COATES C ROBERT
Form DFAN14A
September 12, 2002

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SCHEDULE 14A INFORMATION
PROXY STATEMENT PURSUANT TO SECTION 14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

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NORTHFIELD LABORATORIES INC.

(Name of Registrant as Specified in its Charter)

C. ROBERT COATES

(Name of Person(s) Filing Proxy Statement if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

[X] No fee required.
[ ] $125 per Exchange Act Rules 0-11(c)(1)(ii), 14a-6(i)(1), 14a-6(i)(2) or Item 22(a)(2) of Schedule 14A.
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1) Title of each class of securities to which transaction applies:
2) Aggregate number of securities to which transaction applies:
3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (Set forth the amount on which the filing fee is calculated and state how it was determined):
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1) Amount Previously Paid:
2) Form, Schedule or Registration Statement No.:
3) Filing Party: C. Robert Coates
4) Date Filed: September 12, 2002

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NORTHFIELD LABORATORIES' TRACK RECORD WITH THE FDA

DATE	EVENT	NORTHFIELD STOCK PRICE
April 2, 1997	Northfield Laboratories, Inc. (Northfield) announces through a press release of its own that it "has received clearance from the Food and Drug Administration to begin Phase III trials of its blood substitute, PolyHemeT." The press release also states that "The randomized, controlled study will include about 250 elective surgery patients and once underway is expected to take 12 months to complete."	$12.00
August 12, 1998	Northfield announces through a press release of its own that the FDA had asked it "to expand the number of patients in Phase III clinical trials of its blood substitute, PolyHeme." The press release further states that "[a]t present, Northfield and the FDA have agreed that at least 600 patients would need to participate in an expanded study, seeking to balance the public's concern about blood substitute safety with the compelling need to bring such a product to market."	$13.94
August 16, 2001	Northfield announces through a press release of its own that "it has completed preparation of all of the components of its Biologics License Application (BLA), including collection and analysis of its clinical trial data for PolyHeme." The press release also states that Richard DeWoskin, chairman and chief executive officer said, "[w]e are pleased with the results from our clinical studies and believe the safety and efficacy data that we will present to the FDA are compelling."	$19.84
August 28, 2001	Northfield reports that it "has submitted a Biologics License Application (BLA) to the Food and Drug Administration (FDA) seeking approval to market its patented blood substitute product, PolyHeme, as an ideal oxygen-carrying resuscitative fluid for use in the treatment of urgent, life-threatening blood loss."	$17.30
September 4, 2001	Northfield announces that "the company has requested priority review and fast-track designation, which it hopes will lead to accelerated approval as described in the FDA regulations."	$16.25
October 11, 2001	Northfield announces through a press release of its own that "today" it had "presented data from trauma trials of its patented blood substitute, PolyHeme, at the American College of Surgeons annual meeting in New Orleans."	$13.01

October 12, 2001	The website www.docguide.com reports that "Dr. Steven A. Gould, president of Northfield Laboratories" had presented "the study at the 87th Clinical Congress of the American College of Surgeons." The article, "Polymerized Hemoglobin Safe for Rapid, Massive Transfusion in Trauma Patients" also states that "[i]n the study, 171 trauma patients were offered PolyHeme in place of red blood cells." Furthermore, "Dr. Gould said the study represented a 'simulated' design since 'the patients were treated in a hospital where blood was available.'"	$12.87
October 15, 2001	Northfield announces in its Quarterly Report (SEC form 10-Q) that "[b]onus payments in recognition of the Company filing a Biologics License Application ("BLA") with the FDA for PolyHeme increased payroll expense by $560,000 in the first quarter of fiscal 2002 as compared to the first quarter of fiscal 2001."	$12.71
November 19, 2001	Northfield reports that it "received comments from The U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) on its Biologics License Application (BLA), submitted August 2001. CBER indicated that they are seeking additional information before accepting the application for filing and issued a Refusal-to-File letter to the company." Northfield's press release also included the following comment from Richard DeWoskin, "[r]efusals for first-time submissions are not uncommon."	$13.25
June 27, 2002	The Chicago Tribune reports in a section titled "Bid for Northfield Lab's board" that, Northfield Chief Executive Richard DeWoskin had said, "the application process is not the issue." DeWoskin also added that "the FDA's problems with the application are focused on certain manufacturing processes and 'chemistries' the company plans to use in the production of Poly[H]eme."	$ 4.22
July 26, 2002	An article by TheStreet.com titled "Northfield CEO: PolyHeme May Need More Trials" by Adam Feuerstein reports that Dr. Gould had said "Yes, our trial was uncontrolled" The article further states that, "Northfield's clinical trial enrolled just 171 patients, far fewer than the 600 to 700 patients enrolled by the company's blood substitute rivals.	$ 5.45

KEY QUESTIONS:

* Why did Northfield submit a BLA based on 171 patients when it had agreed with the FDA in 1998 that "at least 600 patients" would be needed?

* Why did Northfield submit a BLA based on a trial that "was uncontrolled" when it had announced back in 1997 that the study would be a "controlled" one?

* Why did Northfield say it would take "12 months to complete" the study, but almost 4 years later (2001) they still had not enrolled 250 patients (the initial goal of the study)?

* Why did Northfield not announce to its shareholders any changes in its trial strategy?

* Why did Northfield's Dr. Steven Gould and other senior managers pay themselves over half a million dollars in bonuses for an application that was not accepted (filed) by the FDA?

* Why did Northfield call the Refusal-To-File "not uncommon" when data from CBER shows that over the last three years it has only happened 3 out of 165 applications or 1.8% of the time?

* What exactly are the manufacturing process issues the FDA has "problems with?"

* Who was in charge of clinical trial design at Northfield?

* What role did Northfield's paid consultant, Dr. Paul Ness, play in Northfield's filing with the FDA?
