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April 16, 2001

VIA HAND DELIVERY

Mr. Mark J. Langer, Clerk
United States Court of Appeals
for the District of Columbia Circuit
U.S. Courthouse, Room 5423
33 Constitution Avenue, N.W.
Washington, D.C. 20001

Dear Mr. Langer:

Enclosed for filing, please find an original and four copies of the Petitioner's Motion to Hold Judicial Review Proceeding in Abeyance Pending Further Action By the U.S. Nuclear Regulatory Commission. Also enclosed are two additional copies for date/time stamping and return to my office via our courier.

Sincerely,



Martin G. Malsch.

Enclosures

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVOSTE CORPORATION,)	
)	
<u>Petitioner,</u>)	
)	
v.)	No. 01-1162
)	
U.S. NUCLEAR REGULATORY COMMISSION and)	
UNITED STATES OF AMERICA,)	
)	
<u>Respondents.</u>)	
)	

**PETITIONER'S MOTION
TO HOLD JUDICIAL REVIEW PROCEEDING IN ABEYANCE
PENDING FURTHER ACTION BY
THE U.S. NUCLEAR REGULATORY COMMISSION**

1. For the reason set forth below, the Petitioner in this case, Novoste Corporation ("Novoste"), respectfully requests that this judicial review proceeding be held in abeyance pending further action of the U.S. Nuclear Regulatory Commission ("NRC"). Respondents' and Petitioner's counsel have conferred on this motion and Respondents have authorized me to advise the Court that they concur that the proceeding should be held in abeyance.

2. Petitioner Novoste developed and is marketing a medical device, called the Beta-Cath system, which uses by-product material, subject to NRC regulation under the Atomic Energy Act. The device is used for treatment of patients with a condition in their coronary arteries called in-stent restenosis (the most famous patient with this condition is Vice President Chaney). Novoste's potential customers (usually medical institutions with designated user physicians) who wish to use the device in Non-Agreement States (those States where NRC has

not relinquished licensing authority under section 274 of the Atomic Energy Act, 42 U.S.C. § 2021) cannot receive or use the device without NRC licensing authorizations. These authorizations (either new licenses or authorizing amendments to existing licenses) are issued from the appropriate NRC regional office.

3. On April 6, 2001, Novoste petitioned this Court to review an action of the NRC applicable to the Beta-Cath system. The NRC action for which review is being sought is an NRC document entitled "Generic Instructions for Licensing the Novoste BetaCath System for Intravascular Brachytherapy Treatments in Response to a Technical Assistance Request from Region IV ("Licensing Instructions").

4. During a January 31, 2001, telephone conference with NRC, Novoste representatives requested that NRC make some important changes to a draft version of the Beta-Cath Licensing Instructions which NRC had made available publically, and informed NRC that written comments on the draft would be provided promptly to NRC. These written comments were provided to NRC on February 12, 2001. However, NRC did not wait for these written comments before taking action, but rather issued the Licensing Instructions to its regional offices on February 5, 2001.

5. NRC has informed Novoste that it will reply to Novoste's February 12, 2001 letter. In effect, NRC is treating Novoste's letter as a request to modify the February 5 Licensing Instructions, although they are still in effect and being applied to NRC regional licensing actions.

6. NRC's response to Novoste's February 12 letter could evidence an NRC decision to modify the existing Licensing Instructions, and thereby alleviate some or all of Novoste's concerns about NRC's licensing approach and Novoste's corresponding ability to market its

product. As a result, some or all of Novoste's concerns about the NRC action for which review is sought may become moot.

7. Thus the resources of the Court would be best served by holding this review proceeding in abeyance pending Novoste's receipt and evaluation of the NRC response.

8. Accordingly, Petitioner respectfully requests the Court to hold this proceeding in abeyance until the NRC response to Novoste's February 12, 2001 letter is received by Novoste. NRC has advised Novoste that Novoste should receive this response by May 15, 2001. The response will be provided promptly to the Court, and promptly thereafter the parties will advise the Court regarding the need to place the case in an active posture.

9. As indicated, counsel for Respondents concur that this proceeding should be held in abeyance.

Respectfully submitted

A handwritten signature in black ink, consisting of a large, stylized 'M' followed by a long, horizontal, slightly wavy line extending to the right.

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Attorney for Petitioner

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVOSTE CORPORATION,

)
)
)
Petitioner,)
)

V.)

) No. 01-1162
)

U.S. NUCLEAR REGULATORY COMMISSION and)
UNITED STATES OF AMERICA,)

Respondents.)
_____)

CERTIFICATE OF SERVICE

I hereby certify that I have served on this 16th day of April, 2001, a copy of the
Petitioner's Joint Motion to Hold Judicial Review Proceeding in Abeyance Pending Further
Action By the U.S. Nuclear Regulatory Commission by first-class mail, postage prepaid, upon the
following:

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