SKYEPHARMA PLC
Form 6-K
October 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 October, 2003

SkyePharma PLC

(Translation of registrant's name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

(Address of principal executive office)

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

Form 20-F X Form 40-F

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-
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For Immediate Release

22 October, 2003

SkyePharma PLC

FORADIL® CERTIHALER RECEIVES 'APPROVABLE' LETTER FROM FDA

LONDON, UK, 22 October 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announced today that the US Food and Drug Administration ('FDA') has issued an 'approvable' letter for FORADIL® CERTIHALER (formoterol fumarate inhalation powder). This means that the product can be approved by the FDA subject to resolution of certain outstanding issues. The FORADIL CERTIHALER was co-developed by SkyePharma PLC and Novartis Pharma AG. The FORADIL CERTIHALER was submitted for regulatory review in the US in December 2002. FORADIL® CERTIHALER embodies two proprietary SkyePharma technologies, the SKYEHALER , a novel breath-activated multi-dose dry powder inhaler (MDDPI) device, and SKYEPROTECT , a powder formulation that protects the drug from atmospheric moisture to ensure product stability and dose-to-dose reproducibility.

Formoterol, the active ingredient in FORADIL® CERTIHALER , is a long-acting beta-agonist bronchodilator, that combines a rapid onset of action (within1-3 minutes) with a long-lasting bronchodilation of 12 hours. This feature offers large benefits for all patients who suffer from obstructive lung diseases. Formoterol is licensed by Novartis Pharma AG from Yamanouchi Pharmaceuticals. The CERTIHALER dry-powder inhaler contains 60 doses giving patients the convenience of 30 days of therapy in a single inhaler. This evolution of the FORADIL® line was developed to provide a valuable and convenient option for asthma patients who require maintenance therapy with a long-acting bronchodilator.

Michael Ashton, SkyePharma's Chief Executive Officer commented 'We are delighted by the FDA's positive reaction to the FORADIL® CERTIHALER submission. Royalty income following ultimate approval of FORADIL® CERTIHALER will be a key part of moving SkyePharma closer to its goal when the greater proportion of our earnings will be derived from product-related revenues.'

In October 2002, Schering-Plough (NYSE: SGP) obtained exclusive U.S. distribution and marketing rights to all FORADIL® products from Novartis Pharma AG. Schering-Plough currently markets FORADIL® AEROLIZER (formoterol fumarate inhalation powder), a single-dose inhalation device. Novartis Pharma AG retains international rights to the FORADIL® product line. Approval of FORADIL® CERTIHALER will trigger an undisclosed milestone payment by Novartis to SkyePharma, which will also earn a royalty on all future FORADIL® CERTIHALER sales. SkyePharma will also manufacture and supply FORADIL® CERTIHALER .

SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technologies that provide easier-to-use and more effective drug formulations. There are now nine approved products incorporating three from SkyePharma's five technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit www.skyepharma.com.

Except for the historical information herein, the matters discussed in this news release include forward-looking statements that may involve a number of risks and uncertainties. Actual results may vary significantly based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. These include without limitation risks in obtaining and maintaining regulatory approval for existing, new or expanded indications for its products, other regulatory risks, risks relating to SkyePharma's ability to manufacture pharmaceutical products on a large scale, risks that customer inventory will be greater than previously thought, risks concerning SkyePharma's ability to manage growth, market a pharmaceutical product on a large scale and integrate and manage an internal sales and marketing organization and maintain or expand sales and market share for its products, risks relating to the ability to ensure regulatory compliance, risks related to the research, development and regulatory approval of new pharmaceutical products, risks related to research and development costs and capabilities, market acceptance of and continuing demand for SkyePharma's products and the impact of increased competition, risks associated with anticipated top

and bottom line growth and the possibility that upside potential will not be achieved, competitive products and pricing, and risks associated with the ownership and use of intellectual property rights. SkyePharma undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.

For further information please contact:

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Tim Anderson / Mark Court

END

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.

SkyePharma PLC

By: /s/ Douglas Parkhill

Name: Douglas Parkhill
Title: Company Secretary

Date: October 22, 2003