

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13010



7 - PROCEDURES

000001

2/18/98
1/21/98 faxed
JAN 15 1998
CHI-6130
8-24-98
PAGE JTK
P 0 U F 10

[REDACTED]
[REDACTED] M.D. - [REDACTED]

DAC *** FINAL PAT RPT *** 01/12/98 0104

NAME: [REDACTED] AGE: 34 SEX: M LOCATION: [REDACTED]

PATIENT #: [REDACTED] ORD PHY: [REDACTED]

PREV PAT#:

ADN DT: 01/07/98 TIME: 1010

COLLECTION-01/10/98 1050

MICROBIOLOGY

H. PYLORI SCREEN ONE HOUR READING = NEGATIVE NEGATIVE
NEGATIVE AT 24 HOURS



[REDACTED]

000002

* [REDACTED] [REDACTED] [REDACTED] *

CLINICAL
RECO: →

1/21/98 faxed
2/18/98
JAN 13 1998

[REDACTED]

MR# [REDACTED] Room# [REDACTED]
Billing# [REDACTED]
Date of Surgery: 1/10/98

Patient Name: [REDACTED]
Attending: [REDACTED] D.O.
Surgeon: [REDACTED]

CHI-6130
8-24-98
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PREOPERATIVE DIAGNOSIS: Abdominal pain, rule out ulcer,
rule out gastritis.

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POSTOPERATIVE DIAGNOSIS: 1. Hiatal hernia, uninflamed, 38
centimeters.
2. Mild distal antral gastritis with erosions, rule
out Helicobacter pylori related.
3. Mild duodenitis.

PROCEDURE PERFORMED: Esophagogastroduodenoscopy and biopsy.

ANESTHESIA:

TECHNIQUE: Mr. [REDACTED] received Versed 6.0 mg IV and
Demerol 50 mg IV. He tolerated the procedure very well.

The Olympus video endoscope system was used. The scope was
advanced without difficulty from the mouth into the
esophagus, stomach and into the duodenum. The esophagus was
carefully visualized. The hiatal hernia was discovered at
30 cm. However, there was no significant inflammation or
erosion. There was no degree of esophagitis. The cardia of
the stomach was seen on forward and retroversion and found
to be normal. The body of the stomach was normal. The
antral folds appeared to be normal but there were scattered
erosions right around the pylorus. There was also edema and
granularity and also a mild degree of friability. A biopsy
was taken for Helicobacter pylori. The pylorus itself was
concentric, opening and closing well. The duodenal bulb was
well seen. There was erythema and inflammation, indicative
of a mild degree of duodenitis. The postbulbar area was
well seen. The ampulla of Vater was seen and found to be
normal. The findings are confirmed upon withdrawal of the
scope. I do believe that these degree of duodenitis and
gastritis findings could have been contributing to Mr.
[REDACTED] symptoms over the past six weeks, however, these
seem to be resolving at this time.

RECOMMENDATION: I would institute a regular H2 antagonist.
Will advise ranitidine or Pepcid on a b.i.d. basis. Will
await the biopsy. If it is positive for Helicobacter pylori
continued...

Recall: No. _____ Yes _____

Date: _____

Letter: _____

OPERATIVE REPORT

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Patient Name: [REDACTED]

then would begin that treatment. I will review with Dr. [REDACTED] Mr. [REDACTED] should continue to try to stay away from caffeinated products, alcohol, salicylate products, spicy foods, citrus foods, etc. Further recommendations will follow.

[REDACTED]
ELECTRONIC SIGNATURE

DD: 1/10/98 DT: 1/11/98
[REDACTED] JOB# [REDACTED]