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Scott A. Williams
Pharmacia Corporation of Pfizer Inc.
P.O. Box 1027
St. Louis MO 63006

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,559,332

Dear Mr. Williams :

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,559,332 for a period of 1,219 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: <http://www.fda.gov/opacom/morechoices/fdaforms/default.html> (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

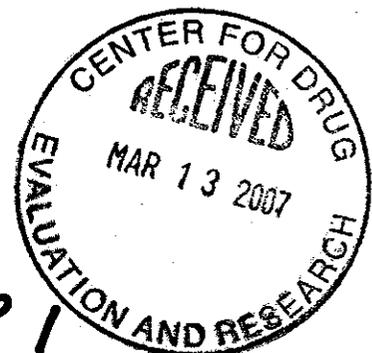
Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: INSPRA® (eplerenone)
FDA Docket No.: 2003E-0254

Attention: Beverly Friedman



2003E-0254

CEPI

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68) PATENT NO. : 4,559,332
(45) ISSUED : December 17, 1985
(75) INVENTOR : Jürgen Grob, et al.
(73) PATENT OWNER : Novartis Corporation
(95) PRODUCT : INSPRA® (eplerenone)

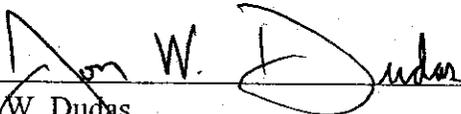
This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,559,332 based upon the regulatory review of the product INSPRA® (eplerenone) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,219 days

from April 9, 2004, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 7th day of March 2007.


Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office