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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, TitleContact numberBeverly Lewis, Directory Regulatory Affairs252-707-7913Jacqueline Hackett, Regulatory Technical Specialist252-707-3252Sandra Pollard, Regulatory Publisher252-707-2154

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

Sincerely,

Jacqueline Hackett

Regulatory Technical Specialist

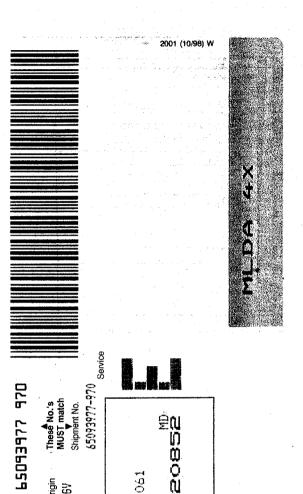
cc: Sandra Pollard

Catalytica Pharmaceuticals, Inc.

Greenville, NC 27835-1887 252-758-3436

www.catalytica-inc.com

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Catalytica Pharmaceuticals Intersection US 13 / NC 11 & US 264 PO Box 1887 Greenville, North Carolina 27834 TO: ZOSSZ ZIP CODE MD

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