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 authoriy of the MHRA reach these lots once they have left the UK?
>

> 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
> 301-827-1134
> dzavagno@oc.fda.gov
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