



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JAN 14 2015

Dear Mr. Chairman:

Thank you for the opportunity for the Food and Drug Administration (FDA) to testify at the December 10, 2014, hearing before the Subcommittee on Health, entitled "Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients." This letter provides responses for the record to questions posed by Subcommittee Members during the hearing.

If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas A. Kraus", with a long horizontal flourish extending to the right.

Thomas A. Kraus
Associate Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking Member

We have restated your questions below in bold type.

Chairman Joseph Pitts

1. How long does the consultation process typically take?

The time frame for an FDA consultation depends upon the quality of the submission the Agency receives and the complexity of the scientific issues considered in the submission. Other factors, such as public health priorities in the program offices charged with evaluating submissions, may also affect the time frame. When the Agency receives high-quality, well-prepared consultation submissions that adequately address all of the relevant safety and regulatory issues, we can complete our evaluation in approximately one year. However, when there are questions that require the developer to provide more information or conduct further studies, or when the submission raises novel or complex regulatory issues, our evaluation takes longer. Generally, however, the process takes approximately one to two years. In a few rare cases, we have had some consultations take up to three years to complete.

Representative Marsha Blackburn

1. How frequently do FDA analysts go back to those engaging in the voluntary consultation process to ask for additional information?

FDA scientists commonly ask for additional information as part of the consultation process. A typical consultation has at least one set of questions sent by FDA to the developer. These questions can range from requesting additional data to requesting clarification of material presented in the submission.

Representative Gene Green

1. How many new consultations are conducted each year, and how long do they take?

The number of submissions received each year varies. In recent years, we have received at least five submissions, with as many as a dozen being received in other years. The time frame for an FDA consultation depends upon the quality of the submission FDA receives and the complexity of the scientific issues considered in the submission. Factors such as other public health priorities in the program offices charged with evaluating submissions may also affect the time frame. Generally, the process takes approximately one to two years, but in a few rare cases, as many as three years.