

## **Egan, William**

---

**From:** Cole, Elaine  
**Sent:** Thursday, September 09, 2004 11:27 AM  
**To:** Meyer, Mary; Cohen, James S; Levandowski, Roland A.; Strickland, Dennis; Malarkey, Mary; Baylor, Norman; Eltermann, John  
**Cc:** Egan, William; Midthun, Karen; Goodman, Jesse; Morrison, Ellen F  
**Subject:** Conference call summary- Chiron 's Fluvirin

This email summarizes a 9/9/2004 conference call among Chiron staff (multiple locations), CDC and CBER (Dr. Egan and I) to update all parties on the status of Chiron's investigation into the non-sterility of certain not-yet-marketed lots of their influenza vaccine.

Chiron is continuing its planned investigations into the non-sterility finding; work is on track and they are confident that they will be able to identify the root cause of the problem in time to have 46-48 million doses available to the US market in early October 2004. Product will not be distributed until all of the data are evaluated. (Testing so far has included in-house lots as well as tests on earlier stages of the production process, with negative test results.)

Chiron has seen only limited media coverage recently; most of that has been articles in local press, rather than national coverage.

Chiron plans to issue a press statement to update the public in the next week or 2 to summarize the progress of their investigation. They will send the statement, or at least the concepts if not the actual document, to FDA and CDC a day or 2 before it issues, so that the federal agencies will be able to respond to inquiries about it.

An MMWR issue goes to print on 9/24 and will contain an update on flu vaccine availability, including the general nature of the upcoming Chiron press statement (lead time issues for the MMWR will likely preclude the actual Chiron statement being in CDC's article.)

Since there have been some rumors in the healthcare/immunization community about possible flu vaccine shortages, FDA and CDC will be in contact with each other to potentially post a short statement to dispel fears of shortages and to state that, overall, more vaccine is expected to be available this season than last year. (OCTMA and OCBQ, please note.)

Chiron reported that the Senate Ageing Committee (chaired by Larry Craig?) may have an exploratory hearing in the near future on the availability of flu vaccine and its impact on the health of senior citizens. This committee held a similar hearing in 2000 or 2001.

(Another status update call will be held in a week.)