CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20011/S14

ADMINISTRATIVE DOCUMENTS

NDA 20-011/S-014 Lupron Depot® (leuprolide acetate for depot suspension) 3.75 mg
NDA 20-708/S-003 Lupron Depot® (leuprolide acetate for depot suspension) 11.25 mg

Division Director's Memo

The application will be signed off at the Division level. No memo is necessary.

NDA 20-011/S-014 Lupron Depot® (leuprolide acetate for depot suspension) 3.75 mg
NDA 20-708/S-003 Lupron Depot® (leuprolide acetate for depot suspension) 11.25 mg

Group Leader's Memo

No Group Leader's memo will be prepared; Narcisa. 4/9/98

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

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.

3LA # 20-011 Supplement # 14 Circle one: (SE1) SE2 SE3 SE4 SE5 SE6

HF 2-550 Trade and generic names/dosage form: LUPRON DEPOT (leuprolide acetate) 3.75mg Action: (AP) AE NA

Applicant TAP HOLDINGS INC. Therapeutic Class 35

Indication(s) previously approved Management of endometriosis; preoperative management of uterine fibroids
Pediatric information in labeling of approved indication(s) is adequate __ inadequate __
Proposed indication in this application Same as above

FOR SUPPLEMENTS, ANSWER THE FOLLOWING QUESTIONS IN RELATION TO THE PROPOSED INDICATION.
IS THE DRUG NEEDED IN ANY PEDIATRIC AGE GROUPS? ___Yes (Continue with questions) ✓ No (Sign and return the form)
WHAT PEDIATRIC AGE GROUPS IS THE DRUG NEEDED? (Check all that apply)
__Neonates (Birth-1month) __Infants (1month-2yrs) __Children (2-12yrs) __Adolecents(12-16yrs)

__ 1. **PEDIATRIC LABELING IS ADEQUATE FOR ALL PEDIATRIC AGE GROUPS.** 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 age groups. Further information is not required.

__ 2. **PEDIATRIC LABELING IS ADEQUATE FOR CERTAIN AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for certain pediatric age groups (e.g., infants, children, and adolescents but not neonates). Further information is not required.

__ 3. **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 formulation is needed, and applicant has agreed to provide the appropriate formulation.

__ b. A new dosing formulation is needed, however the sponsor is either not willing to provide it or is in negotiations with FDA.

__ c. 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, attach memo describing status of discussions.

__ d. 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 ARE NOT NEEDED.** The drug/biologic product has little potential for use in pediatric patients. Attach memo explaining why pediatric studies are not needed.

__ 5. **If none of the above apply, attach an explanation, as necessary.**

ARE THERE ANY PEDIATRIC PHASE IV COMMITMENTS IN THE ACTION LETTER? ___ Yes ___ No
ATTACH AN EXPLANATION FOR ANY OF THE FOREGOING ITEMS, AS NECESSARY.

This page was completed based on information from _____ (e.g., medical review, medical officer, team leader)

/S/ PROJECT MANAGER 4/6/98
Signature of Preparer and Title Date

Orig NDA/BLA #_____
HF_____/Div File
NDA/BLA Action Package
HFD-006/ KRoberts

(revised 10/20/97)

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT, KHYATI ROBERTS, HFD-6 (ROBERTSK)

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

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.

BLA # 20-708 Supplement # 003 Circle one: (SE1) SE2 SE3 SE4 SE5 SE6

LUPRON DEPOT

HFD-580 Trade and generic names/dosage form: (leuprolide acetate) 11.25mg Action: (AP) AE NA

Applicant TAP HOLDINGS, INC. Therapeutic Class 35

Indication(s) previously approved management of endometriosis; preoperative management of uterine fibroids

Pediatric information in labeling of approved indication(s) is adequate ___ inadequate ___

Proposed indication in this application Same as above

FOR SUPPLEMENTS, ANSWER THE FOLLOWING QUESTIONS IN RELATION TO THE PROPOSED INDICATION.

IS THE DRUG NEEDED IN ANY PEDIATRIC AGE GROUPS? ___Yes (Continue with questions) ✓ No (Sign and return the form)

WHAT PEDIATRIC AGE GROUPS IS THE DRUG NEEDED? (Check all that apply)

__Neonates (Birth-1month) __Infants (1month-2yrs) __Children (2-12yrs) __Adolecents(12-16yrs)

___ 1. **PEDIATRIC LABELING IS ADEQUATE FOR ALL PEDIATRIC AGE GROUPS.** 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 age groups. Further information is not required.

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___ 3. **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 formulation is needed, and applicant has agreed to provide the appropriate formulation.

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___ c. The applicant has committed to doing such studies as will be required.

- ___ (1) Studies are ongoing,
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- ___ (3) Protocols were submitted and are under review.
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___ d. 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 ARE NOT NEEDED.** The drug/biologic product has little potential for use in pediatric patients. Attach memo explaining why pediatric studies are not needed.

___ 5. **If none of the above apply, attach an explanation, as necessary.**

ARE THERE ANY PEDIATRIC PHASE IV COMMITMENTS IN THE ACTION LETTER? ___Yes ___No

ATTACH AN EXPLANATION FOR ANY OF THE FOREGOING ITEMS, AS NECESSARY.

This page was completed based on information from _____ (e.g., medical review, medical officer, team leader)

/S/ PROJECT MANAGER 4/9/98

Signature of Preparer and Title Date

Orig NDA/BLA #_____

HF_____/Div File

NDA/BLA Action Package

HFD-006/ KRoberts

(revised 10/20/97)

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT, KHYATI ROBERTS, HFD-6 (ROBERTSK)

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Pharmacology Review

No Pharmacology review is required.

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Chemistry Review

No Chemistry Review is required.

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EER

There were no manufacturing changes - no EER is required.

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Microbiology Review

No microbiology review is required.

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Statistical Review

No statistical review is required.

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FDA Correspondence

There was no written correspondence sent to sponsor.

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Advisory Committee Meeting Minutes

These applications were not the subject of an Advisory Committee Meeting.

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Federal Register Notices

These applications were not the subject of any Federal Register Notices.

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Advertising Material

No advertising material has been submitted.

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DSI Audit of Clinical Studies

No clinical audits were required.

Patent Certification

This is to certify that the patent information for the new patent nos. 5,575,987, 5,631,020, 5,631,021 and 5,643,607 which cover the method of manufacturing of Lupron Depot, the subject of this supplemental application has been submitted to the agency before.

Aruna Dabholkar, M.D.
Associate Director, Regulatory Affairs
(847) 317-4893
(847) 317-5795 (fax)

NDA 20-011, S-014

The supplemental application is supported by one clinical study. No other study was included to allow for fully integrated summaries of safety and efficacy. Therefore, the ISS and ISE summaries were not submitted with the application.

Aruna Dabholkar, M.D.
Associate Director, Regulatory Affairs
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