Catalytica
Pharmaceuticals

2453 '01 JAN 17 A10:51

January 12, 2001

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

Re: Participation in Pilot Project [Docket No. 00N1669]

To Whom It May Concern:

Catalytica Pharmaceuticals, Inc. (C*P) would like to participate in the pilot project for Electronic Filing of Drug Registration and Listing Information as published in the Federal Register Notice on January 9, 2001 Docket No. 00N1669. As a contract manufacturer, C*P is presented with a variety of product listings which could provide a diversity of potential issues that would challenge the prototype system.

C*P has a registered establishment in Greenville, North Carolina with approximately 100 products listed. The Greenville site produces human, biologic, and veterinary products which are prescription, over the counter, and active pharmaceutical ingredients. Currently, products are manufactured and/or repackaged at the site.

The following individuals would be participating on behalf of Catalytica Pharmaceuticals, Inc.

Name, Title	**Contact number**
Beverly Lewis, Directory Regulatory Affairs	252-707-7913
Jacqueline Hackett, Regulatory Technical Specialist	252-707-3252
Sandra Pollard, Regulatory Publisher	252-707-2154

Any correspondence should be mailed to my attention at Catalytica Pharmaceuticals, Inc. P.O. Box 1887, Greenville, North Carolina 27835.

Sincerely,

Jacqueline E. Hackett

Jacqueline Hackett
Regulatory Technical Specialist

cc: Sandra Pollard

00N-1669

Catalytica Pharmaceuticals, Inc.
P.O. Box 1887
Greenville, NC 27835-1887
252-758-3436
www.catalytica-inc.com

Lb 3

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GREENVILLE NC
USA 27835

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ROCKVILLE MD
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TO: Dockets Management Branch (HFA-305)
NAME
FDA
ATTENTION
5630 Fishers Lane, Room 1061
STREET ADDRESS
Rockville MD 20852
CITY STATE ZIP CODE

Catalytica Pharmaceuticals
Intersection US 13 / NC 11 & US 264
PO Box 1887
Greenville, North Carolina 27834

016217

PURCHASE ORDER NO.	RETURN AUTHORIZATION NO.	CONSIGNEE PHONE NO.