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# Congress of the United States

House of Representatives

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November 22, 2004

Dr. Lester Crawford  
Acting Commissioner  
U.S. Food and Drug Administration  
5600 Fisher Lane  
Rockville, Maryland 20857

Dear Commissioner Crawford,

On November 17, 2004, you were among the witnesses who testified before the House Government Reform Committee at a hearing on the Nation's Flu Shot Shortage. During this hearing, I stated that the flu situation has already led to the death of four people in New York City and congratulated New York City Mayor Michael Bloomberg for working with the States of Illinois and New Mexico to acquire 200,000 doses from European suppliers. To ensure that these doses reach those in greatest need in the most timely manner, I joined in writing a letter with 8 members of the New York Congressional Delegation on November 15, 2004, to ask that you expedite the process for review of those doses (enclosed). To that end, at the hearing, I inquired about the status of the approval process.

I write to seek clarification about the process and timeline for approval of the vaccine doses being sought by NYC, IL, and NM.

At the hearing, I asked you to explain the process for getting the much-needed flu vaccine to New York City residents and when we could expect the vaccine would be made available. You testified that you received the flu vaccine lot numbers and they had been authenticated for the IL, NYC, NM purchase and that you hoped to get the pedigree information and know where those lots had been. You further testified that once FDA receives the pedigree information which should take, 2-3 days and that FDA's determination regarding approval would come shortly thereafter.

For clarification, please explain what you mean by reviewing the pedigree and what the review entails? Further, please outline in detail, the processes that are yet to ensue and the various timelines for such processes - for the NYC, IL, NM acquisition. I understand this is a very complicated issue, so I would like to better understand it. In short, I would like to know

when NYC high-risk individuals can expect to have the vaccine available.

I thank you for your assistance in this matter. I look forward to your response to this letter in the very near future.

Sincerely,

A handwritten signature in black ink, appearing to read "Carolyn B. Maloney". The signature is fluid and cursive, with the first name being the most prominent.

**CAROLYN B. MALONEY**  
**Member of Congress**

Enclosure