COATES C ROBERT
Form DFAN14A
September 04, 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.
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2) Form, Schedule or Registration Statement No.:
3) Filing Party: C. Robert Coates
4) Date Filed: September 03, 2002

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Press Release

SOURCE: C. Robert Coates

ROBERT COATES AND BERT WILLIAMS JOINED BY EXPERT ON FDA

LAKE FOREST, Ill., Sept. 4 -- C. Robert Coates, running with Bert Williams as independent candidates for seats on the board of Northfield Laboratories Inc. (Nasdaq: NFLD), said Dr. Jur Strobos, former Director of Policy Research for the U.S. Food and Drug Administration, has joined the Coates/Williams team as an adviser.

"The future success of Northfield depends on its interaction with the FDA," said Coates. "For that reason, we have added Jur Strobos, a recognized expert, to our advisory group."

Dr. Strobos received his M.D. at the University of Chicago, practiced as a trauma surgeon, and then received his J.D. at the University of Pennsylvania. He served as Director of Policy in the FDA's Office of the Commissioner for 3-1/2 years before re-entering the private sector in 1995 as a shareholder/partner of the law firm of Greenberg Traurig. He is now with Olsson, Frank & Weeda in Washington, D.C.

Since 1986, Dr. Strobos has specialized in new medical product development. His area of expertise includes development of successful strategies for, and management of, the clinical and regulatory process for new medical products. This work includes the design, completion and submission of clinical, statistical, chemical, compliance and other scientific data supporting new drug or device approval as well as associated activities such as public relations, development of marketing strategies and communications with professionals, support for public offerings and negotiations with potential strategic alliance partners.

Dr. Strobos' experience will be valuable to shareholders in understanding Northfield's dealings with the FDA. Northfield has made repeated references to its ongoing constructive dialogue with the agency. However, it has been almost a year since the FDA issued Northfield a refusal-to-file (RTF) letter for its only potential revenue source, PolyHeme. And the company has never provided a detailed account to its shareholders.

Dr. Strobos, who was at the FDA when the original RTF regulation was issued, and is considered a foremost authority on the subject, addressed Northfield's RTF, saying: "I have concerns about Northfield's expertise in dealing with the FDA. Regulatory expertise is essential for this company. For example, an RTF letter is provided by the FDA only in the setting of a wholly inadequate filing that is apparent to anyone on even a cursory examination. The purpose of an RTF is not to provide an opinion on the safety and efficacy of the product but to tell the company that simple well known and required components of an application are missing."

The Center for Biologics Evaluation & Research (CBER) division of the FDA has summarized data on filings and RTFs in its annual reports. Of 165 biologics reviewed during the fiscal period 1999 to 2001 only three, or 1.8%, received an RTF. (www.fda.gov/cber/inside/annrptpart5.htm). This is in direct contradiction to a statement issued by Northfield Laboratories on Nov. 19, 2001 saying, "Refusals for first-time submissions are not uncommon."

Dr. Strobos also addressed comments made by Northfield in an Aug. 29 press release titled "Northfield Builds Support for PolyHeme in Medical and Scientific Communities." Northfield said that as a result of the statements by Mr. Coates, "it was necessary for Northfield to provide a letter to the FDA confirming that Mr. Coates is not authorized to speak on behalf of Northfield and that we do not share the views expressed in his press releases."

Dr. Strobos said, "A company should not send a letter to the FDA regarding a

proxy contest. No such response is required by the FDA. And, the candidate may lose in which case his statements are irrelevant; or the candidate may win, in which case the response will have to be withdrawn. It is simply not a wise action."

Coates and Williams said the quickest way to realize shareholder value is to bring in a major pharmaceutical company now to provide the necessary capital and management talent to gain FDA approval for PolyHeme.

They remind shareholders to elect two directors who will represent their interests and hold management accountable by casting the white ballots for the September 13 election.

If you are a shareholder with comments, suggestions or questions about receiving a Coates-Williams proxy, please call Simon Goldberg of the Robert Coates Group at 1-800-295-0841, extension 240 or e-mail us at sgoldberg@rcoates.com .

SOURCE: C. Robert Coates