CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-406 / S-017

Trade Name: Prevacid 15 mg and 30 mg Capsules, Oral Suspension and Tablets

Generic Name: lansoprazole

Sponsor: TAP Holdings, Inc.

Approval Date: September 17, 1997

Indications: For an additional manufacturing facility for the drug substance
# Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:
20-406 / S-017

APPROVAL LETTER
TAP Holdings Inc.
Attention: Judy Decker Wargel
2355 Waukegan Road
Deerfield, IL 60015

Dear Ms. Wargel:


We acknowledge receipt of your submissions dated July 9 and August 13, 1997.

The supplemental application provides for an additional manufacturing facility for the drug substance.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely yours,

ERIC P. DUFFY 9/17/97

Eric P. Duffy, Ph.D.
Chemistry Team Leader
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-406 / S-017

CHEMISTRY REVIEW(S)
3. Name and Address of Applicant (City & State):
   AP Holdings, Inc.
   2355 Waukegan Road
   Deerfield, IL 60015

4. AF Number: APR 30 1997

5. Supplement(s)

6. Name of Drug: Prevacid®

7. Nonproprietary Name: lansoprazole
   Numbers: SCM-017
   Dates: January 31, 1997

8. Supplement Provides for: qualification of a second
   Takeda manufacturing facility to produce lansoprazole
   bulk drug substance.

9. Amendments and Other (Reports, etc.) Dates:
   Acceptable EER 2/21/97

10. Pharmacological Category: anti-ulcer

11. How Dispensed: RX X OTC

12. Related IND/NDA/DMF(s):

13. Dosage Form: Delayed-Release Capsules

14. Potency: 15 and 30 mg

15. Chemical Name and Structure:
   2-[[3-methyl-4-(2,2,3-trifluoroethoxy) -2-pyridyl-
   [methyl] -sulfinyl]benzimidazole

   ![Chemical Structure Diagram]

16. Records and Reports:
   Current Yes X No __

   Reviewed Yes X No __

17. Comments: Review notes show table comparing new and old procedures. Stability
   data for drug product in blister pack is forthcoming. The applicant should be
   asked to explain some concerns in the manufacturing procedure in an IR letter.
   cc: NDA 20-406/SCM-017
   HFD-180/Div File
   HFD-181/CSO
   HFD-180/SFredd
   HFD-180/ASHaw
   R/D init by: EDuffy 2-21-97
   ABS/dob F/T 4-28-97
   WP: c:\wpfiles\chem\S\20406017.1AS
   EDUFFY 4/30/97

18. Conclusions and Recommendations: The applicant should be sent an Information
   Request letter. (IR)

19. Reviewer
   Name: Arthur B. Shaw, Ph. D.
   Signature: __________
   Date Completed: March 6, 1997
4 Page(s) Withheld

√ Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE (Check One):
☐ Initial ☐ Follow-Up ☐ FUR

LIST NAME: Arthur Shaw

DIVISION: Gastrointestinal and Coagulation Drug Products

MAIL CODE: HFD-180

APPLICATION AND SUPPLEMENT NUMBER: NDA 20-406/S-017

BRAND NAME: Prevacid

ESTABLISHED NAME: lansoprazole

DOSAGE STRENGTH: 15 and 30 mg Delayed-Release Capsules

STERILE: ☐ Yes ☒ No

PROFILE CLASS: CTR

PRIORITY CLASSIFICATION (See SMG CDER-4820.3): Type 1S

APPLICANT’S NAME: TAP Holdings, Inc.

ADDRESS: Bannockburn Lake Office Plaza
2355 Waukegan Road
Deerfield, IL 60015

COMMENTS: This supplement provides for an additional manufacturing facility for the drug substance. This facility is a new building located at the current facility, Takeda’s Hikari plant in Hikari, Japan.

FACILITIES TO BE EVALUATED
(Name and Complete Address) RESPONSIBILITY DMF NUMBER/PROFILE CODE FKEY/CIRTS ID HFD-324 USE ONLY

1. Takeda Chemical Industries, Ltd. Hikari Plant, Building G-27
4720 Takeda Mitsui Hikari Yamaguchi 743, Japan Manufacturing of bulk drug CSN

2.

3.

4.

5.

FOR HFD-324 USE ONLY:

CSO DATE RECEIVED

CGMP COMPLIANCE STATUS DATE

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-406 / S-017

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
TAP Holdings Inc.
Attention: Judy Decker Wargel
2355 Waukegan Road
Deerfield, IL 60015

Dear Ms. Wargel:

Please refer to your pending January 31, 1997 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid(R) (lansoprazole) Delayed-Release Capsules.

To complete our review of your submission, we request the following:

1. Please explain why the

2. [b(4)]

We would appreciate your prompt written response so we can continue our evaluation of your supplemental application.

If you have any questions, please contact Maria R. Walsh, M.S., Project Manager, at (301) 443-0487.

Sincerely yours,

ERIC P. DUFFY 6/17/97

Eric P. Duffy, Ph.D.
Chemistry Team Leader
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
cc:
Original NDA 20-406/S-017
HFD-180/Div. Files
HFD-180/CSO/M.Walsh
HFD-180/A.Shaw
E.Duffy
HFD-820/ONDC Division Director (only for CMC related issues)

Drafted by: M.Walsh 5/5/97
Initialed by: A.Shaw 5/5/97
E.Duffy 6/16/97
final: M.Walsh 6/17/97
filename: 20406S17.ir

INFORMATION REQUEST (IR)
February 13, 1997

Division of Gastrointestinal and Coagulation Drug Products
Document Control Room 6B-24
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Attn: Stephen B. Fredd, M.D.

RE: PREVACID® (Lansoprazole) Delayed-Release Capsules
NDA: 20-406
General Correspondence SNDA 017

Dear Dr. Fredd:

Our original submission of this SNDA on January 31, 1997, contained several errors due to glitches in spell-checking of the document. These occurred on pages 008, 009, 022, and 023 (NDA pagination, lower right corner). I spoke to Ms. Walsh about this on February 11, 1997. She suggested I send the replacement pages as correspondence to the SNDA.

Enclosed are three sets of replacement pages (archival, chemistry and field copy). Also included are the original pages with the errors highlighted. As you can see, the scientific integrity of the report was not affected.

Should you have any questions or need further clarification, please do not hesitate to contact me.

Sincerely,

Judy Decker Wargel
Associate Director, Regulatory Affairs
Phone: (847) 317-5781
Fax: (847) 317-5795

JDW/pjp

cc: Raymond Mlecko
cc: Original NDA 20-406/S-017
    HFD-180/Div. Files
    HFD-180/CSO/M.Walsh
    HFD-180/A.Shaw
    E.Duffy
    HFD-820/ONDC Division Director
    HFD-92/DDM-DIAB
    DISTRICT OFFICE

Drafted by: M.Walsh 9/10/97
Initialed by: E.Duffy
final: M.Walsh
filename: 20406S17.AP

APPROVAL (AP)
NDA 20-406/S-017

TAP Holdings Inc.
Attention: Judy Decker Wargel
2355 Waukegan Road
Deerfield, IL  60015

Dear Ms. Wargel:

We acknowledge receipt of your supplemental application for the following:

Name of Drug Product: Prevacid (lansoprazole) Delayed-Release Capsules

NDA Number: NDA 20-406

Supplement Number: S-017

Therapeutic Classification: Standard

Date of Supplement: January 31, 1997

Date of Receipt: February 3, 1997

This supplement provides for an additional manufacturing facility for the drug substance.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on April 4, 1997 in accordance with 21 CFR 314.101(a).

All communications concerning this supplemental application should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and Coagulation Drug Products,
HFD-180
Attention: DOCUMENT CONTROL ROOM
5600 Fishers Lane
Rockville, Maryland  20857
If you have any questions, please contact me at (301) 443-0487.

Sincerely yours,

Maria R. Walsh, M.S.
Project Manager
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
cc:
Original NDA 20-406/S-017
HFD-180/Div. Files
HFD-180/CSO/M. Walsh
HFD-180/A. Shaw
E. Duffy
DISTRICT OFFICE

Final: M. Walsh/2/6/97

SUPPLEMENT ACKNOWLEDGEMENT (AC)
January 31, 1997

Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Document Control Room 6B-24
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Attn: Stephen B. Fredd, M.D.

RE: PREVACID® (Lansoprazole) Delayed-Release Capsules
NDA: 20-406
Supplemental Application for Manufacturing Change
New Facility

SNDA 017

Dear Dr. Fredd:

The sponsor, TAP Holdings Inc., submits this Supplemental Application under the provisions of Section 505 (i) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.70 (b) (3).

The purpose of this supplement is to qualify a second Takeda manufacturing facility to produce lansoprazole bulk drug for formulation into lansoprazole drug product for export to the United States. This second facility is located next to the current facility at Takeda’s Hikari plant in Hikari, Japan.

The _____ scheme for producing lansoprazole remains unchanged. There are, however, some changes in equipment and processes as well as an increase in scale. These changes are thoroughly described in the overview as well in Takeda Report No. A-29-2270.

Takeda has produced three scale-up lots (H702, H703 and H704) in this new facility and placed them on stability. Interim results are presented in Takeda Report No. A-29-2264. One of these lots, H702, was run through the entire manufacturing procedure. Both 15 mg and 30 mg capsules produced from this lot of bulk drug were sent to the United States and packaged by Abbott Laboratories in HDPE bottles of 100 count and placed on stability. This plan was presented to the Agency on June 10, 1996 (IND Amendment No. 294) and their concurrence received by letter dated July 22, 1996. Results showed no difference in the stability profile from capsules produced from bulk drug from the new facility as compared to capsules utilizing bulk drug produced in the current facility. A comparison of results in tabular form is included as well as the stability reports.

[Signature]

2/1/1997
Stability data will also be generated in the blister pack and submitted as an amendment to this SNDA per an agreement with the Agency (teleconference with Ms. Walsh on January 7, 1997).

Finally, this new bulk facility has been validated and is ready for an FDA preapproval inspection if the Agency wishes to request one.

If you have any questions, please direct them to my attention.

Sincerely,

Judy Decker Wargel
Associate Director, Regulatory Affairs
Phone: (847) 317-5781
Fax: (847) 317-5795

JDW/pjp
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

USER FEE COVER SHEET

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Office of Management and Budget
Paperwork Reduction Project (0910-0297)
Washington, DC 20503

See Instructions on Reverse Before Completing This Form.

1. APPLICANT'S NAME AND ADDRESS
   TAP Holdings Inc.
   2355 Waukegan Road
   Deerfield, IL 60015

2. USER FEE BILLING NAME, ADDRESS, AND CONTACT
   TAP Holdings Inc.
   2355 Waukegan Road
   Deerfield, IL 60015
   Contact: Judy Decker Wargel
   Associate Director, Regulatory Affairs

3. TELEPHONE NUMBER (Include Area Code)
   (847) 317-5781

4. PRODUCT NAME
   PREVACID® (lansoprazole) Delayed-Release Capsules

5. DOES THIS APPLICATION CONTAIN CLINICAL DATA?
   ☐ YES ☐ NO
   IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

6. USER FEE I.D. NUMBER

7. LICENSE NUMBER/INDICATION NUMBER

8. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.
   □ A LARGE VOLUME PARENTERAL DRUG PRODUCT
   □ THE APPLICATION IS SUBMITTED UNDER 505(b)(2)
   ☐ APPROVED BEFORE 9/1/92
   (See reverse before checking box.)
   □ AN INSULIN PRODUCT SUBMITTED UNDER 506
   FOR BIOLOGICAL PRODUCTS ONLY
   □ WHOLE BLOOD OR BLOOD COMPONENT FOR
   ☐ A CRUDE ALLERGENIC EXTRACT PRODUCT
   TRANSFUSION
   □ BOVINE BLOOD PRODUCT FOR TOPICAL
   ☐ AN "IN VITRO" DIAGNOSTIC BIOLOGIC PRODUCT
   APPLICATION LICENSED BEFORE 9/1/92
   LICENSED UNDER 351 OF THE PHS ACT

9. a. HAS THIS APPLICATION QUALIFIED FOR A SMALL BUSINESS EXCEPTION?
   ☐ YES (See reverse if answered YES)
   ☐ NO

b. HAS A WAIVER OF APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION?
   ☐ YES (See reverse if answered YES)
   ☐ NO

This completed form must be signed and accompany each new drug or biologic product, original or supplement.

SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE
Judy Decker Wargel

TITLE
Associate Director, Regulatory Affairs

DATE
January 31, 1997

FORM FDA 3397 (12/93)
MEMORANDUM OF TELECON

DATE: January 7, 1997

APPLICATION NUMBER: NDA 20-406/SCM-017; Prevacid (lansoprazole) Delayed-Release Capsules

BETWEEN:
   Name: Judy Decker Wargel
   Phone: (847) 317-5781
   Representing: TAP Holdings, Inc.

AND
   Name: Maria R. Walsh, Project Manager
   Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: Stability Data for Future Supplement for New Bulk Drug Facility

TODAY’S CALL: Ms. Wargel called me about the Agency’s letter of July 22, 1996 regarding the sponsor’s proposal for a future supplement providing for a new bulk drug facility. Point #2 of that letter requested that the sponsor compare the accelerated stability data of the drug product manufactured with the bulk drug from the new facility with that of the drug product manufactured with the bulk drug from the current facility in both bottles and blisters. Ms. Wargel stated that the request for data in blisters was inadvertently overlooked when stability studies were initiated. The sponsor intends to put the blisters on stability as soon as possible. Ms. Wargel asked me if the sponsor can submit the supplement as planned at the end of January and amend the application with the stability data in blisters.

After conferring with Dr. Arthur Shaw, Chemistry Reviewer, I informed Ms. Wargel that this was acceptable. The call was then concluded.

Maria R. Walsh 2/10/97
Project Manager

cc: Original NDA 20-406/S-017
    HFD-180/Div. File
    HFD-180/M.Walsh
    HFD-180/A.Shaw
    E.Duffy

TELECON
June 30, 1994

Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Document Control Room 6B-24
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Attn: Stephen B. Fredd, M.D.

RE: Lansoprazole (Prevacid®) NDA 20-406
Amendment No. 017

Dear Dr. Fredd:

In accordance with section 505(b) of the Food, Drug and Cosmetic Act and 21 CFR 314.60, TAP Pharmaceuticals Inc., submits this amendment to the pending NDA for lansoprazole.

Appended is the complete safety update for lansoprazole as requested by Dr. Hugo Gallo-Torres. The update includes the following items:

Volume 20.1: Submission Contents, Updated Marketing Status, Membership and Consensus Statement from Eye Safety Subcommittee, Eye Findings from Clinical Studies and an Overview of Retinal Atrophy and Results from Mechanistic Studies. In addition to the archival copy of this volume, four review copies (pharmacology, pharmacokinetics, clinical and statistical) are being submitted.

Volume 20.2: Preclinical study reports and references cited in the overview not included in the NDA. Two copies, archival and review (pharmacology), of this volume are included.

Volumes 20.3 - 20.11: Reports for pharmacokinetic studies which have become available since filing the NDA. Two copies of this volume are included, one archival, the other review (pharmacokinetics).

Volumes 20.12 - 20.25: Clinical study reports which have become available since filing the NDA are being submitted as additional evidence of the safety of lansoprazole. A review (clinical) copy is included as well as the archival copy.
Volumes 20.26 - 20.30: Updated Integrated Summary of Safety for the clinical reviewer. Two copies are included, one archival, the other review (clinical).

Volumes 20.31 - 20.35: Updated Integrated Summary of Safety for the statistical reviewer. Two copies are included, one archival, the other review (statistical).

Volumes 20.36 - 20.39: Case Report Forms for patients who died during a clinical study or discontinued due to an adverse event. Two copies are included, one archival, the other review (clinical).

Should you have any questions about the contents of this submission, please do not hesitate to call me.

Sincerely,

[Signature]

Judy Decker Wargel
Regulatory Products Manager
Phone: (708) 317-5781
Fax: (708) 317-5795

JDW/pjp
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**PUBLIC HEALTH SERVICE**  
**FOOD AND DRUG ADMINISTRATION**  
**APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE**  
**OR AN ANTIBIOTIC DRUG FOR HUMAN USE**  
*(Title 21, Code of Federal Regulations, 314)*

**NOTE:** No application may be filed unless a completed application form has been received (21 CFR Part 314).

**NAME OF APPLICANT**  
TAP Pharmaceuticals Inc.

**DATE OF SUBMISSION**  
June 30, 1994

**ADDRESS (Number, Street, City, State and Zip Code)**  
2355 Waukegan Road  
Deerfield, IL 60015

**TELEPHONE NO. (Include Area Code)**  
(708) 317-5781

**NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued)**  
20-406

### DRUG PRODUCT

**ESTABLISHED NAME (e.g., USP/USAN)**  
Lansoprazole

**PROPRIETARY NAME (If any)**  
Prevacid®

**CODE NAME (If any)**  
AG-1749, A-65006

**CHEMICAL NAME**  
2[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl]benzimidazole

**DOSAGE FORM**  
Capsules

**ROUTE OF ADMINISTRATION**  
Oral

**STRENGTH(S)**  
15 mg  
30 mg

**PROPOSED INDICATIONS FOR USE**

- Reflux esophagitis
- Reflux esophagitis: maintenance of healing
- Duodenal ulcer
- Gastric ulcer
- Pathological hypersecretory conditions including Zollinger-Ellison syndrome

**LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:**

**INFORMATION ON APPLICATION**

**TYPE OF APPLICATION (Check one)**

☐ THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50)  ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

** Если ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION**

**NAME OF DRUG**

**HOLDER OF APPROVED APPLICATION**

**TYPE SUBMISSION (Check one)**

☐ PRESUBMISSION  ☑ AN AMENDMENT TO A PENDING APPLICATION  ☐ SUPPLEMENTAL APPLICATION

☐ ORIGINAL APPLICATION  ☐ RESUBMISSION

**SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION (e.g., Part 314.70(b)(2)(iv))**

**PROPOSED MARKETING STATUS (Check one)**

☑ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx)  ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)

---

**FORM FDA 356h (6/92)**  
**PREVIOUS EDITION IS OBSOLETE.**
**CONTENTS OF APPLICATION**

This application contains the following items: (Check all that apply)

1. Index

2. Summary (21 CFR 314.50 (c))

3. Chemistry, manufacturing, and control section (21 CFR 314.50 (d) (1))

4. a. Samples (21 CFR 314.50 (e) (1)) (Submit only upon FDA's request)
   
   b. Methods Validation Package (21 CFR 314.50 (e) (2) (i))
   
   c. Labeling (21 CFR 314.50 (e) (2) (iii))
      
      i. draft labeling (4 copies)
      
      ii. final printed labeling (12 copies)

5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2))

6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3))

7. Microbiology section (21 CFR 314.50 (d) (4))

8. Clinical data section (21 CFR 314.50 (d) (5))

9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b))

10. Statistical section (21 CFR 314.50 (d) (6))

11. Case report tabulations (21 CFR 314.50 (f) (1))

12. Case reports forms (21 CFR 314.50 (f) (1))

13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))

14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))

15. OTHER (Specify)

I agree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after the initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including the following:

2. Labeling regulations in 21 CFR 201
3. In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202
5. Regulations on reports in 21 CFR 314.80 and 314.81.

If this application applies to a drug product that FDA has proposed for scheduling under the controlled substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

**NAME OF RESPONSIBLE OFFICIAL OR AGENT**

Judy Decker Wargel

Regulatory Products Manager

**SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT**

Judy Decker Wargel

**DATE**

June 30, 1994

**ADDRESS (Street, City, State, Zip Code)**

2355 Waukegan Road

Deerfield, IL 60015

**TELEPHONE NO. (Include Area Code)**

(708) 317-5781

**WARNING:** A willfully false statement is a criminal offense. U.S.C. Title 18, Sec.1001.