will undoubtedly save lives.

My team that is working hard to secure more flu vaccine, antiviral medication, and complete its investigational work at Chiron Corporation's manufacturing plant is the same team that maintains the responsive materials that you have requested. While we are working diligently to compile all of the materials and will continue to fully cooperate with your Committee's review, in an effort to balance all of these priorities, I am respectfully requesting additional time in order to respond to your request.

Thank you for your consideration in this matter. I look forward to working with you on this important public health matter.

Sincerely,

Lester M. Crawford, DVM, PhD
Acting Commissioner of Food and Drugs