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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852

To Whom It May Concern:

Attached please find electronic comments submitted to docket number 2004N-0408, Regulatory Site Visit Training Program. This document serves as a paper response to this docket.

If you have any questions or concerns, please contact me at 856-424-6200 or suzanne.sensabaugh@sicor.com.

Sincerely yours,

Suzanne M. Sensabaugh, MS, MBA
VP, Regulatory Affairs
SICOR Inc., Biotechnology Division

2004N-0408

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Docket Management Comment Form
Docket: 2004N-0408 - Regulatory Site Visit Training Program
Temporary Comment Number: 11340

Submitter: Ms. Suzanne Sensabaugh	Date: 10/18/04
Organization: SICOR, Inc.	
Category: Drug Industry	
Issue Areas/Comments	
General	
<p>SICOR Inc., a biopharmaceutical company involved in the discovery, development, manufacturing and marketing of biopharmaceutical generic products (termed 'follow on protein products' by FDA) is offering site visits of its facilities located in Vilnius, Lithuania and Toluca, Mexico. SICOR Inc. has been in the business of recombinant protein product manufacture for 20 years. At least 9 million doses have been given in over 17 countries for one of our products. Drug substance and drug product are produced in state-of-the-art manufacturing facilities devoted to the production of biotechnology products. These facilities were designed and constructed according to current cGMP standards of both the European Union and United States and have received a GMP certificate from the Therapeutic Goods Administration (TGA), Australia. Although the regulatory authority for innovative therapeutic protein products resides with CDER, CBER remains active in policy making in this area. SICOR Inc. presented data and information on our biopharmaceutical generic products in the public workshop 'Scientific Considerations Related to Developing Follow-on Protein Products' on September 14 and 15, 2004, to CBER scientific staff. Participation by SICOR Inc. in the CBER Regulatory Site Visit Training Program will improve the mutual understanding and provide an avenue for open dialog between FDA and a company in this industry. SICOR Inc. wishes to also include CDER staff in this site visit request as the knowledge gained from such a visit will also benefit CDER scientific staff who are responsible for decision making in this product area. Thank you for the opportunity to participate in this program. Please address all questions to Ms. Suzanne Sensabaugh, VP, RA, SICOR Inc., Biotechnology Division, 856-424-6200 or suzanne.sensabaugh@sicor.com.</p>	
Attachments	
No Attachments	





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