



# SOLVAY PHARMACEUTICALS

## BUSINESS GROUP INFLUENZA

P.O. Box 900  
1380 DA Weesp  
The Netherlands  
Trade register Hilversum No. 32039508

To : Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852  
USA

Date : October 28, 2004

Subject : CBER Regulatory Site Visit Training Program  
Your reference: Docket No. 2004N-0408  
Our reference : JM/jm/3360/letter/04.110

Dear Sir, Madam,

Herewith I would formally like to express the interest of my company to participate in the CBER Regulatory Site Visit Training Program as described in Docket No. 2004N-0408 published in the Federal Register, volume 69, no. 184 on September 23, 2004.

Solvay Pharmaceuticals is an EU-based mid-size pharmaceutical multinational, represented in the US by Solvay Pharmaceuticals Inc., Marietta (GA). It has over 50 years experience in influenza vaccine manufacturing, currently marketing almost 10% of the global volume of influenza vaccines and one of the top four manufacturers. Additionally we just completed the construction of a approximately 36,000 sqft cell culture-based influenza vaccine manufacturing facility next to the classical egg-based facility on our site in Weesp (NL), which will drastically increase our vaccine production capacity. This cell culture-based facility will be used to generate product for the markets in which we currently are present with the egg-based vaccine, but we also intend to introduce the cell culture-based vaccine in the US. Therefore we have started discussions with CBER and are performing a development program to obtain a marketing authorization for the US.

The actual vaccine shortages in the US show the vulnerability of influenza vaccine manufacturing and therefore we are very interested to participate in this initiative to provide an avenue for open dialog with CBER. Any input on this new technology platform is very much appreciated and will guide us in the introduction of this technology in the US, thereby supporting public health authorities in adding an option to solve some of the vulnerability issues. This very situation of vaccine shortages however is also the reason for the submission of our request to participate later than the deadline of October 25; I apologize for that, but taking the unusually hectic situation into account I hope you still are willing to take this request into consideration.

Overall we hope that the timelines for qualification, validation and commercial operation of our cell culture-based influenza vaccine facility can fit with the Regulatory Site Visit Training Program. However, we appreciate your understanding that we may have certain reserves to actual requests for site visits, as these may not fit with facility start up activities. Could you therefore provide us with more information about what the effort of Solvay will be to support the Regulatory Site Visit Training Program, if these visits will

*Confidentiality. The information in this letter is confidential. It is intended only for the use of the named recipient. If you are not the intended recipient, please notify us immediately so that we can arrange to collect this letter from you. You should not disclose the contents to any other person, nor make any copies.*

2004N-0408

LET 3



mimic a regular CBÉR inspection, how long they will take and what kind of feedback will be given to Solvay.

If you need any additional or more detailed information, please do not hesitate to contact me.

Kindest regards,

Jeroen Medema  
Business Group Influenza, research and development  
Solvay Pharmaceuticals  
Tel (+)31 294 477314  
Fax (+)31 294 477160  
e-mail jeroen.medema@solvay.com

Confidentiality. The information in this fax is confidential. It is intended only for the use of the named recipient. If you are not the intended recipient, please notify us immediately so that we can arrange to collect this fax from you. You should not disclose the contents to any other person, nor make any copies.

TEL 3

8090-UP006