

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 20-237/S-007

ADMINISTRATIVE DOCUMENTS

Certification Statement

MGI PHARMA, INC. hereby certifies that it did not and will not use, in any capacity, the services of a person debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, in connection with the supplement application submitted to NDA #20-237 on February 11, 1997.

MGI PHARMA, INC.

Dated: 2/19/97-----

By: Joe H. Gustafson-----
Joe H. Gustafson, Ph. D.
Director, Regulatory Affairs

precautions
ng receipt of
apply to

uct until the

ary 19, 1997

te'

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

NDA/PLA # 20-237 Supplement # 007 Circle one: SE1 SE2 SE3 SE4 SE5 SE6

HFD-540 Trade (generic) name/dosage form: SACIBEN (PILOCARPINE) Action: AB AE NA

Applicant MGI PHARMA Therapeutic Class MUSCARINIC ANTAGONIST

Indication(s) previously approved TREATMENT OF XEROSTOMIA INDUCED BY RADIATION THERAPY
Pediatric labeling of approved indication(s) is adequate inadequate

Indication in this application TREATMENT OF THE SYMPTOMS OF DRY EYES ASSOCIATED WITH SIDBAREN'S SYNDROME
(For supplements, answer the following questions in relation to the proposed indication.)

1. PEDIATRIC LABELING IS ADEQUATE. Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric subgroups. Further information is not required.
2. PEDIATRIC STUDIES ARE NEEDED. There is potential for use in children, and further information is required to permit adequate labeling for this use.

- a. A new dosing formation is needed, and applicant has agreed to provide the appropriate formulation.
- b. The applicant has committed to doing such studies as will be required.
- (1) Studies are ongoing,
- (2) Protocols were submitted and approved.
- (3) Protocols were submitted and are under review.
- (4) If no protocol has been submitted, explain the status of discussions on the back of this form.
- c. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

3. PEDIATRIC STUDIES ARE NOT NEEDED. The drug/biologic product has little potential for use in children. Explain, on the back of this form, why pediatric studies are not needed.

4. EXPLAIN. If none of the above apply, explain, as necessary, on the back of this form.

EXPLAIN, AS NECESSARY, ANY OF THE FOREGOING ITEMS ON THE BACK OF THIS FORM.

Signature of Preparer and Title (PM, CSO, MO, other) _____

2/3/98
Date

cc: Orig NDA/PLA # 20-237
HFD-540 / Div File
NDA/PLA Action Package
HFD-510/GTroendle (plus, for CDER APs and AEs, copy of action letter and labeling)

NOTE: A new Pediatric Page must be completed at the time of each action even though one was prepared at the time of the last action.

Sjögren's syndrome is not a disease that affects children.
As such, it is extremely unlikely that the drug would
be used in children.

Frederick W. Hyman, DDS, MPH
February 3, 1998

2/10/98



Food and Drug Administration
Rockville MD 20857

NDA 20-237/S-007

DIU
etc

FEB 11 1997

MGI PHARMA, INC.
Suite 300E, Opus Center
9900 Bren Road East
Minnetonka, MN 55343

Attention: Jo H. Gustafson, Ph.D.

Dear Dr. Gustafson:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Salagen Tablets

NDA Number: 20-237

Supplement Number: S-007

Date of Supplement: February 11, 1997

Date of Receipt: February 12, 1997

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on April 13, 1997 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products, HFD-540
Office of Drug Evaluation V
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Mary J. Kozma-Fornaro
Supervisor, Project Management Staff
Division of Anti-Infective Drug Products, HFD-540
Office of Drug Evaluation V
Center for Drug Evaluation and Research

NDA 20-237/S-007
Page 2

cc:

Original NDA 20-237/S-007

HFD-540/Div. Files

HFD-540/CSO/~~K.D. White~~ H BLATT

SUPPLEMENT ACKNOWLEDGEMENT