CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19726/S18

ADMINISTRATIVE DOCUMENTS

Item 13: Patent Information

For further information regarding this section, please contact:

Sandra L. Acquaviva
Manager, Marketed Products Group
(302) 886–2192
Zeneca Pharmaceuticals
A Business Unit of Zeneca Inc.
1800 Concord Pike
PO Box 15437
Wilmington, DE 19850–5437

Zeneca Pharmaceuticals,
A Business Unit of Zeneca Inc.
Drug Regulatory Affairs Department
Wilmington, DE 19850-5437

ZOLADEX® (goserelin acetate implant)

ITEM 13: Pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, the attached information is made of record.

A. PATENT INFORMATION ON ANY PATENT WHICH CLAIMS THE DRUG OR A METHOD OF USING THE DRUG.

1. Active Ingredient(s):

   pyro-Glu-His-Trp-Ser-Tyr-D-Ser(Bu^t)-Leu-Arg-Pro-Azgly-NH_2 acetate

2. Strength(s):

   3.6 mg

3. Trade Name:

   ZOLADEX® (goserelin acetate implant)

4. Dosage Form, Route of Administration:

   Implant, Subcutaneous

5. Applicant Firm Name/Holder of the New Drug Application:

   Zeneca Limited
   Macclesfield, Chesire, England

   US Agent:
   Zeneca Pharmaceuticals
   A Business Unit of Zeneca Inc.
   1800 Concord Pike
   Wilmington, DE 19850-5437

6. NDA Number:

   19-726

7. Approval Date:

   December 29, 1989

8. Applicable Patent(s):

   (i) US Patent No. 4,100,274

   (a) Expiration date:

   April 22, 1999.

   (b) Type of Patent:

   US Patent No. 4,100,274 contains drug substance claims, method of use claims, and pharmaceutical composition claims.

   (c) Name of Patent Owner:

   Zeneca Limited, Macclesfield, Chesire, England is the beneficial owner of US Patent No. 4,100,274.

   (d) Agent Authorized to Receive Notice:

   The agent of the patent owner in the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the act and 21 CFR sections 314.52 and 314.95 is:

   Cushman, Darby and Cushman
   1100 New York Avenue
   Washington, DC 20005-3918

   (e) Original Declaration:

   The undersigned declares that US Patent No. 4,100,274 covers the formulation, composition, and/or method of use of ZOLADEX® (goserelin acetate implant). This product is currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

(ii) US Patent No. 4,767,628

(a) Expiration Date:

August 30, 2005

(b) Type of patent:

US Patent No. 4,767,628 contains claims to the pharmaceutical composition depot form of the product.

(c) Name of Patent Owner:

Zeneca Limited, Macclesfield, Chesire, England is the beneficial owner of US Patent No. 4,767,628.

(d) Agent Authorized to Receive Notice:

The agent of the patent owner in the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the act and 21 CFR sections 314.52 and 314.95 is:

Cushman, Darby and Cushman
1100 New York Avenue
Washington, DC 2005-3918

(e) Original Declaration

The undersigned declares that US Patent No. 4,767,628 covers the formulation, composition, and/or method of use of ZOLADEX® (goserelin acetate implant). This product is currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

(iii) US Patent No. 5,366,734

(a) Expiration Date:

November 22, 2011

(b) Type of Patent:

US Patent No. 5,366,734 contains claims to a method of using the pharmaceutical composition depot form of the product.

(c) Name of Patent Owner:

Zeneca Limited, Macclesfield, Chesire, England is the beneficial owner of US Patent No. 5,366,734.

(d) Agent Authorized to Receive Notice:

The agent of the patent owner in the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the act and 21 CFR sections 314.52 and 314.95 is:

Cushman, Darby and Cushman
1100 New York Avenue
Washington, DC 20005-3918

(e) Original Declaration:

The undersigned declares that US Patent No. 5,366,734 covers the formulation, composition, and/or method of use of ZOLADEX® (goserelin acetate implant). This product is currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

Ruth H. Newtson

RUTH H. NEWTSON
CHIEF IP COUNSEL
PHARMACEUTICALS

DRUG STUDIES IN PEDIATRIC PATIENTS
(To be completed for all NME's recommended for approval)

NDA # 19-726/S-018 Trade (generic) names Zoladex (goserelin acetate implant)

Check any of the following that apply and explain, as necessary, on the next page:

____ 1. A proposed claim in the draft labeling is directed toward a specific pediatric illness. The application contains adequate and well-controlled studies in pediatric patients to support that claim.

____ 2. The draft labeling includes pediatric dosing information that is not based on adequate and well-controlled studies in children. The application contains a request under 21 CFR 210.58 or 314.126(c) for waiver of the requirement at 21 CFR 201.57(f) for A&WC studies in children.

____ a. The application contains data showing that the course of the disease and the effects of the drug are sufficiently similar in adults and children to permit extrapolation of the data from adults to children. The waiver request should be granted and a statement to that effect is included in the action letter.

____ b. The information included in the application does not adequately support the waiver request. The request should not be granted and a statement to that effect is included in the action letter. (Complete #3 or #4 below as appropriate.)

____ 3. Pediatric studies (e.g., dose-finding, pharmacokinetic, adverse reaction, adequate and well-controlled for safety and efficacy) should be done after approval. The drug product has some potential for use in children, but there is no reason to expect early widespread pediatric use (because, for example, alternative drugs are available or the condition is uncommon in children).

____ a. The applicant has committed to doing such studies as will be required.

____ (1) Studies are ongoing.
____ (2) Protocols have been submitted and approved.
____ (3) Protocols have been submitted and are under review.
____ (4) If no protocol has been submitted, on the next page explain the status of discussions.

____ b. 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.

✓ 4. Pediatric studies do not need to be encouraged because the drug product has little potential for use in children.

____ 5. If none of the above apply, explain.

Explain, as necessary, the foregoing items: _____

Signature of Preparer

5/7/97
Date

cc: Orig NDA
HFD-___/Div File
NDA Action Package

ZENECA
Pharmaceuticals
A Business Unit of Zeneca Inc.

1800 Concord Pike
PO Box 15437
Wilmington, DE 19850-5437
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Fax (302) 886-2822

William J. Kennedy, Ph.D.
Vice President
Drug Regulatory Affairs Department

JUN 2 6 1996

Re: ZOLADEX® (goserelin acetate implant)
NDA 19-276
Supplement - Endometrial Thinning Application

In response to the requirements of the Generic Drug Enforcement Act of 1992, I hereby certify on behalf of Zeneca Pharmaceuticals, a Business Unit of Zeneca Inc., that we did not and will not use in connection with this application, the services of any person in any capacity debarred under section 306 (a) or (b).

Sincerely,

William J. Kennedy, Ph.D.

WJK/car/4434/68

NDA 19-726/S-018
Zoladex (goserelin acetate implant), 3.6 mg

Division Director's Memo

The Primary Medical review was completed by the Division Director. In addition, the application will be signed off at the Division level. No memo is required.

NDA 19-726/S-018
Zoladex (goserelin acetate implant), 3.6 mg

Group Leader's Memo

No Group Leader's memo will be prepared; the medical review has been done in conjunction with both the Deputy Director and the Division Director; neither of which felt a memo was required.

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Safety Update Review

Included in Medical Officer review dated June 21, 1997.

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Advertising Material

No advertising material has been submitted.

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Federal Register Notices

This application was not the subject of any Federal Register Notices.

NDA 19-726/S-018
Zoladex (goserelin acetate implant), 3.6 mg

EER

There were no manufacturing changes - no EER is required.