Is the Flu Vaccine Supply in Jeopardy?

THE QA PHARM

By THE QA PHARM

 The answer depends on who you listen to: the FDA or the EVP at CSL Biotherapies.

According to the FDA Warning Letter issued on June 15, 2011, the issues are among the most significant as any we have seen in recent years following the company withdrawal of the vaccine after reports of seizures with use in children.

Any observer and student of FDA enforcement recognizes the serious combination of observations:

- No documentation of adverse events.
- Lack of production and process controls.
- Inadequate investigations into batch or component failures.
- Failure to reject components that did not meet specifications.
- Inappropriate laboratory methods.

The list is lengthy. The list is significant. The list is serious.

And the Warning Letter is topped off with the universal conclusion that we have seen with McNeil, BMS, Ningbo Smart and others reported in this blog — “Your Quality Unit is not fulfilling its responsibilities.”

When the FDA doubts the Quality Unit — it doubts everything.

So what about the flu supply from one of the world’s largest flu vaccine manufacturers? Are they too big to fail? Will they be permitted to supply the U.S.?

Don’t count on it.

Remember the 2003 production problems at Chiron’s Liverpool flu vaccine manufacturing plant? Remember the shortage? Remember the politics and congressional hearings?

So what’s different this time? Let’s hope a lot.

For starters, the Warning Letter was issued within a record two and a half months of the inspection. Also, the FDA requested a meeting with the CEO and other senior management, which is the equivalent of saying, “We’re in this mess together.”

So, how does the EVP at CSL view their issues?

Mr. Jeff Davies, CSL’s EVP was interviewed on “PM with Mark Colvin” on June 22, 2011.

Mark Colvin asked Mr. Davies why he thought that CSL failed to satisfy the FDA. Mr. Davies replied, “I think they’re just concerned how we documented that process.”

It’s going to be a very interesting meeting with the FDA if CSL’s going in position is that it’s all a matter of paperwork.

Let’s hope for the global flu vaccine supply that it isn’t.

What are your thoughts? Please comment below.