

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

DmB

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[Docket No. 01E-0363]

Determination of Regulatory Review Period for Purposes of Patent Extension; MIFEPREX; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 26, 2002, the comment period for the regulatory review period determination for MIFEPREX, published in the FEDERAL REGISTER of January 25, 2002 (67 FR 3724). The agency is taking this action in response to a request for an extension.

DATES: Submit written or electronic comments on the regulatory review period determination for MIFEPREX by April 26, 2002.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

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Office of Regulatory Policy (HFD-007),  
Food and Drug Administration,  
5600 Fishers Lane,  
Rockville, MD 20857,  
301-594-2041.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of January 25, 2002 (67 FR 3724), FDA published a document entitled "Determination of Regulatory Review Period for Purposes of Patent Extension; MIFEPREX." The document set forth the determination of the regulatory review period for purposes of patent term extension for the human drug product MIFEPREX. The document announced that FDA determined that the applicable regulatory review period for MIFEPREX was 2,249 days, and that of this time, 593 days had occurred during the testing phase of the regulatory review period, while 1,656 days had occurred during the approval phase. The notice explained how these periods of time were derived.

FDA received a letter dated March 22, 2002, from an attorney representing the Population Council (the patent holder) and others, requesting that the agency extend the comment period on the regulatory review period for 30 days, until April 26, 2002, explaining that additional time was needed to reach a licensing agreement. FDA has determined that it is appropriate to grant this request.

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments on the regulatory review period determination for MIFEPREX on or before April 26, 2002. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments

are to be identified with the docket number found in brackets in  
the heading of this

document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 3/27/02  
March 27, 2002.

Jane A. Axelrad

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

