CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 050757/S02

ADMINISTRATIVE/CORRESPONDENCE DOCUMENTS

EXCLUSIVITY SUMMARY FOR NDA # 50-757, S002

Trade Name: PREVPAC (PREVACID, Biaxin Filmtab and Amoxil)
Generic Name: lansoprazole, clarithromycin and amoxacillin
Applicant Name: TAP Holdongs, Inc. HFD # 590
Approval Date If Known: 1/ /99

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?
1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA? YES /__/ NO /X/

b) Is it an effectiveness supplement? YES /X/ NO /__/

If yes, what type? (SE1, SE2, etc.) SE2

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.") YES / /NO /X/

Review referenced to NDA 20-406, S021 approved 6/20/98

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?
YES /___/ NO /X/
If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety? No

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

Form OGD-011347 Revised 10/13/98
cc: Original NDA Division File HFD-93 Mary Ann Holovac

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such) YES / / NO /X /

If yes, NDA # Drug Name:

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /X /

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES (N/A)
(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /__/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.) YES /__/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation. YES /X/ NO / /

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement? YES / / NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application? YES /___/ NO / /

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO. YES /___/ NO //
If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product? YES /__/ NO / /

If yes, explain:

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Referenced to NDA 20-406, S021 approved 6/20/98

Investigation #1 M95-399	YES / /	NO /X/
Investigation #2 N/A	YES /___/	NO /___/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

_____ _____

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Referenced to NDA 20-406, S021 approved 6/20/98

Investigation #1	YES /___/	NO /X/
Investigation #2	YES /___/	NO /___/

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

_____ _____

_____ _____

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"): M95-399

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1

YES /X/ NO /___/ Explain: _____

Investigation #2

IND # _____ YES /___/ NO /___/ Explain: _____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study? N/A

Investigation #1

YES /___/ Explain _____ NO /___/ Explain _____

Investigation #2

YES /___/ Explain _____ NO /___/ Explain _____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /X/

If yes, explain: _____

Signature: /S/ Date: 1/12/99
Title: Project Manager

Signature of Office/Division Director: /S/ Date: 1/12/99

APPEARS THIS WAY
ON ORIGINAL

cc: Original NDA 50-757 Division File HFD-93 Mary Ann Holovac

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number:	50757	**Trade Name:**	PREVPAC(AMOXICILLIN/CLARITHROMYCIN/LANSO
Supplement Number:	2	**Generic Name:**	AMOXICILLIN/CLARITHROMYCIN/LANSOPRAZOLE
Supplement Type:	SE2	**Dosage Form:**	CAP
Regulatory Action:		**Proposed Indication:**	H. pylori

IS THERE PEDIATRIC CONTENT IN THIS SUBMISSION? NO

What are the INTENDED Pediatric Age Groups for this submission?

____NeoNates (0-30 Days)____Children (25 Months-12 years)
____Infants (1-24 Months) ____Adolescents (13-16 Years)

Label Status -
Formulation Status -
Studies Needed -
Study Status -

APPEARS THIS WAY
ON ORIGINAL

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

COMMENTS:

Not indicated for pediatric patients at this time.

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER, ROBIN ANDERSON

/S/ 1/12/99

Signature Date

APPEARS THIS WAY
ON ORIGINAL

TAP HOLDINGS INC.
parent of TAP Pharmaceuticals Inc.

Lake Office Plaza
Waukegan Rd.
Deerfield, IL 60015

ORIGINAL

NDA SUPPL AMENDMENT
SE2-002/BL

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
JAN 19 1999
MEGA DOC RM

January 18, 1999

Division of Special Pathogens & Immunologic Drug Products (HFD-590)
Office of Drug Evaluation
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Document Control Room, 1st Floor
9201 Corporate Boulevard
Rockville, MD 20850

Attn: Mark Goldberger, M.D., Division Director

RE: NDA 50-757 - PREVPAC® (lansoprazole/amoxicillin/clarithromycin)
Supplement No. 001 - Amendment No. 001

Labeling Supplement for 10-Day *Helicobacter pylori* Triple Therapy

Dear Dr. Goldberger:

In accordance with section 507(b) of the Food, Drug and Cosmetic Act and 21 CFR 314.60, TAP Holdings Inc. submits this correspondence regarding NDA 50-757.

Per a telephone request made by Ms. Robin Anderson, Project Manager, on January 12, 1999, TAP is submitting a clean copy of the draft package insert for the above mentioned product that was submitted to the division on October 5, 1998.

This labeling is identical to that which was submitted to the Agency on October 5, 1998, with the following exceptions:

1. The text that contained "strikethroughs" (information that would be deleted from the final version) has been removed from the enclosed version.

2. In the paragraph following the header "**Amoxicillin Susceptibility Test Results and Clinical/Bacteriological Outcomes,**" we noticed that the word 'pretreatment" was misspelled in the second sentence. This misspelling has been corrected in the enclosed version.

3. In the version of the package insert that was submitted on October 5, 1998, we noted PREVPAC™ as trademark and we should have noted it as a registered trademark PREVPAC®. This has been corrected in the enclosed version.

If you have any questions regarding this submission, please do not hesitate to contact me.

Sincerely,

Mike Orme for

Linda J. Peters, M.S.
Manager, Regulatory Affairs
(847) 374-5481
(847) 317-5795 FAX

APPEARS THIS WAY
ON ORIGINAL