

Zavagno, Denise

From: Sinclair-Jenkins, Bernadette [Bernadette.Sinclair-Jenkins@mhra.gsi.gov.uk]
Sent: Wednesday, October 06, 2004 10:49 AM
To: Zavagno, Denise
Subject: RE: questions regarding the suspension

Dear Ms Zavagno

I am writing to confirm receipt of your e-mail. I have forwarded your e-mail to the MHRA's legal advisor for consideration.

Bernadette Sinclair-Jenkins
Manager, Divisional Secretariat, Policy and Borderline Unit
Inspection and Enforcement Division
MHRA

-----Original Message-----

From: Zavagno, Denise [mailto:DZavagno@OC.FDA.GOV]
Sent: 06 October 2004 15:34
To: Sinclair-Jenkins, Bernadette
Cc: Raza, Mark
Subject: questions regarding the suspension

- > Ms. Sinclair-Jenkins,
- >
- > Thank you so much for speaking today with Mr. Mark Raza and me regarding
- > the suspension of Chiron's license to manufacture flu vaccine. As we
- > explained, we are requesting a copy of the law or regulation which
- > provides the licensing authority in the United Kingdom with the power to
- > order the suspension, so we can better understand how this action affects
- > the supply of flu vaccine by Chiron. We also have the following questions
- > about the suspension:
- >
- > 1. Under the law or regulation that led to the suspension, does the
- > manufacturer have any remedies once the suspension is ordered? Can the
- > manufacturer ask for a hearing, or request that the amount of time
- > designated in the suspension letter be shortened? Can the manufacturer
- > ask that the batches or lots be retested? Are there any provisions for
- > reconditioning the lots?
- >
- > 2. Could you please explain how the suspension order affects lots that
- > were manufactured since March 2? Why was this date chosen? Could you
- > please generally describe the evidence to support the fact that lots
- > manufactured more than seven months ago are implicated?
- >
- > 3. What is the status of the lots that have already left the UK and are
- > physically located in the USA? Who is in control of those lots and who
- > has authority to release them. We understand that a "qualified person"
- > must release them, and that the "qualified person" is an employee of the
- > manufacturer, but how does he know when and if to release lots? How does
- > the authority of the MHRA reach these lots once they have left the UK?
- >

10/19/2004

> Thank you very much for forwarding these questions to your legal
> department. Please do not hesitate to give us a call at the number we
> provided this morning, if you have any questions or comments.

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> Denise M. Zavagno
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> Food & Drug Division, OGC
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