

February 8, 2001

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

Re: Docket No. 00N-1669 - Request for Participation in Pilot Program

Dear Sir/Madam:

Gensia Sicor respectfully requests consideration as a volunteer to participate in the pilot project involving the electronic filing of drug registration and listing information. Pursuant to Docket No. 00N-1669, the following information is provided:

Participant's Name:

Rosalie A. Lowe, Director, Regulatory Affairs

Company Name:

Gensia Sicor Pharmaceuticals, Inc. 19 Hughes, Irvine, CA, 92618-1902

Company Address:

(949) 457-2808

Telephone Number: Number of Listed Products:

Approximately 113

Number of Registered Facilities:

s: 1

Types of Products Processed:

Human

Processes Performed: Kind of Product Processed: Manufacture, Distribute Prescription Parenterals

We would appreciate a more detailed scope of the project to confirm that the electronic transfer of information can be appropriately cleared through Gensia Sicor's firewall.

Thank you in advance for you consideration. Please feel free to contact me at the number listed above.

Sincerely,

Rosalie A. Lowe

Director, Regulatory Affairs

RAL:wp

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00N-1669

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From: Regulatory Affairs (949)455-4794 GENSIA SICOR PHARMACEUTICALS 19 HUGHES ST

SHIPPER'S FEDEX ACCOUNT #

FedEx.

IRVINE, CA, 92618

To: Dockets Management Branch (301)594-0340

Food and Drug Administration

5630 Fishers Lane, Room 1061 HFA-305

Rockville, MD, 20857

Ref: 4830



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