SANOFI SYNTHELABO SA
Form 6-K
May 30, 2003

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULES 13a-16 OR 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the Month of May 2003
SANOFI-SYNTHELABO
(Exact name of registrant as specified in its charter)

174, avenue de France, 75013 Paris, FRANCE
(Address of principal executive offices)

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

Form 20-F __X__ Form 40-F ____

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__

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____.

Investor Relations Paris, May 29, 2003

FDA Cardiovascular & Renal Drugs Advisory Committee Votes That Alfuzosin is Not Associated With a Clinically-Relevant Prolongation of the QT Interval

Sanofi-Synthélabo announced today that the Cardiovascular & Renal Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted unanimously (with one member abstaining) that the Company s clinical investigations showed that alfuzosin is not associated with a clinically-relevant prolongation of the QT interval. Alfuzosin is an alpha1-blocker in a 10 mg once-daily extended release formulation being reviewed by the FDA for the treatment of signs and symptoms of benign prostatic hyperplasia.

Sanofi-Synthélabo presented results from clinical trials specifically designed to measure potential changes to the QT interval. The QT interval is one of the parameters measured in an ECG (Electrocardiogram), which reflects cardiac repolarization (or time for the heart to electrically recharge).

These data were supported by an extensive worldwide safety database from over 15 years of clinical experience, which translates into 1.35 billion days (3.7 million patient years) of patient therapy. Alfuzosin, a compound from Sanofi-Synthélabo research, is marketed throughout Europe, Latin America, Africa and Asia in more than 80 countries. The once-daily formulation (Xatral® OD) is registered in 70 countries worldwide; it is currently marketed in 14 countries in Europe and in more than 35 other countries.

The committee s recommendation will be considered by the FDA in its final review of the new drug application (NDA), which Sanofi-Synthélabo submitted in December 2000 and for which Sanofi-Synthélabo received an approvable letter in October 2001.

Benign prostatic hyperplasia is a very common disorder, leading to urinary symptoms of varying severity. The resulting moderate to severe symptoms affect 22% of men aged 50-59 years, but up to 45% of men aged 70-80 years. These symptoms have a significant impact on quality of life including sexuality and may lead to serious complications such as acute urinary retention. Clinical efficacy data for alfuzosin from three placebo-controlled trials were previously submitted to the FDA and demonstrated efficacy compared to placebo in urinary flow improvement without the need for dose titration.

About Sanofi-Synthélabo

Sanofi-Synthelabo is a major global research-based pharmaceutical group with 32,500 employees in more than 100 countries. The company is headquartered in Paris and listed in Paris (Euronext : SAN) and in New York (NYSE : SNY). With consolidated sales of EUR 7.4 billion in 2002, Sanofi-Synthelabo ranks 7th in Europe and among the world s top 20 pharmaceutical companies. With an R&D portfolio of 52 compounds in development, Sanofi-Synthelabo is focused on a core group of four therapeutic areas: cardiovascular disease and thrombosis; diseases of the central nervous system; internal medicine; and oncology.

Forward Looking Statement

This release contains statements that constitute forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based on management s current expectations or beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the

forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements : the ability of Sanofi-Synthélabo to expand its presence profitably in the United States; the success of Sanofi-Synthélabo s research and development programs; the ability of Sanofi-Synthélabo to protect its intellectual property rights; and the risks associated with reimbursement of health care costs and pricing reforms, particularly in the United States and France.

Investors and security holders may obtain a free copy of documents filed by Sanofi-Synthélabo with the U.S. Securities and Exchange Commission at www.sec.gov or directly from Sanofi-Synthélabo on the web site www. sanofi-synthelabo.com

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: May 30, 2003

SANOFI-SYNTHELABO

By: /s/ Marie-Hélène Laimay
Name: Marie-Hélène Laimay
Title: Senior Vice President and
Chief Financial Officer