SERONO S A
Form 6-K
May 22, 2003

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13A-16 OR 15D-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the month of May, 2003

Serono S.A.
(Registrant's Name)

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1-15096
(Commission File No.)

(Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.)

Form 20-F X Form 40-F
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(Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b)(1).) _____

(Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b)(7).) _____

(Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.)

Yes No X
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(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____)

SERONO PFIZER

MEDIA RELEASE

FOR IMMEDIATE RELEASE

REBIF(R) LABELING CHANGES REFLECT EFFICACY AND CONVENIENCE OF THE FASTEST GROWING MS TREATMENT IN THE U.S.

UPDATED LABEL SAYS PATIENTS TREATED WITH REBIF(R) ARE MORE LIKELY TO REMAIN RELAPSE FREE AT 24 AND 48 WEEKS VS. PATIENTS TREATED WITH AVONEX(R)

ROCKLAND, MA, AND NEW YORK, NY, MAY 22, 2003 - Serono, Inc. and Pfizer Inc, co-promoters of Rebif(R) (interferon beta-1a) in the US, announced today that the U.S. Food and Drug Administration (FDA) has approved additional efficacy and product stability information for Rebif(R). The new label changes reflect the treatment's efficacy and convenience in treating multiple sclerosis.

The new labeling changes include an update to the Clinical Studies section to add 48-week data from the EVIDENCE study(1). This head-to-head study of Rebif(R) and Avonex(R) (interferon beta-1a) compared the proportion of MS patients treated with Rebif(R) or Avonex(R) who were relapse free after 24 weeks (primary end point) and 48 weeks. The label expansion will now reflect that, "Patients treated with Rebif(R) 44 mcg sc tiw were more likely to remain relapse free at 24 and 48 weeks than were patients treated with Avonex(R) 30 mcg im qw."

"Serono and Pfizer are pleased with the FDA's approval of the new label changes for Rebif(R). The label expansion reflects additional scientific data demonstrating Rebif(R)'s clinical superiority over Avonex(R) at reducing frequency of relapses in patients with relapsing remitting MS at both 24 and 48 weeks," said Gordon Francis, M.D., Vice President, Neurology Clinical Development Unit, Serono, Inc.

Furthermore, the FDA also approved label changes related to Rebif(R) temporary storage at room temperature. This change enhances Rebif(R)'s ease-of-use for people who are currently taking the therapy to treat their MS. The label expansion will include that, "Rebif(R) may be stored at or below 25 degrees C/77 degrees F for up to 30 days and away from heat or light" and will be reflected in the Stability and

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(1) Panitch H, Goodin DS, Francis G, et al. Randomized, comparative study of interferon beta-1a treatment regimens in MS: The EVIDENCE (Evidence for Interferon Dose-response European-North American Comparative Efficacy) Trial. Neurology 2002; 59: 1496-1506.

Storage section. The same room temperature storage conditions were already allowed in the other countries where Rebif is approved.

"With Rebif(R)'s temporary room temperature labeling, we are building on our commitment to offer consumers not only a highly efficacious MS treatment, but also the added convenience that patients seek," said Deborah Brown, Executive Vice President, Neurology, Serono, Inc.

Christy Demory, an attorney from North Carolina, who takes Rebif(R), welcomed the change. "Between family and work, I am always on the go and sometimes need to carry Rebif(R) with me to my office or on an overnight outing or when I travel, so it's great to have the flexibility of leaving it out at room temperature," she said. "It's one less thing I have to think about."

A revised patient Medication Guide will also be available that reflects new storage and needle disposal information.

48-WEEK EVIDENCE DATA SUMMARIZED

The expanded Rebif(R) label now contains data from the head-to-head EVIDENCE study of 677 patients with relapsing remitting MS. The study compared the proportion of MS patients treated with either Rebif(R) or Avonex(R) who were relapse-free after 24 weeks (primary endpoint) and 48 weeks. The data showed that 75% of patients who received Rebif(R) (44 mcg administered subcutaneously, three times weekly) did not have a relapse after 24 weeks of treatment compared to 63% of patients treated with Avonex(R) (30 mcg administered intramuscularly, once weekly) (p