NORTHFIELD LABORATORIES INC /DE/
Form DEFA14A
August 28, 2001

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SCHEDULE 14A
(RULE 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT
SCHEDULE 14A INFORMATION

PROXY STATEMENT PURSUANT TO SECTION 14(a) OF THE SECURITIES EXCHANGE ACT OF 1934 (AMENDMENT NO.)

Filed by the registrant [X]

Filed by a party other than the registrant [ ]

Check the appropriate box:

[ ] Preliminary proxy statement. [ ] Confidential, for use of the Commission only (as permitted by Rule 14a-6(e)(2)).

[ ] Definitive proxy statement.

[X] Definitive additional materials.

[ ] Soliciting material pursuant to Rule 14a-12

Northfield Laboratories

(Name of Registrant as Specified in Its Charter)

(Name of Person(s) Filing Proxy Statement if Other Than the Registrant)

Payment of filing fee (check the appropriate box):

[X] No fee required.

[ ] Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

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(2) Aggregate number of securities to which transaction applies:

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(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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(4) Proposed maximum aggregate value of transaction:

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(5) Total fee paid:

[ ] Fee paid previously with preliminary materials.

[ ] Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the form or schedule and the date of its filing.

(1) Amount Previously Paid:

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(2) Form, Schedule or Registration Statement No.:

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(3) Filing Party:

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(4) Date Filed:

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FOR IMMEDIATE RELEASE
TUESDAY, AUGUST 28, 2001

NORTHFIELD LABORATORIES SUBMITS BIOLOGICS LICENSE APPLICATION TO FDA FOR APPROVAL OF ITS BLOOD SUBSTITUTE, POLYHEME(TM)

EVANSTON, ILLINOIS, AUGUST 28, 2001 -- NORTHFIELD LABORATORIES INC. (NASDAQ/NMS: NFLD), a leading developer of an oxygen-carrying blood substitute, today reported 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.

"The submission of the BLA for PolyHeme is a significant milestone for Northfield, and marks a first for a blood substitute for human use in the U.S.," said Richard DeWoskin, chairman and chief executive officer. "PolyHeme provides a remarkable clinical benefit, and represents more than 16 years of product development, clinical studies and data analysis. More importantly, it addresses

a large market opportunity and fills an important clinical need.

"We plan to continue working with the FDA to support the strength of our application and to provide any additional information that may be necessary to achieve a favorable determination," said DeWoskin.

Dr. Steven A. Gould, president, said, "The data from our clinical trials demonstrate that PolyHeme will support life in seriously injured, bleeding patients in the virtual absence of circulating red blood cells, and thereby improve survival in situations when blood cannot be used. We believe these results demonstrate the ability of PolyHeme to effectively and safely transport oxygen. This extraordinary survival benefit indicates that PolyHeme is capable of addressing a critical, unmet medical need, and has led us to file for priority review and fast-track status with the FDA, which we hope will lead to accelerated approval of PolyHeme."

PolyHeme is the only blood substitute that has been safely infused rapidly and at large enough dosages to be considered a substitute for acute blood loss in trauma and surgical settings. As a result of the process used to manufacture this product, essentially a solution of polymerized hemoglobin, PolyHeme has a longer shelf life than blood, requires no cross matching and does not transmit disease.

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The current market for blood in the United States is estimated to be in the multiple billions of dollars. There were 12.4 million units of blood transfused into approximately 4 million recipients in 1999, according to the latest figures available from the National Blood Data Resource Center. Of that amount, about 2.5 million units are used in urgent, acute blood loss situations - Northfield's primary focus.

ANNUAL BUSINESS UPDATE
The company will provide more detail on its regulatory progress in its annual business update on August 31, 2001. This presentation will be webcast after the close of the market, at 4:30 p.m. central time, that day. Anyone interested in accessing the presentation should log on to www.northfieldlabs.com or www.videonewswire.com, or, for those without Internet access, you may dial in to 888-413-4411 to listen to the call. A replay of the webcast will be available for 30 days after the presentation. The telephonic replay will be available for seven days by dialing 888-266-2086 and providing the passcode, 5458560.

Northfield's annual meeting will take place earlier that day at 2:00 p.m. central time to vote on business matters as outlined in its August 3rd proxy statement. Only questions related to those business matters will be taken at the meeting. The business update will not be webcast at corporate headquarters.

ABOUT THE COMPANY
Northfield Laboratories was founded in 1985. The company is headquartered in Evanston, Illinois, and its stock is traded on the Nasdaq National Market System under the symbol NFLD.

Statements in this release that are not strictly historical are "forward-looking" statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks, which may cause the company's actual results in the future to differ materially from expected

results. Northfield cautions that the FDA approval process for PolyHeme continues to be subject to significant risks and uncertainties. The FDA could refuse to accept Northfield's BLA in its current form. If Northfield's BLA is accepted, the FDA could deny its approval for the commercial sale of PolyHeme or could require additional clinical tests as a condition to its approval. If FDA approval for the commercial sale of PolyHeme is granted, the indication uses for which PolyHeme may be marketed could be significantly limited by the FDA. Other risks may include: competition from other blood substitute products; the company's ability to obtain regulatory approval to market PolyHeme commercially; the company's and/or its representative's ability to successfully market and sell PolyHeme; the company's ability to manufacture PolyHeme in sufficient quantities; the company's ability to obtain an adequate supply of raw materials; the company's ability to maintain intellectual property protection for its proprietary product and to defend its existing intellectual property rights from challenges by third parties; the availability of capital to finance planned growth; and the extent to which the hospitals and physicians using PolyHeme are able to obtain third-party reimbursement, as described in the company's filing with the Securities and Exchange Commission.

VISIT THE NORTHFIELD WEBSITE AT: WWW.NORTHFIELDLABS.COM

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