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pharmaceuticals

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October 16, 2001

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Dear Sir or Madam,

The undersigned submits this petition in accordance with 21 CFR 10.30 to request the Commissioner of Food and Drugs to require an acceptable *in vivo* bioequivalence study conducted under fasting and fed conditions as a requirement for approval of an abbreviated new drug application (ANDA) for a generic version of Skelaxin (metaxalone) Tablets, 400 mg.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration require, as a condition of approval an abbreviated new drug application for a generic version of Skelaxin (metaxalone) Tablets, 400 mg, an acceptable bioequivalence study that demonstrates the generic product is bioequivalent to the reference product when administered under both fasting and fed conditions. [Please note that Elan recognizes that the FDA, as described below, has initiated a process whereby they propose to notify industry of the need for an *in vivo* fasting study as a condition of ANDA approval. Should and when that decision become final and FDA publishes final notice in the Orange Book, and responds to the URL petition that an *in vivo* fasting study will be required for ANDA approvals for this drug product, the portion of this petition relating to the *in vivo* fasting study should be considered as withdrawn by Elan. However, the portion of the petition requesting a food effect study as a condition of ANDA approval shall remain active.]

B. Statement of Grounds

The petitioner is aware of the March 6, 2001 petition filed by URL Mutual Pharmaceutical Co. Inc. (Docket No. 01P-0117/CP1) requesting the Food and Drug Administration require an acceptable *in vivo* fasting bioequivalence study demonstrating that the generic product and the reference product are

A member of the Elan group

01P-0481

CP 1

bioequivalent as a condition of approval generic version of Skelaxin (metaxalone) Tablets, 400 mg. In support of their request, URL Mutual included the results of two *in vivo* bioequivalence fasting studies and three separate *in vitro* dissolution tests.

As a result of the data presented in the URL petition, the Division of Bioequivalence, Office of Generic Drugs, has published a proposal to change the designation for metaxalone tablets from a "non bioproblem" to a "bioproblem" drug. This change in designation recognizes that there is no defined *in vivo/in vitro* correlation and will thus require the submission of an *in vivo* bioequivalence study demonstrating that any generic metaxalone product is bioequivalent to Skelaxin. We agree that metaxalone should be designated as a bioproblem drug.

In addition, based on the results of a pharmacokinetics study showing a marked food effect on metaxalone, we are requesting that the abbreviated new drug application approval requirements be further modified to include acceptable bioequivalence to the reference product when administered under both the fed and fasting conditions.

Upon review of the data contained in the URL petition Elan concluded that an *in vivo* fasting study should be required as a subject of approval for a generic product. Based on this realization and a desire to further characterize the pharmacokinetic performance of its product, in July 2001 Elan initiated a study to determine if food has an effect on Skelaxin absorption. A single 400 mg dose of Skelaxin was administered under fasting (10 hour overnight fast) and fed (standard high fat breakfast) conditions in a two treatment, randomized, crossover study in 42 healthy volunteers (31 males, 11 females). The results indicate that the bioavailability was significantly increased when Skelaxin was administered with food in that both the rate (C_{max}) and extent of absorption (AUC_{0-t}) were increased. There was no significant difference noted for AUC_{0-8} . A copy of the final report, conducted in accordance with Protocol No. AN121607 is attached for your review.

In addition, concurrently with the filing of this petition Elan has submitted a labeling supplement to the Skelaxin NDA to revise the labeling to reflect the results of this study.

C. Environmental Impact

Categorical exclusion is claimed under 21 CFR 25.31.

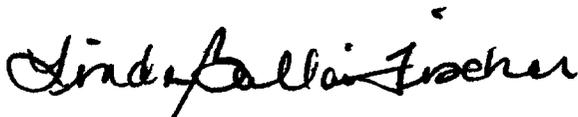
D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,



Linda Ballal Fischer
Director, Regulatory Affairs

Cc: Gary Buehler
Director, Office of Generic Drugs (HFD-600)

Jonca Bull, M.D. -- Cover letter only
Acting Director, Division of Anti-Inflammatory, Analgesic
And Ophthalmic Drug Products (HFD-550)

**Elan Pharmaceuticals
Petition to
Commissioner of Drugs
October 16, 2001
Clinical Documentation**

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STUDY REPORT

**BIOAVAILABILITY STUDY OF SKELAXIN® (METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS**

PROTOCOL NUMBER AN151607

CLINICAL STUDY REPORT

This study was performed in accordance with Good Clinical practice guidelines.
The final study report incorporates ICH 1996 Guidelines and is archived at
Elan Pharmaceuticals.

**BIOAVAILABILITY STUDY OF SKELAXIN® (METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS**

AN151607

CLINICAL STUDY REPORT

IND Number:

Name of Product: Skelaxin® (metaxalone)

Phase of Development: Phase I

Date Study Initiated: July 18, 2001

Date of Last observation: August 21, 2001

Design: Single center, single dose, open-label, two-period, randomized, crossover trial in healthy subjects

Sponsor: Elan Pharmaceuticals, Inc.
800 Gateway Boulevard
South San Francisco, CA 94080

Principal Investigator: Alan K. Copa, Pharm.D.
PRACS Institute, Ltd.

Prepared by: PRACS Institute, Ltd.

Date of Report: October 1, 2001

This study was performed in accordance with Good Clinical Practice guidelines. The final study report incorporates ICH 1996 Guidelines and is archived at [Elan Pharmaceuticals, Inc.]

SIGNATURE PAGE

**BIOAVAILABILITY STUDY OF SKELAXIN® (METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS
(AN151607-101)**

Sponsor Name: Elan Pharmaceuticals, Inc.
Document Version: 1

Prepared by:

Brenda L. Kroger
Brenda L. Kroger, M.S.
Statistician

10/01/01
Date

Reviewed at PRACS Institute, Ltd. by:

Alan K. Copa
Alan K. Copa, Pharm D.
Director, Clinical Research

10/01/01
Date

Reviewed by Quality Assurance by:

Thomas E. Ary
Thomas E. Ary, Ph.D.
Director, Compliance

10/01/01
Date

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of this study.

Approved by:

Jaymin Shah
Jaymin Shah, Ph.D.
Director, Clinical Pharmacology

10/11/01
Date

Michael B. Scaife
Michael Scaife, Ph.D.
Vice President, Regulatory Affairs

10/11/01
Date

Kent Shellenberger
Kent Shellenberger, Ph.D.
Vice President, Clinical Affairs

12 Oct. 01
Date

2.0 SYNOPSIS

NAME OF COMPANY: Elan Pharmaceuticals, Inc.		INDIVIDUAL STUDY SYNOPSIS Page 1 of 3	
NAME OF FINISHED PRODUCT: Skelaxin®	INDIVIDUAL STUDY REFERRING TO PART OF DOSSIER		(FOR NATIONAL AUTHORITY USE ONLY)
	Volume:		
NAME OF ACTIVE INGREDIENT: Metaxalone	Page:		
	Title of Study: Bioavailability Study of Skelaxin® (metaxalone) 400 mg Administered With and Without Food to Healthy Volunteers		
Date of Protocol:		July 03, 2001	
Date of Amendment 1:		July 11, 2001	
Investigators: Principal Investigator: Sub-Investigators:		Alan K. Copa, Pharm D. James D. Carlson, Pharm D. Bruce L. Dahl, M.D. David Jacobson, M.D. Corey Nyhus, M.D. Ronald Borowicz, M.D.	
Study Centers: PRACS Institute, Ltd. 2615 North University Drive Fargo, ND 58102			
Study Period: Date of First Treatment: Date of Last Observation:		Phase of Development: Phase I	
July 21, 2001		August 21, 2001	
Primary Objectives: To evaluate the effect of food on the bioavailability of Skelaxin® (metaxalone) 400 mg in healthy volunteers.			

<p>Methodology: This study was a single center, single dose, open-label, two-period, randomized, crossover trial in healthy volunteers. At each study period, a single oral dose of Skelaxin[®] (metaxalone) was administered to the volunteers under a specified treatment condition dependent on the randomization schedule on days 1 and 8. The treatment conditions were as follows: Treatment A: Skelaxin[®] (metaxalone) tablet 400 mg administered with food Treatment B: Skelaxin[®] (metaxalone) tablet 400 mg administered without food Washout period between study administrations was from days 2 to 7. Blood sampling (17 per subject each period) for drug content analysis occurred within one hour prior to dosing (0 hour) and after dose administration at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 16, 24, and 36 hours.</p>
<p>Number of Patients: Forty-four healthy subjects enrolled in the study (31 male, 13 female). Forty-two subjects successfully completed the study and were used for the pharmacokinetic, statistical, and safety analyses. Subjects 01 and 10 were dropped by the Investigator prior to Period II dosing.</p>
<p>Diagnosis and Main Criteria for Inclusion: Agreed to voluntarily participate and sign informed consent document; healthy volunteers ages 18-55; within 20% of ideal body weight by Metropolitan Height and Weight Tables.</p>
<p>Test Product, Dose, and Mode of Administration, Batch No.: Skelaxin[®] 400 mg Tablets Lot No.: SKLWW263F</p>
<p>Duration of Treatment: Each period was single-dose administration. Dosing periods were separated by a washout of approximately 6 days.</p>
<p>Reference Therapy, Dose, and Mode of Administration, Batch No.: None</p>
<p>Criteria for Evaluation: The following pharmacokinetic parameters were calculated for metaxalone: AUC_{0-t}, AUC_{0-∞}, C_{max}, T_{max}, K_{el}, and t_½.</p>

<p>Statistical Methods: Descriptive statistics with means, standard deviations, coefficients of variation and ranges (min.) and (max.). ANOVA for ln-transformed $AUC_{(last)}$, $AUC_{(inf)}$, and C_{max} and untransformed T_{max}, K_{el}, and $T_{1/2}$ at the alpha level of 0.05. Ratios of geometric least-squares means (administered with food/administered without food) and 90% geometric confidence interval around the ratio for ln-transformed $AUC_{(last)}$, $AUC_{(inf)}$, and C_{max}.</p>
<p>Summary of Results:</p> <p>Safety: During the study, a total of 18 adverse events were experienced post-dose by the subjects who completed the study: 4 adverse events were considered unrelated by the investigator and 14 adverse events were considered related to the study drug.</p> <p>Pharmacokinetics and Pharmacodynamics: During the study there were no protocol deviations to confound the pharmacokinetic and bioavailability analyses. Study results were not corrected for drug potency.</p> <ul style="list-style-type: none">• Ratio (A/B) of least-squares means for $AUC_{(last)}$, $AUC_{(inf)}$ and C_{max} were 123.48%, 115.35% and 177.53%, respectively demonstrating that Skelaxin[®] administered with food increased both the rate and extent of absorption of metaxalone.• ANOVA detected statistically significant differences between treatments for ln-transformed $AUC_{(last)}$, $AUC_{(inf)}$, and C_{max}, as well as for untransformed $AUC_{(last)}$, $AUC_{(inf)}$, C_{max}, $T_{1/2}$, and K_{el}.• ANOVA did not detect any statistically significant differences between treatments for untransformed T_{max}.
<p>Conclusions: All study treatments were well tolerated by all subjects. Administration with food increases both the rate and extent of absorption of Skelaxin[®] (metaxalone) tablets 400 mg when administered as a single dose. Bioavailability of Skelaxin[®] (metaxalone) tablet 400 mg increased when administered with food.</p>
<p>Date of Report: October 1, 2001</p>

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4.0 LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

AE	Adverse Event
AUC _(last)	Experimental area under the curve calculated according to the linear trapezoidal rule
AUC _(inf)	Area under the curve extrapolated to the infinite
CRF	Case Report Form
C _{max}	Maximal plasma concentration
CS	Clinically Significant
ECG	Electrocardiogram
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HIV	Human Immunodeficiency Virus
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
K _{el}	Slope of the Terminal Linear Portion of Concentration vs. Time Curve
NCS	Not Clinically Significant
PK	Pharmacokinetic
QA	Quality Assurance
SAE	Serious Adverse Event
SD	Standard Deviation
T _{1/2}	Terminal half-life
T _{max}	Time to reach the maximal plasma concentration

5.0 ETHICS

5.1 Institutional Review Board (IRB)

Prior to the initiation of the study, the investigator sent the study protocol, protocol amendments, consent and reference drug's package insert to the Institutional Review Board (IRB). The investigator obtained signed evidence of protocol approval from the IRB and forwarded the approval letter to the Sponsor. The IRB approvals and list of IRB members consulted are presented in Appendix 17.1.3.

The July 03, 2001 protocol and July 06, 2001 informed consent document were approved by the PRACS Institute, Ltd. Institutional Review Board on July 18, 2001. The July 11, 2001 protocol amendment and July 10, 2001 informed consent form were approved by the PRACS Institute, Ltd. Institutional Review Board (IRB) on July 19, 2001. The July 19, 2001 informed consent was approved by the PRACS Institute Ltd. Institutional Review Board (IRB) on July 20, 2001. The changes to the original protocol were clarifications or editorial in nature and did not impact subject safety.

These changes are outlined in the attachment to the IRB Approval Form received July 20, 2001.

5.2 Ethical Conduct of the Study

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki, and other principles of the ICH Good Clinical Practice Guideline^{1,2}.

5.3 Patient Information and Consent

At the screening visit, subjects signed the PRACS Institute, Ltd. 'Consent To Be Screened' Form No. 136 approved by the PRACS Institute, Ltd. IRB (Appendix 17.1.2). During the screening visit the study specific informed consent (Elan Pharmaceuticals, Inc. AN151607-101; PRACS R01-433) was reviewed with the subject emphasizing the nature of the study, the drug product tested, potential adverse events, conduct of the study, and dates of confinement and ambulatory procedures. At the Period I check-in, subjects signed the study specific Elan Pharmaceuticals, Inc. AN151607-101; PRACS R01-433 Informed Consent (Appendix 17.1.2). All subjects gave written informed consent to participate in the Elan Pharmaceuticals, Inc. AN151607-101; PRACS R01-433 study and were allowed to ask and have answered questions concerning the conduct of the study prior to enrollment in the study.

6.0 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

Clinical Research Investigators and Facilities:

Alan K. Copa, Pharm.D., Principal Investigator
James D. Carlson, Pharm.D., Sub- Investigator
PRACS Institute, Ltd.
Fargo, ND 58102

Activities: Study management, on-site protocol activities, dosing,
and sample collection

Bruce L. Dahl, M.D., Medical Investigator
David Jacobson, M.D., Sub-Investigator
Corey Nyhus, M.D., Sub-Investigator
Ronald Borowicz, M.D., Sub-Investigator
MeritCare Clinic West Fargo
West Fargo, ND 58078

Activities: Physical examination, medical record review and
medical investigator on-site and on-call professional services

Clinical Laboratory Facilities:

<i>D. Dax Taylor, M.D.</i>	<i>[Hepatitis B surface antigen,</i>
<i>Quest Diagnostics, Inc.</i>	<i>Hepatitis C antibody,</i>
<i>Wood Dale, IL 60191-1024</i>	<i>HIV antibody]</i>

Gary Erdmann, Ph.D.	[Hematology, Chemistry,
PRACS Institute Clinical Laboratory	Urinalysis, Drug Screen,
Fargo, ND 58102	Pregnancy Screen]

Activities: Certified reference clinical laboratories, clinical lab
sample analysis

Analytical Investigator & Facility:

Gary Erdmann, Ph.D.
PRACS Institute, Ltd.
Fargo, ND 58102

Activities: Responsible for bioanalytical analyses.

Statistical Analysis:

Brenda L. Krogen, M.S.
PRACS Institute, Ltd.
Fargo, ND 58102

Activities: Responsible for pharmacokinetic and statistical
analyses.

7.0 INTRODUCTION

Metaxalone is a central nervous system depressant that has sedative and skeletal muscle relaxant effects. Metaxalone is indicated as an adjunct to rest, physical therapy and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions.

Pharmacokinetic studies have not been conducted to date to evaluate the effect of food on the pharmacokinetics of metaxalone. This study compares the bioavailability of 400 mg of the current marketed drug Skelaxin[®] (metaxalone) administered to healthy volunteers with and without food.

8.0 STUDY OBJECTIVES

The primary objective is to evaluate the bioavailability of Skelaxin[®] (metaxalone) when administered to subjects with and without food.

9.0 INVESTIGATIONAL PLAN

9.1 Overall Study Design and Plan

A single center, single dose, open-label, two-period, randomized, crossover trial in healthy subjects. The study duration was approximately 32 days. The two study drug treatments are as follows:

Treatment A: Skelaxin[®] (metaxalone) tablet 400 mg administered with food

Treatment B: Skelaxin[®] (metaxalone) tablet 400 mg administered without food

In fed treatment condition A, study drug was taken 15 minutes after the test meal. The test meal was consumed over a 15 minute time period. There was a 6-day washout period between study drug administrations.

Seventeen blood samples were collected, starting with baseline (0 hour) and at the following time points: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 16, 24, and 36 hours.

A total of 44 subjects (31 males / 13 females) were enrolled and dosed. Only the plasma of subjects who completed the study were assayed and used for the pharmacokinetic analysis.

9.2 Discussion of Study Design

This was a single center, single dose, open label, two-period crossover trial in healthy subjects.

9.3 Selection of Study Population

9.3.1 Inclusion Criteria

- Agreed to participate voluntarily and signed and dated an IRB-approved written, subject informed consent form;
- Between the ages of 18 and 55 inclusive at the time of screening as determined by medical history, physical examination, and laboratory testing;
- Within $\pm 20\%$ of the ideal body weight of the Metropolitan Height and Weight Tables;
- Female subjects of childbearing potential were not pregnant or lactating and were willing to use a medically appropriate form of barrier contraception for the duration of the study.

9.3.2 Exclusion Criteria

- Not competent to provide informed consent;
- Displays clinically significant abnormalities on screening evaluations which consist of: physical examination, supine and standing heart rate and blood pressure, temperature, 12 lead ECG, and clinical laboratory tests. Deviations from the established normal ranges may be acceptable for study participation if, in the opinion of the investigator and Sponsor, they are not clinically meaningful or are viewed as normal for that individual. Individual screening tests may be repeated by the investigator to confirm accuracy of the original determinations or to further evaluate the clinical significance of deviations;
- Evidence for, or a history of clinically meaningful psychiatric, neurological, cardiovascular, pulmonary, gastrointestinal, hepatobiliary, renal, genitourinary, hematological, oncological, endocrinological, rheumatological or infectious disease;
- Known to be HIV positive, hepatitis B antigen positive, or hepatitis C antibody positive;
- History of drug or alcohol addiction or abuse;
- Use of tobacco products;
- Blood donation within 30 days of screening or plasma within 14 days of screening;
- History of clinically significant drug allergies or allergic responses to metaxalone or related drugs;
- Use of any drugs known to induce or inhibit hepatic drug metabolism within 30 days prior to screening;

- Use of prescribed medication, within 14 days prior to screening and throughout the conduct of the study;
- Participation in a clinical trial of an investigational drug or device within 30 days of the treatment phase;
- Considered by the investigator to be unsuitable for study participation, for any reason.

9.3.3 Removal of Patients from Therapy or Assessment

Subjects were discontinued or withdrawn from the study for any of the following reasons, which were recorded on the appropriate case report form (CRF):

- At the patient's request
- At the discretion of the Investigator, if deemed appropriate, for any reason
- At the discretion of the Sponsor, if deemed appropriate, for any reason

The plasma samples for discontinued subjects were not assayed for drug concentration.

9.4 Treatments

9.4.1 Treatments Administered

Each administration was a single oral dose of one Skelaxin® 400 mg tablet with or without food. The study drug was administered as follows:

Treatment A: 1 tablet of Skelaxin® (metaxalone) with 240 mL of room temperature water with food:

Breakfast was given to the subjects 30 minutes prior to dosing and eaten within a 15 minute period. The dose of study drug was administered to the subjects 15 minutes after the breakfast was finished. The breakfast consisted of the following:

- 2 eggs (fried in butter)
- 2 strips of bacon
- 2 slices of toast with butter
- 4 ounces of hash brown potatoes
- 1 glass whole milk (8 ounces)

Treatment B: 1 tablet of Skelaxin® (metaxalone) with 240 mL of room temperature water without food.

The study drug was administered with 240 mL room temperature water. A mouth check was performed to verify that the subjects swallowed the dose.

Subjects were sequentially dosed at 1 minute intervals. The actual time of dosing was recorded on the Master Flow Sheet (refer to the Appendix 16.3.2 Clinical Study Data). Drug administration (1 x 400 mg capsule) was assisted with 240 mL of room temperature water consumed under direct observation. Immediately after administration of product, the subject's oral cavity was checked to confirm complete medication and fluid consumption. Dosing was completed as scheduled in 42 of 44 subjects.

9.4.2 Identity of Investigational Product

Name: Skelaxin[®]
Substance: Metaxalone
Dosage Form: Tablet
Content: 400 mg
Route: Oral
Batch/Lot No.: SKLWW263F
Expiration Date: FEB03
Manufacturer: West-Ward Pharmaceutical Corp

9.4.3 Method of Assigning Patients to Treatment Groups

Subjects were randomly allocated to one of the following sequences: AB or BA where A was the treatment administered with food and B was the treatment administered without food.

PRACS Institute, Ltd. generated the randomization schedule. All subjects received the same study medication each study period. The randomization schedule is located in Appendix 17.1.7.

9.4.4 Selection of Doses in the Study

The dose selected (Skelaxin[®] 400 mg) is the daily recommended dose for this product.

9.4.5 Selection and Timing of Dose for Each Patient

Subjects were sequentially dosed at 1 minute intervals. All subjects received the same study drug at the same dose.

Fasted Condition:

Subjects fasted for at least 10 hours. No water was allowed for one

hour before and one hour after drug administration.

Fed Conditions:

Breakfast was given to the subjects 30 minutes prior to dosing and eaten within a 15 minute period. The dose of study drug was administered to the subjects 15 minutes after the breakfast had been finished.

9.4.6 Blinding

Not Applicable

9.4.7 Prior and Concomitant Therapy

At each visit the investigator obtained information about concomitant illnesses and therapeutic interventions. The investigator recorded the dates of onset and remission of all symptoms and diagnosed conditions, as well as the name, daily dose and dates of prescribed and self medications, surgery, etc.

9.4.8 Treatment Compliance

At each admission to the clinical research facility, all subjects were questioned regarding their compliance to the protocol since their previous visit. Subjects were continuously monitored by PRACS Institute, Ltd. staff throughout the confinement portion of the study.

9.5 Efficacy and Safety Variables

9.5.1 Efficacy and Safety Measurements Assessed and Flow Chart

Efficacy was not an objective of the study design. Safety measurements performed over the course of the study were as follows:

1. A medical history and physical examination was performed at the screening visit and at the post-study visit.
2. Vital signs (supine and standing blood pressure, pulse, and oral temperature) were measured at all visits and on the PK profile days at pre-dose and approximately 2 hours post-dose.
3. Clinical laboratory tests, including serum pregnancy, were performed at screening and on days 1, 10, and 18.

9.5.2 Appropriateness of Measurements

The measurements performed are standard procedures for the conduct of bioavailability studies.

9.5.3 Primary Efficacy Variable

Not applicable.

9.5.4 Drug Concentration Measurements

Blood samples (10 mL) for each measurement of metaxalone plasma levels were collected at the following time points:

- Baseline (0 hour)
- 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 16, 24, and 36 hours after drug administration.

The total blood volume taken per subject for pharmacokinetic analysis was approximately 340 mL (corresponding to 2 x 17 samples) over a period of approximately three weeks.

Each blood sample was drawn by direct venipuncture and collected into a 10 mL EDTA vacutainer. Plasma samples were transferred by pipette into 2 polypropylene tubes, frozen and stored at approximately -20°C. All plasma samples (microtubes) were stored in freezer at approximately -20°C prior to analysis.

9.6 Data Quality Assurance

All parts of the clinical phase of the study and all documentation were subject to inspection by the Company's independent quality assurance (QA) unit. Nonclinical (analytical) parts of the study were also subject to QA audit.

9.7 Statistical Methods Planned in the Protocol and Determination of Sample Size

9.7.1 Statistical and Analysis Plans

All pharmacokinetic parameters were analyzed by non-compartmental methods. The following PK parameters were calculated for the two PK profiles:

- T_{max} : Time to maximum concentration;
- C_{max} : Observed maximum concentration;
- k_{el} : Slope of terminal linear portion of concentration-time curve;
- $T_{1/2}$: Half-life of metaxalone calculated as: $0.693/k_{el}$;
- $AUC_{(last)}$: Area under the curve to last quantifiable concentration as measured by the trapezoidal rule;
- $AUC_{(inf)}$: The AUC value extrapolated to infinity calculated as: $AUC_{(inf)} = AUC_{(last)} + C(t)_{last}/k_{el}$ where $C(t)_{last}$ is the last measurable concentration.

All statistical analyses were performed using SAS® version 6.08 or higher. The PK parameters between the two treatments were compared using an appropriate ANOVA model that includes term for treatment, sequence, and period effect. Ninety percent confidence interval was computed for the C_{max} and AUC values of the fed treatment with fasting as the reference treatment.

9.7.2 Determination of Sample Size

This was a descriptive study to determine the bioavailability of Skelaxin® (metaxalone) when administered with and without food. Due to the descriptive nature of the study, no power calculation was done.

9.8 Changes in the Conduct of the Study or Planned Analyses

No changes were made during the conduct of the study or with the planned analyses that could have altered the study outcomes.

10. STUDY PATIENTS

10.1 Disposition of Patients

The study was successfully completed by 42 of 44 subjects enrolled. At enrollment, all 44 subjects met study inclusion and exclusion criteria as

documented by an acceptable medical history, medication history, physical examination, sitting blood pressure, heart rate, electrocardiogram, clinical laboratory evaluations, a non-reactive HIV antibody screen, and negative screens for hepatitis B surface antigen, pregnancy (females only), and drugs of abuse within twenty-eight days prior to Period I dose administration. All female subjects had a negative pregnancy screen prior to each dose administration. All subjects gave written informed consent and were allowed to ask and have answered questions concerning the conduct of the study prior to enrollment in the study. The trial was conducted under medical supervision (B. Dahl).

	Age (years)	
	Mean ± Standard Deviation	Range
Male Subjects	23.5 ± 5.4	18 – 42
Female Subjects	23.7 ± 6.6	18 – 39
All Subjects	23.5 ± 5.7	18 – 42

	Weight (kg)	
	Mean ± Standard Deviation	Range
Male Subjects	80.7 ± 11.8	59.8 – 107.4
Female Subjects	67.3 ± 9.4	48.5 – 82.9
All Subjects	76.7 ± 12.7	48.5 – 107.4

	Height (cm)	
	Mean ± Standard Deviation	Range
Male Subjects	178.1 ± 7.0	165.1 – 190.5
Female Subjects	164.5 ± 5.8	152.4 – 172.7
All Subjects	174.1 ± 9.1	152.4 – 190.5

The weight of the volunteers was not more than ± 20% of the normal for height and body frame as per the Desirable Weights for Men and Women – 1983 Metropolitan Height and Weight Table.

Section 15.1 includes a table presenting the demographic data for all 44 subjects enrolled in the study.

10.2 Protocol Deviations

Deviations from the protocol instructions of no drug treatment within 30 days of screening occurred for the following subjects:

Event No.	Subject No.	Subject Init.	Medication	Average Daily Dose	Problem	Study Day(s)
01	02	RAW	Aspirin 325 mg	2 tabs	Headache	-07
02	10	AKH	Advil (Ibuprofen 200 mg)	2 tabs	Headache	-11
03	12	CMP	Tylenol (Acetaminophen 325 mg)	2 tabs	Headache	-05
04	15	WLE	Ibuprofen 200 mg	6 tabs	Both Knees Ache	-16
05	19	CLH	Multivitamin	1 tab	Health Supplement	-20 to -09
06	33	DMT	Multivitamin	1 tab	Health Supplement	Stopped -04
07	33	DMT	Ibuprofen 200 mg	9 tabs	Menstrual Cramps	-18 to -17
08	35	AMK	NoDoz (Caffeine 200 mg)	2 caplets	Help Stay Awake	-17
09	35	AMK	Aspirin 325 mg	2 tabs	Headache	-08
10	35	AMK	Tums (Calcium Carbonate 500 mg)	2 tabs	Heartburn	-07
11	39	JDF	Ibuprofen 200 mg	12 tabs	Tendonitis Left Knee	Stopped -16
12	39	JDF	Multivitamin	1 caplet	Health Supplement	Stopped -08
13	39	JDF	Glucosamine/ Chondritin 500/250 mg	1 cap	Health Supplement	Stopped -08
14	43	KAO	Ibuprofen 200 mg	4 tabs	Headache	-18 to -15

In the opinion of the clinical investigators, the reported protocol deviations did not affect the study results nor did they compromise the outcome or validity of the study.

The following subjects reported concurrent problems and medication usage over the course of the study:

Event No.	Subject No.	Subject Init.	Problem	Medication	Average Daily Dose	Study Day(s)
01	06	BAZ	L-Lysine 500 mg	1 tab	Cold Sore - Top Right Lip	07

In the opinion of the clinical investigators, the medication use reported between study Periods I and II was not anticipated to compromise the outcome or validity of the study, and continued study participation was allowed.

11. EFFICACY EVALUATION

Not Applicable

12. PHARMACOKINETIC AND PHARMACODYNAMIC PARAMETERS

12.1 Pharmacokinetics

The pharmacokinetic parameters were calculated using WinNonlin™, Version 3.1, software designed specifically for analyzing pharmacokinetic data. WinNonlin™ Model 200 for extravascular input was utilized. All other computations were completed using SAS®, Version 8.1 for Windows. Microsoft® Excel® 97 was used to produce tables and graphs.

The following pharmacokinetic parameters were computed from the plasma concentration data using the actual sample collection times:

- T_{max} : Time to maximum concentration;
- C_{max} : Observed maximum concentration;
- k_{el} : Slope of terminal linear portion of concentration-time curve;
- $T_{1/2}$: Half-life of metaxalone calculated as: $0.693/K_{el}$;
- $AUC_{(last)}$: Area under the curve to last quantifiable concentration as measured by the trapezoidal rule;
- $AUC_{(inf)}$: The AUC value extrapolated to infinity calculated as:
 $AUC_{(inf)} = AUC_{(last)} + C(t)_{last}/K_{el}$
 where $C(t)_{last}$ is the last measurable concentration.

Natural logarithmic (ln) transformations were computed for $AUC_{(last)}$, $AUC_{(inf)}$, and C_{max} .

An analysis of variance (ANOVA) was performed on each of the pharmacokinetic parameters using SAS® software. The ANOVA model containing factors for sequence of products, subjects within sequence, periods and products was utilized in comparing the effects between Skelaxin® administered with food and without food as the reference

treatment. Differences were declared to be significant at the 5% level.

The ratio of the geometric means for the ln-transformed data and the corresponding 90% confidence intervals were calculated for $AUC_{(last)}$, $AUC_{(inf)}$, and C_{max} . The calculations for the confidence intervals used the least squares means (LSMEANS) and the standard error of the estimate, both generated by the SAS® software.

The lower limit of quantitation for metaxalone was 10 ng/mL. For statistical analysis, subject sample values below the lower limit of quantitation (BLQ) were reported as zero.

The following tables summarize the results of the analyses performed on the pharmacokinetic parameters.

Metaxalone	Ln-Transformed $AUC_{(last)}$	Ln-Transformed AUC_{inf}	Ln-Transformed C_{max}
Treatment A Geometric Mean	7525.00	7630.53	1536.23
Treatment B Geometric Mean	6094.12	6615.24	865.34
% Ratio	123.48	115.35	177.53
90% Confidence Interval	(116.40, 130.99)	(109.24, 121.80)	(156.62, 201.23)

Metaxalone	$AUC_{(last)}$	AUC_{inf}	C_{max}	T_{max}	$T_{1/2}$
Treatment A Least Squares Mean	8439.62	8541.31	1773.61	4.29	2.37
Treatment B Least Squares Mean	6961.81	7478.90	983.37	3.32	9.04

With a 5% significance level, the ANOVA detected statistically significant differences between treatments for ln-transformed $AUC_{(last)}$, AUC_{inf} , and C_{max} , as well as for untransformed $AUC_{(last)}$, $AUC_{(inf)}$, C_{max} , T_{max} , $T_{1/2}$, and K_{el} . The ANOVA detected no statistically significant differences between periods or between sequences.

The mean $T_{1/2}$ (half-life) of metaxalone with food and without food were 2.37 and 9.04 hours respectively. The exact reason for this discrepancy is unclear. However, the AUC_{last} is outside the confidence interval, indicating a significant food effect.

12.2 Pharmacodynamics

Not applicable

13. SAFETY EVALUATION

13.1 Extent of Exposure

The drug product received from Elan Pharmaceuticals, Inc. was as follows:

SKELAXIN® 400 mg Tablets - 1 Bottle of 500 tablets by West-Ward Pharmaceutical Corp., Manufactured for Elan Pharmaceuticals Inc.; Lot No. SKLWW263F; Exp. Date: FEB03.

All subjects received the following test product both of the dosing periods:

Test Product – Skelaxin® 400 mg Tablets
[West-Ward Pharmaceutical Corp., Manufactured for
Elan Pharmaceuticals Inc.]

Subjects were randomized to receive the test product administered with or without food and were randomized in such a manner that each subject received both regimens over the course of the study.

Treatment A: 1 tablet of Skelaxin® (metaxalone) with 240 mL of room temperature water with food:

Breakfast was given to the subjects 30 minutes prior to dosing and eaten within a 15 minute period. The dose of study drug was administered to the subjects 15 minutes after the breakfast was finished. The breakfast consisted of the following:

- 2 eggs (fried in butter)
- 2 strips of bacon
- 2 slices of toast with butter
- 4 ounces of hash brown potatoes
- 1 glass whole milk (8 ounces)

Treatment B: 1 tablet of Skelaxin® (metaxalone) with 240 mL of room temperature water without food, after fasting for approximately 10 hours.

Subjects were sequentially dosed at 1 minute intervals. The actual time of dosing was recorded on the Master Flow Sheet (refer to the Appendix 16.3.2 Clinical Study Data). Drug administration (1 x 400 mg tablet) was

assisted with 240 mL of room temperature water consumed under direct observation. Immediately after administration of product, the subject's oral cavity was checked to confirm complete medication and fluid consumption. Dosing was completed as scheduled in 42 of 44 subjects. The deviations were as follows:

Event No.	Subject No.	Subject Init.	Event	Reason for Dosing Deviation
01	01	ANJ	Subject was dropped by investigator prior to Period II dosing	Subject was unable to consume scheduled breakfast prior to Period II dosing.
02	10	AKH	Subject was dropped by investigator prior to Period II dosing	Positive drug abuse screen prior to Period II dosing

All safety data required at the end of the study was collected for Subjects 01 (ANJ) and 10 (AKH).

Under the investigator's direction, an accurate dispensing log was maintained to record dates and amount of medication dispensed to each subject in the trial. In addition, an entry on the case report form for each subject provides a record of this activity.

All unused study product is accounted for, and will be retained in a secure, controlled environment at PRACS Institute, Ltd. for the appropriate period of time as per FDA requirements.

The subjects remained in an upright position for at least 6 hours following dose administration. During confinement, only non-strenuous activity was permitted. Subjects were continuously monitored by PRACS Institute, Ltd. staff throughout the confinement portion of the study. During the ambulatory portion of the study, staff were available during regular working hours and via an answering service for subject queries.

No fluid except that given with the drug administration and the breakfast (dependent on randomization) was allowed from 1 hour prior to dose administration until 1 hour after dosing. At 2 hours post-dose, all subjects consumed 240 mL of water.

Subjects fasted for 4.25 hours following dose administration. Subjects were served standardized meals and beverages. Meals were the same in content and quantity during each confinement period. No grapefruit products, caffeine, or xanthine-containing food or drink were allowed during the confinement portion of the study.

13.2 Adverse Events

13.2.1 Brief Summary of Adverse Events

During the study, adverse events were mild in severity and no serious or severe adverse events were reported. A total of 18 adverse events by 13 subjects were experienced post-dose by the subjects who completed the study: 4 adverse events were considered unrelated by the investigators and 14 adverse events were considered related to the study drug.

13.2.2 Display of Adverse Events

Adverse events are listed in tables by treatment in Section 15.3.1.

13.2.3 Analysis of Adverse Events

Of the eighteen reported adverse events, fourteen were related to study medication. In the opinion of the investigators, the other four adverse events were unrelated to study medication. None of the adverse events were considered serious or required terminating any subject from study participation.

13.2.4 Listing of Adverse Events by Subject

All adverse events for each subject are listed Appendix 17.2.7.

13.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

No deaths, other serious adverse events, or other significant adverse events occurred.

13.4 Clinical Laboratory Evaluation

13.4.1 Evaluation of Each Laboratory Parameter

Refer to Appendix 17.2.8 for individual laboratory listings of the tests: Hematology, Chemistry, Urinalysis, Drug of Abuse and HIV/HEP B&C.

13.5 Vital Signs, Physical Findings, and Other Observations Related to Safety

No changes were noted from the screening to the post-study physical examination that were considered clinically abnormal by the Medical Investigator.

13.6 Safety Conclusions

The clinical portion of the project was completed without any significant sequelae attributable to the investigational drug. In general, all blood sample collections were successfully completed as per protocol design. The safety monitoring was completed to the satisfaction of the clinical investigators. The clinical laboratory values were considered unremarkable and none of the values outside of the reference range at study exit were considered directly attributable to the product. In the opinion of the investigators, the clinical portion of the project was successfully completed and all study treatments were well tolerated.

14. DISCUSSION AND OVERALL CONCLUSIONS

There were no protocol deviations to confound the pharmacokinetic and bioavailability analyses.

- Ratio of least-squares means for $AUC_{(last)}$, $AUC_{(inf)}$, and C_{max} were 123.48%, 115.35% and 177.53%, respectively, demonstrating that Skelaxin[®] administered with food increased both the rate and extent of absorption of metaxalone.
- ANOVA detected statistically significant differences between treatments for ln-transformed $AUC_{(last)}$, AUC_{inf} , and C_{max} , as well as for untransformed $AUC_{(last)}$, $AUC_{(inf)}$, C_{max} , T_{max} , $T_{1/2}$, and K_{el} .

Bioavailability of Skelaxin[®] (metaxalone) tablet 400 mg increased when administered with food.

All study treatments were found to be safe and well tolerated.

15. TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

15.1 Demographic Data Summary Table

Subject No.	Subject Init.	Subject Chart	Gender	Demographic Data			
				Age (yr)	Weight (kg)	Height (cm)	Body Frame
01	ANJ	104248	Female	18	63	162.6	Medium
02	RAW	100515	Male	20	77	172.7	Medium
03	TLS	104659	Female	24	48.5	160	Medium
04	KRE	104492	Male	23	91.5	190.5	Medium
05	SAP	98555	Male	22	82.4	177.8	Medium
06	BAZ	104752	Male	25	83.4	182.9	Medium
07	CRT	95514	Male	24	59.8	170.2	Medium
08	NBJ	96528	Male	27	81.5	177.8	Large
09	ADR	97501	Male	24	75.2	170.2	Medium
10	AKH	104678	Female	18	58.9	165.1	Medium
11	CWB	104677	Male	20	70.7	182.9	Medium
12	CMP	96298	Male	25	96.9	190.5	Medium
13	KWJ	102585	Male	22	70.7	180.3	Medium
14	JEJ	104687	Female	19	65.7	157.5	Medium
15	WLE	104727	Male	18	73.8	185.4	Medium
16	HMH	104682	Female	20	68.9	172.7	Medium
17	CDD	98427	Male	23	74.7	177.8	Large
18	JME	97021	Male	21	71.6	172.7	Medium
19	CLH	104690	Female	24	82.9	165.1	Large
20	CRG	104693	Male	19	61.2	177.8	Medium
21	KRM	100930	Male	20	71.6	172.7	Medium
22	TMF	104746	Male	21	101	185.4	Large
23	GPA	102915	Male	18	90.6	172.7	Large
24	BDH	102153	Male	21	81.1	180.3	Medium
25	RMK	97683	Male	42	90.1	180.3	Medium
26	JLP	100918	Male	24	107.4	190.5	Large
27	AIF	104673	Female	28	64.3	162.6	Medium
28	SMR	99920	Male	21	68.9	175.3	Medium
29	AJA	104608	Male	20	82	172.7	Medium
30	NCG	101775	Male	21	94.7	182.9	Medium
31	PAZ	101800	Male	23	84.3	172.7	Medium
32	MJH	99638	Male	20	82.9	185.4	Medium
33	DMT	104724	Female	34	60.7	165.1	Medium
34	ACT	95922	Female	39	79.7	165.1	Large
35	AMK	104718	Female	20	69.8	152.4	Large
36	DLJ	104707	Male	34	75.2	170.2	Small
37	MAL	100844	Male	21	63.4	167.6	Medium

(continued)

Subject No.	Subject Init.	Subject Chart	Gender	Demographic Data			
				Age (yr)	Weight (kg)	Height (cm)	Body Frame
38	THP	102279	Female	19	67.5	172.7	Large
39	JDF	104299	Male	22	87.9	172.7	Large
40	TEM	102629	Male	37	98.3	188	Large
41	JNH	91906	Male	29	68.9	165.1	Medium
42	N-F	99843	Male	21	83.8	177.8	Large
43	KAO	104700	Female	19	64.8	170.2	Large
44	BAH	104681	Female	26	79.7	167.6	Medium

15.2 Efficacy Data Summary Figures and Tables

Not Applicable

15.3 Safety Data Summary Figures and Tables

15.3.1 Displays of Adverse Events

Adverse Events: Number of Observed and Rate, with Subject Identification

Treatment A: Skelaxin® administered with Food

Event	Mild		Moderate		Severe		Total		Total
	Related	NR	Related	NR	Related	NR	Related	NR	
Headache	2 (25%) 17 34	1 (13%) 36							3
Nausea	1 (13%) 33								1
Pain Abdomen (Stomachache)	1 (13%) 43								1
Pain Chest	1 (13%) 17								1
Stomatitis Ulcer (Canker Sore)		1 (13%) 26							1
Vomit (Vomited)	1 (13%) 34								1

(%) Denotes the percent of total adverse events within treatment.
 XX Refers to the subject study number

Treatment B: Skelaxin® administered without food

Event	Mild		Moderate		Severe		Total		Total
	Related	NR	Related	NR	Related	NR	Related	NR	
Headache	7 (70%)								7
	12								
	15								
	17								
	33								
	35								
Cold Sore Top Right Lip		1 (10%)							1
		06							
Dyspepsia (Heartburn)	1 (10%)								1
	22								
Pain Abdomen (Stomachache)	1 (10%)								1
	20								

(%) Denotes the percent of total adverse events within treatment.

XX Refers to the subject study number

15.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

Not Applicable

15.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Not Applicable

15.3.4 Abnormal Laboratory Value Listing

The following hematology laboratory test results were outside the reference range at screening. The results were deemed not clinically significant by the medical investigator, and subject enrollment was allowed.

Subject No.	Laboratory Parameter	Laboratory Result	Reference Range
06	WBC	3.6 L	4.5 - 11.0 k/mm ³
07	WBC	3.8 L	4.5 - 11.0 k/mm ³
09	WBC	4.4 L	4.5 - 11.0 k/mm ³
09	Hct	39.5 L	40 - 50 %
09	Platelets	123 L	125 - 500 k/mm ³
36	WBC	4.0 L	4.5 - 11.0 k/mm ³

L: Below the Lower Limit of Normal

The following concurrent (Periods I and II check-in) hematology laboratory test results were outside the reference range and deemed not clinically significant by the clinical investigators.

Subject No.	Laboratory Parameter	Laboratory Result	Reference Range
02	Hgb	17.6 H	13.5 - 17.5 g/dL
02	Hct	50.9 H	40 - 50 %
06	WBC	3.5 L	4.5 - 11.0 k/mm ³
06	WBC	4.4 L	4.5 - 11.0 k/mm ³
09	WBC	4.0 L	4.5 - 11.0 k/mm ³
09	RBC	4.21 L	4.34 - 6.00 k/mm ³
09	Hgb	13.0 L	13.5 - 17.5 g/dL
09	Hct	38.3 L	40 - 50 %
30	Hct	50.4 H	40 - 50 %
30	Hct	51.2 H	40 - 50 %
31	Hct	50.1 H	40 - 50 %
36	WBC	3.5 L	4.5 - 11.0 k/mm ³
40	Hct	50.6 H	40 - 50 %

L: Below the Lower Limit of Normal; H: Above the Upper Limit of Normal

The following hematology laboratory test results were outside the reference range at study exit. The results were deemed not clinically significant by the medical investigator, and no repeat measurements were requested.

Subject No.	Laboratory Parameter	Laboratory Result	Reference Range
03	RBC	3.79 L	4.34 - 6.00 k/mm ³
09	WBC	4.4 L	4.5 - 11.0 k/mm ³
15	Hct	51.6 H	40 - 50 %

L: Below the Lower Limit of Normal; H: Above the Upper Limit of Normal

At study exit follow-up hematology laboratory testing was requested for Subjects 20 (CRG) and 38 (THP).

Subject No.	Laboratory Parameter	Laboratory Result	Repeat Result	Repeat Result	Comment
20	Monos	16.3% H	17.2% H	14.0% H	NCS
20	Neut	42.9% H	48.1% H		NCS
38	WBC	12.3 H	7.2		WNL
38	RBC	3.59 L	3.81		WNL
38	Hgb	11.0 L	11.4 L		NCS
38	Hct	31.6 L	32.9 L		NCS
38	Lymphs	8.1% L	16.5% L		NCS
38	Segs	81% H			
38	Neut	88.3% H	73.4% H		NCS

L: Below the Lower Limit of Normal; H: Above the Upper Limit of Normal

Follow-up was completed as requested for Subjects 20 (CRG) and 38 (THP).

The following screening clinical chemistry laboratory test results were outside the reference range and deemed not clinically significant by the medical investigator. Subject enrollment was allowed.

Subject No.	Laboratory Parameter	Laboratory Result	Reference Range
02	Total Bili	1.3 H	0.2 - 1.2 mg/dL
03	Calcium	10.8 H	8.4 - 10.2 mg/dL
04	Calcium	10.3 H	8.4 - 10.2 mg/dL
05	Chloride	111 H	99 - 110 mmol/L
05	Glucose	61 L	70 - 110 mg/dL
06	Total Bili	1.3 H	0.2 - 1.2 mg/dL
07	Total Bili	2.1 H	0.2 - 1.2 mg/dL
07	Total Protein	6.3 L	6.4 - 8.3 mg/dL
09	Calcium	10.4 H	8.4 - 10.2 mg/dL
09	Chloride	111 H	99 - 110 mmol/L
11	SGPT (ALT)	43 H	0 - 40 IU/L
11	Total Bili	1.3 H	0.2 - 1.2 mg/dL
12	Calcium	10.4 H	8.4 - 10.2 mg/dL
12	Total Bili	1.5 H	0.2 - 1.2 mg/dL
14	Calcium	11.0 H	8.4 - 10.2 mg/dL
14	Phosphorus	4.8 H	2.5 - 4.6 mg/dL
14	Sodium	146 H	135 - 145 mmol/L
15	Total Bili	1.5 H	0.2 - 1.2 mg/dL
17	BUN	26 H	6 - 22 mg/dL
18	Potassium	5.4 H	3.5 - 5.3 mmol/L
20	Calcium	10.4 H	8.4 - 10.2 mg/dL
22	Calcium	10.3 H	8.4 - 10.2 mg/dL
22	SGPT (ALT)	46 H	0 - 40 IU/L
22	Uric Acid	7.7 H	2.6 - 7.2 mg/dL
23	Calcium	10.3 H	8.4 - 10.2 mg/dL
24	BUN	24 H	6 - 22 mg/dL
24	Phosphorus	5.0 H	2.5 - 4.6 mg/dL
26	Creatinine	0.3 L	0.6 - 1.4 mg/dL
26	Glucose	111 H	70 - 110 mg/dL
26	Uric Acid	7.3 H	2.6 - 7.2 mg/dL
30	Total Bili	1.9 H	0.2 - 1.2 mg/dL
30	Uric Acid	8.2 H	2.6 - 7.2 mg/dL
31	Total Bili	1.3 H	0.2 - 1.2 mg/dL
32	SGPT (ALT)	43 H	0 - 40 IU/L
34	LDH	82 L	91 - 180 IU/L
35	Calcium	11.1 H	8.4 - 10.2 mg/dL
35	Potassium	5.5 H	3.5 - 5.3 mmol/L
37	Uric Acid	8.5 H	2.6 - 7.2 mg/dL
40	BUN	23 H	6 - 22 mg/dL
43	Uric Acid	2.3 L	2.6 - 7.2 mg/dL

L: Below the Lower Limit of Normal; H: Above the Upper Limit of Normal

The following concurrent (Periods I and II check-in) clinical chemistry laboratory test results were outside the reference range and deemed not clinically significant by the clinical investigators.

Subject No.	Laboratory Parameter	Laboratory Result	Reference Range
01	Chloride	111 H	99 - 110 mmol/L
02	Total Bili	1.4 H	0.2 - 1.2 mg/dL
05	Chloride	111 H	99 - 110 mmol/L
06	Total Bili	1.7 H	0.2 - 1.2 mg/dL
06	Total Bili	1.3 H	0.2 - 1.2 mg/dL
07	Total Bili	1.6 H	0.2 - 1.2 mg/dL
07	Total Bili	1.5 H	0.2 - 1.2 mg/dL
09	Chloride	111 H	99 - 110 mmol/L
09	Total Bili	1.3 H	0.2 - 1.2 mg/dL
10	Total Protein	6.1 L	6.4 - 8.3 mg/dL
11	Calcium	10.6 H	8.4 - 10.2 mg/dL
11	Potassium	5.8 H	3.5 - 5.3 mmol/L
11	Uric Acid	7.5 H	2.6 - 7.2 mg/dL
13	Phosphorus	4.7 H	2.5 - 4.6 mg/dL
15	Total Bili	1.7 H	0.2 - 1.2 mg/dL
17	BUN	23 H	6 - 22 mg/dL
17	Chloride	111 H	99 - 110 mmol/L
17	Glucose	113 H	70 - 110 mg/dL
18	SGPT (ALT)	44 H	0 - 40 IU/L
20	LDH	90 L	91 - 180 IU/L
21	Phosphorus	4.7 H	2.5 - 4.6 mg/dL
22	SGPT (ALT)	41 H	0 - 40 IU/L
22	SGPT (ALT)	42 H	0 - 40 IU/L
22	Uric Acid	7.8 H	2.6 - 7.2 mg/dL
22	Uric Acid	8.3 H	2.6 - 7.2 mg/dL
25	Chloride	111 H	99 - 110 mmol/L
26	Total Bili	1.7 H	0.2 - 1.2 mg/dL
26	Total Bili	1.5 H	0.2 - 1.2 mg/dL
26	Uric Acid	7.7 H	2.6 - 7.2 mg/dL
26	Uric Acid	8.2 H	2.6 - 7.2 mg/dL
28	LDH	88 L	91 - 180 IU/L
31	Potassium	5.7 H	3.5 - 5.3 mmol/L
32	SGPT (ALT)	42 H	0 - 40 IU/L
32	SGPT (ALT)	45 H	0 - 40 IU/L
33	Total Protein	6.3 L	6.4 - 8.3 mg/dL
34	Glucose	116 H	70 - 110 mg/dL
34	LDH	86 L	91 - 180 IU/L
34	LDH	85 L	91 - 180 IU/L
35	Chloride	112 H	99 - 110 mmol/L
35	Potassium	5.6 H	3.5 - 5.3 mmol/L
37	Uric Acid	7.4 H	2.6 - 7.2 mg/dL
42	SGOT (AST)	74 H	0 - 42 IU/L
42	SGPT (ALT)	58 H	0 - 40 IU/L
43	Uric Acid	2.4 L	2.6 - 7.2 mg/dL
43	Uric Acid	2.5 L	2.6 - 7.2 mg/dL
44	Total Bili	1.3 H	0.2 - 1.2 mg/dL

L: Below the Lower Limit of Normal; H: Above the Upper Limit of Normal

The following exit clinical chemistry laboratory test results were outside the reference range and deemed not clinically significant by the medical investigator. No repeat measurements were requested.

Subject No.	Laboratory Parameter	Laboratory Result	Reference Range
06	Total Bili	1.4 H	0.2 - 1.2 mg/dL
06	Uric Acid	7.7 H	2.6 - 7.2 mg/dL
07	Total Bili	1.3 H	0.2 - 1.2 mg/dL
09	LDH	183 H	91 - 180 IU/L
11	Potassium	5.8 H	3.5 - 5.3 mmol/L
15	LDH	182 H	91 - 180 IU/L
15	Potassium	5.8 H	3.5 - 5.3 mmol/L
17	Phosphorus	4.7 H	2.5 - 4.6 mg/dL
18	Potassium	5.5 H	3.5 - 5.3 mmol/L
22	LDH	182 H	91 - 180 IU/L
22	Uric Acid	8.7 H	2.6 - 7.2 mg/dL
23	Albumin	5.1 H	3.5 - 5.0 g/dL
23	Uric Acid	7.4 H	2.6 - 7.2 mg/dL
24	Albumin	5.1 H	3.5 - 5.0 g/dL
26	Uric Acid	7.5 H	2.6 - 7.2 mg/dL
27	Potassium	5.5 H	3.5 - 5.3 mmol/L
30	Calcium	10.4 H	8.4 - 10.2 mg/dL
31	Potassium	5.5 H	3.5 - 5.3 mmol/L
33	Phosphorus	4.9 H	2.5 - 4.6 mg/dL
34	Creatinine	0.5 L	0.6 - 1.4 mg/dL
39	LDH	188 H	91 - 180 IU/L
39	Potassium	5.5 H	3.5 - 5.3 mmol/L
40	Potassium	5.8 H	3.5 - 5.3 mmol/L
41	Potassium	5.5 H	3.5 - 5.3 mmol/L
42	SGOT (AST)	44 H	0 - 42 IU/L
43	Potassium	5.4 H	3.5 - 5.3 mmol/L
43	Sodium	148 H	135 - 145 mmol/L
43	Uric Acid	2.3 L	2.6 - 7.2 mg/dL

L: Below the Lower Limit of Normal; H: Above the Upper Limit of Normal

At study exit follow-up clinical chemistry laboratory testing was requested for Subjects 05 (SAP), 08 (NBJ), 22 (TMF), 35 (AMK), and 42 (N-F).

Subject No.	Laboratory Parameter	Laboratory Result	Repeat Result	Repeat Result	Comment
05	Glucose	130 H	102		WNL
08	Potassium	6.0 H	5.7 H		NCS
22	SGPT (ALT)	59 H	54 H	32	WNL
35	Potassium	6.7 H	5.1		WNL
42	SGPT (ALT)	50 H	37		WNL

L: Below the Lower Limit of Normal; H: Above the Upper Limit of Normal

Follow-up was completed as requested for Subjects 05 (SAP), 08 (NBJ), 22 (TMF), 35 (AMK), and 42 (N-F).

The HIV antibody and hepatitis B surface antigen screen, and hepatitis C antibody were non-reactive and negative, respectively, for all subjects.

The screening and check-in (Periods I and II) urinalysis values were unremarkable. The pregnancy screen at the screening visit, each check-in, and study exit were negative for all female subjects. Subject 10 (AKH) had a positive drug abuse screen prior to Period II dosing.

There were no clinically significant changes in the clinical laboratory measurements over the course of the study, which could be reasonably associated with the formulations under investigation. All clinical laboratory values were reviewed by the medical investigator and follow-up completed as requested.

16. REFERENCE LIST

- 1 Department of Health and Human Services, FDA. ICH, *Good Clinical Practice: Consolidated Guideline*. May 9, 1997. Federal Register, Vol. 62, No 90, 25692-25709.
- 2 EMEA *Note for Guidance on Good Clinical Practice (ICH Topic E6, Step 5)*. January 17, 1997.

APPENDICES

17. APPENDICES

17.1 Study Information

17.1.1 Protocol and Protocol Amendments

17.1.2 Sample Case Report Form

17.1.3 Institutional Review Board and Representative Informed Consent Documents

17.1.4 List of Investigators

17.1.5 Signature of Principal Investigator

17.1.6 Randomization Scheme

17.1.7 Certificate of Analysis

17.1.8 Documentation of Statistical Methods

Statistical methods are documented in Section 12.1.

17.1.9 Documentation of Inter-Laboratory Standardization Methods and Procedures

17.1.10 Publications Based on the Study

No publications have been based on the study to date.

17.1.11 Important Publications Referenced in Report

No publications were referenced in the report.

17.2 Subject Data Listings

17.2.1 Discontinued Subjects

Reported in Section 13.1.

17.2.2 Protocol Deviations

Reported in Section 10.2.

17.2.3 Subjects Excluded from the Pharmacokinetic Analysis

No subjects were excluded from the pharmacokinetic analysis.

17.2.4 Demographic data.

Reported in Section 15.1.

17.2.5 Plasma Concentration Data and Pharmacokinetic Data

17.2.6 Individual Adverse Event Listings

17.2.7 Listing of Individual Laboratory Measurements

17.3. Case Report Forms

17.3.1 Case Report Forms (for deaths, other serious adverse events,
and withdrawals due to adverse events)

17.3.2 Other Case Report Forms

17.4 Individual Subject Data Listings

Study Information

SECTION 17.1
STUDY INFORMATION



SECTION 17.1.1

Protocol and Protocol Amendments

Elan Pharmaceuticals, Inc.

AMENDMENT #1 TO THE PROTOCOL AN151607-101
11 July 2001

BIOAVAILABILITY STUDY OF SKELAXIN® (METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS

Changes to the 3 July 2001 version of the protocol are as follows:

Protocol Synopsis

Estimated Study Duration: change to "Approximately 30 days"

Schedule of Events

Change the following titles:

Washout Period from "Days 3-8" to "Days 3-6"

"Day 9" to "Day 7"

"Day 10" to "Day 8"

"Day 11" to "Day 9"

3.1 Study Design

2nd sentence: Change to "The study duration will be approximately 30 days."

3.2 Number of Sites and Subjects

2nd sentence: Change to "Each subject will be administered two treatments with a 6 day washout period between treatments."

3.3 Estimated Study Duration

3rd sentence: Change to "Each subject will undergo a washout period from Day 2 through Day 7."

4th sentence: Change to "The second single dose will be administered on Day 8 and PK samples will be again collected up to 36 hours post-dose."

7.3 Clinical Laboratory Tests and Results

1st sentence: Change to "Routine clinical laboratory tests will be performed at screening, Day 1, Day 8 and the post-study visit and include the following:"

7.4 Pharmacokinetic Evaluation

1st sentence: Change to "Prior to dosing on the administration days (Days 1 and 8), a PK blood sample for Skelaxin® (metaxalone) analysis will be obtained.

2nd sentence: Change to read "Blood samples will also be obtained at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 16, 24, and 36 hours post-dose."

8.2 Day -1

4th bullet: Change to "Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature);"

8.3 Day 1

Pre-dose

2nd bullet: "Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature);"

3rd bullet: Change to "Obtain blood and urine samples for clinical laboratory tests and pre-dose PK sample for Skelaxin (metaxalone) within 30 – 45 minutes prior to study drug administration."

Post-Study Drug Administration

2nd bullet: Change to "Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) two hours post-study drug administration;"

8.4 Day 2

2nd bullet: Change to "Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) prior to obtaining the 24 hour PK blood sample;"

4th bullet: Change to "Remind subject about next study visit on Day 7."

8.5 Day 9 (Subject to arrive at study unit in the evening for overnight stay)

Change the title to "8.5 Day 7 (Subject to arrive at study unit in the evening for overnight stay)."

2nd bullet: Change to "Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) prior to the 24 hour blood sample;"

8.6 Day 10 (Subject to arrive at study unit in the evening for overnight stay)

Change the title to "8.6 Day 8 (Study drug administration, PK sampling, and overnight stay)."

Pre-dose

2nd bullet: Change to "Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature);"

3rd bullet: Change to "Obtain blood and urine samples for clinical laboratory tests and pre-dose PK sample for Skelaxin (metaxalone) within 30 – 45 minutes prior to study drug administration;"

Post-Study Drug Administration

▪ 2nd bullet: Change to "Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) two hours post-study drug administration;"

8.7 Day 11

Change the title to "8.7 Day 9."

▪ 2nd bullet: Change to "Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) prior to the 24 hour blood sample;"

CLINICAL RESEARCH PROTOCOL
AN151607-101

BIOAVAILABILITY STUDY OF SKELAXIN® (METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS

Amendment #1 Date: July 11, 2001

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South San Francisco, CA 94080

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ELAN PHARMACEUTICALS, INC.
CLINICAL RESEARCH PROTOCOL
AN151607-101

BIOAVAILABILITY STUDY OF SKELAXIN®(METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS

Protocol Date: July 3, 2001
Amendment #1: July 11, 2001

Prepared by:

Rebecca E. Tupper
Rebecca E. Tupper
Clinical Research Associate

7/16/01
Date

Approved by:

Jaymin Shah
Jaymin Shah, Ph.D.
Director, Clinical Pharmacology

7/16/01
Date

Michael Scaife
Michael Scaife, Ph.D.
Vice President, Regulatory Affairs

7/17/01
Date

Kent Shellenberger
Kent Shellenberger, Ph.D.
Vice President, Clinical Affairs

17 July 01
Date

CONFIDENTIALITY AND INVESTIGATOR STATEMENT
ELAN PHARMACEUTICALS, INC.
CLINICAL RESEARCH PROTOCOL
AN151607-101

JULY 11, 2001

BIOAVAILABILITY STUDY OF SKELAXIN®(METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS

The information contained in this document and all information provided to you related to metaxalone ("drug") are the confidential and proprietary information of Elan Pharmaceuticals, Inc. (Sponsor) and except as may be required by federal, state or local laws or regulations, may not be disclosed to others without prior written permission of Sponsor. The Principal Investigator may, however, disclose such information to supervised individuals working on the Drug, provided such individuals agree to be bound to maintain the confidentiality of such Drug information.

I agree to abide by the statement of confidentiality.

I agree to conduct the study according to this protocol and have read and agree to comply with the Investigator's obligations (Section 14). Any changes in procedure will only be made if necessary to protect the safety, rights or welfare of subjects.

I agree to comply with the current International Conference on Harmonisation Tripartite Guideline on Good Clinical Practice plus appropriate FDA CFRs.

I agree to conduct the study in person or to supervise the study.

I agree to ensure that all who assist me in the conduct of the study have access to the study protocol and any amendments and are aware of their obligations.

Alan Corp
Principal Investigator Signature

07/19/01
Date

Investigator send signed original to Elan. Keep copy for files.

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PROTOCOL SYNOPSIS

Title	Bioavailability Study of Skelaxin® (metaxalone) 400 mg Administered With and Without Food to Healthy Volunteers
Study Phase	I
Indication	Muscle Pain
Primary Objective	To evaluate the effect of food on the bioavailability of Skelaxin® (metaxalone) 400 mg in healthy volunteers
Study Design	Single center, single dose, open-label, two-period, randomized, crossover trial in healthy subjects
Number of Sites And Subjects	44 subjects to achieve 42 evaluable subjects at one site
Estimated Study Duration	Approximately 30 days
Summary of Subject Eligibility Criteria	<p><u>Inclusion:</u> Agreed to voluntarily participate and sign informed consent document; healthy volunteers ages 18 – 55; within 20% of ideal body weight.</p> <p><u>Exclusion:</u> Abnormalities on physical examination or clinical laboratory tests; history of clinically meaningful abnormalities or drug/alcohol addiction or abuse; history of drug allergies, allergic response to metaxalone or use of drugs which could affect metaxalone metabolism; known to be positive for HIV, hepatitis B or C; clinically significant illness within 4 weeks of screening; use of tobacco products; females who are pregnant or breastfeeding; blood donation within 30 days of screening or plasma donation within 14 days of screening; use of prescribed medication within 14 days of screening or non-prescribed medications within 3 days prior to screening; participated in clinical trial within 30 days; considered to be unsuitable for participation.</p>

Drug, Drug Dosage and Formulation	Treatment A: metaxalone tablet 400 mg administered with food Treatment B: metaxalone tablet 400 mg administered without food
Route of Administration	Oral
Procedures	Some of the procedures performed at screening and during the study include: medical history, physical examination, vital signs, 12 lead ECG, clinical laboratory testing, plasma sample collection for metaxalone PK analyses and adverse events assessments
Primary Endpoint	Pharmacokinetic parameters following metaxalone tablet 400mg with food compared to metaxalone tablet 400 mg without food
Statistical Considerations	PK parameters consisting of: T_{max} , C_{max} , K_{el} , $t_{1/2}$, $AUC_{(0-last)}$, $AUC_{(0-inf)}$. Adverse events will be presented on all subjects who receive study drug.
Sponsor	Elan Pharmaceuticals, Inc. 700 Gateway Blvd. South San Francisco, CA 94080

SCHEDULE OF EVENTS

Procedure	Screen	Treatment Period 1			Wash-out	Treatment Period 2			Post-study
	Day -14 to -1	Day -1 Overnight	Day 1 Overnight	Day 2	Days 3-6 wash-out	Day 7 over-night	Day 8 over-night	Day 9	Post-Study Visit
Informed consent	X								
Inclusion/Exclusion	X	X							
Medical history	X								
Physical exam	X								X
Vital signs	X	X	X ¹	X		X	X ¹	X	X
12 lead ECG	X								X
Fast overnight (10 hours)		X				X			
Hematology, chemistry, urinalysis	X		X				X		X
Serum Pregnancy	X								X
Drug/alcohol screen	X	X				X			
PK samples			X ²				X ²		X
Breakfast (for Treatment A only) ³									
Study drug administration ⁴			X				X		
Adverse events			X	X		X	X	X	X
Concomitant medication	X	X		X		X		X	X

¹Obtain vital signs pre-dose and two hours post-study drug administration.

²Obtain PK samples at pre-dose, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 16, 24 and 36 hours post-dose.

³Breakfast to be given to subjects 30 minutes prior to dosing and eaten within a 15 minute period.

⁴Study Drug to be administered to subjects receiving Treatment A 15 minutes after breakfast has been finished.

1.0 INTRODUCTION—RATIONALE

1.1 Background on Skelaxin® (Metaxalone)

Metaxalone is a central nervous system depressant that has sedative and skeletal muscle relaxant effects. Metaxalone is indicated as an adjunct to rest, physical therapy and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions.¹

Two pharmacokinetic studies comparing the bioavailability of generic metaxalone 400 mg tablets and to the innovator Skelaxin® 400 mg tablets under fasting conditions, have been conducted.

Both of these studies, Study P99-466 & P99-642 were randomized, two-way crossover studies in healthy male and female subjects under fasting conditions. The washout period between the two treatments was one week. The results of both these studies were that the generic tablets were not bioequivalent to the Skelaxin® tablets.

In study P99-466, for Skelaxin® the average time to maximum plasma concentration observed was about 3.4 hours with a range of 1 – 5 hours and the mean half-life of metaxalone in plasma was observed to be 6.69 hours with the range of 3.4 – 15.2 hours.

Pharmacokinetics studies have not been conducted to date to evaluate the effect of food on the pharmacokinetics of metaxalone.

The most frequent reactions to metaxalone include nausea, vomiting, gastrointestinal upset, drowsiness, dizziness, headache, and nervousness or "irritability". The recommended dose for adults and children over 12 years of age is two tablets (800 mg) three or four times a day.¹

1.2 Rationale

This study will compare the bioavailability of 400 mg of the current marketed drug Skelaxin®(metaxalone) administered to healthy volunteers with and without food. The outcome of this study may help to determine the effect of food on the pharmacokinetics and disposition of metaxalone in patients.

2.0 OBJECTIVES AND ENDPOINTS

2.1 Primary Objective

The primary objective is to evaluate the bioavailability of Skelaxin®(metaxalone) when administered to subjects with and without food.

2.2 Clinical and Statistical Hypothesis

There is no clinical or statistical hypothesis defined for this study as this is a descriptive study to determine the bioavailability of Skelaxin®(metaxalone) when administered with and without food.

3.0 STUDY PLAN

3.1 Study Design

This is a single center, single dose, open-label, two-period, randomized, crossover trial in healthy subjects. The study duration will be approximately 30 days. The two study drug treatments are as follows:

Treatment A: Skelaxin®(metaxalone) tablet 400 mg administered with food

Treatment B: Skelaxin®(metaxalone) tablet 400 mg administered without food

3.2 Number of Sites and Subjects

The total number of subjects to be enrolled is approximately 44, to achieve at least 42 evaluable subjects at one site. Each subject will be administered two treatments with a 6 day washout period between treatments.

3.3 Estimated Study Duration

All subjects will be screened up to 14 days prior to being dosed with the first study treatment. The first single dose will be administered on Day 1 and PK samples will be collected up to 36 hours post-dose. Each subject will undergo a washout period from Day 2 through Day 7. The second single dose will be administered on Day 8 and PK samples will be again collected up to 36 hours post-dose. A post-study visit will be within approximately 7 days following completion of the second PK sampling period.

4.0 SUBJECT SELECTION

4.1 Inclusion Criteria

- Have agreed to participate voluntarily and signed and dated an IRB-approved written, subject informed consent form;

- Between the ages of 18 and 55 inclusive at the time of screening as determined by medical history, physical examination, and laboratory testing;
- Within 20% of ideal body weight according to the Metropolitan Height and Weight Tables;
- Female subjects of childbearing potential must not be pregnant or lactating or must be willing to use a medically appropriate form of barrier contraception for the duration of the study.

4.2 Exclusion Criteria

- Not competent to provide informed consent;
- Displays clinically significant abnormalities on screening evaluations which consist of: physical examination, supine and standing heart rate and blood pressure, temperature, 12 lead ECG, and clinical laboratory tests. Deviations from the established normal ranges may be acceptable for study participation if, in the opinion of the investigator and Sponsor, they are not clinically meaningful or are viewed as normal for that individual. Individual screening tests may be repeated by the investigator to confirm accuracy of the original determinations or to further evaluate the clinical significance of deviations;
- Evidence for, or a history of clinically meaningful psychiatric, neurological, cardiovascular, pulmonary, gastrointestinal, hepatobiliary, renal, genitourinary, hematological, oncological, endocrinological, rheumatological or infectious disease;
- Known to be HIV positive, hepatitis B antigen positive, or hepatitis C antibody positive;
- History of drug or alcohol addiction or abuse;
- Use of tobacco products;
- Blood donation within 30 days of screening or plasma within 14 days of screening;
- History of clinically significant drug allergies or allergic responses to metaxalone or related drugs;
- Use of any drugs known to induce or inhibit hepatic drug metabolism within 30 days prior to screening;
- Use of prescribed medication, within 14 days prior to screening and throughout the conduct of the study;

- Participation in a clinical trial of an investigational drug or device within 30 days of the treatment phase;
- Considered by the investigator to be unsuitable for study participation, for any reason.

5.0 SUBJECT ENROLLMENT AND RANDOMIZATION

Prior to shipment of study drug and before subjects may be enrolled in the study, Sponsor requires a copy of the critical documents outlined in Section 13.0, which include IRB (Institutional Review Board) approval of the protocol and informed consent form.

A subject is considered enrolled in the study after signing and dating a written informed consent document, undergoing all screening procedures, and meeting all trial requirements. Subjects who meet all eligibility requirements will be randomly assigned to the order in which they will receive the two single doses of Skelaxin®(metaxalone).

6.0 STUDY DRUG AND TREATMENT

6.1 Formulation, Packaging and Labelling

Skelaxin® (metaxalone) will be provided by the sponsor in the 400 mg strength for the study. A sufficient quantity of drug, including retention samples, will be provided for the study. All drugs will be of the same lot. The drugs will be identified by the lot number and the expiration date which will be recorded.

Skelaxin® is supplied for oral administration as tablets containing 400 mg metaxalone. Each tablet contains the labeled amount of metaxalone plus certain inactive ingredients.

6.2 Storage and Handling

All clinical supplies for use in the study will be maintained at room temperature in a locked, secure area under supervision by the Principal Investigator or pharmacist, or as required by the study site. An accurate record will be kept of the dispensing, return and disposal of the materials.

6.3 Drug Accountability and Return of Study Supplies

The Study Pharmacist or designee will be responsible for accurately monitoring the storage, dispensing and use of all study medications according to accepted medical and pharmaceutical practice. All records must be made available to the Sponsor (or its agent) and appropriate regulatory agencies upon request. All unused study medication will be returned to the Sponsor at the end of the study. The site will maintain an accountability record of all returned study drug.

6.4 Study Drug Dosage, Administration and Schedule

The appropriate strengths of study drug will be dispensed by the pharmacist or designee for each dose. A single dose will be administered to each subject by study unit personnel for each of the two treatment periods according to a randomization sequence prepared by a study statistician.

The study drug will be administered as follows:

Treatment A: 1 tablet of Skelaxin® (metaxalone) with 240 mL of room temperature water with food

Breakfast will be given to the subjects 30 minutes prior to dosing and eaten within a 15 minute period. The dose of study drug will be administered to the subjects 15 minutes after the breakfast has been finished.

The breakfast will consist of the following:

- 2 eggs (fried in butter)
- 2 strips of bacon
- 2 slices of toast with butter
- 4 ounces of hash brown potatoes
- 1 glass whole milk (8 ounces)

Treatment B: 1 tablet of Skelaxin® (metaxalone) with 240 mL of room temperature water without food

6.5 Overdose

Gastric lavage and supportive therapy as indicated. When determining the LD₅₀ in rats and mice, progressive sedation, hypnosis and finally respiratory failure were noted as the dosage increased. In dogs, no LD₅₀ could be determined as the higher doses produced an emetic action in 15 to 30 minutes. No documented case of major toxicity has been reported.

6.6 Concomitant Therapy

Medication use is prohibited throughout the study unless required for the treatment of an adverse event. Investigators may prescribe any concomitant therapy deemed necessary to provide adequate supportive care. Intermittent or as needed ("PRN") use of any medication during the study for an adverse event must be recorded on the Adverse Event form in addition to the Concomitant Medication Form.

Use of non-prescribed medication within three days prior to screening and throughout the study is prohibited. In addition, use of prescribed medication within 7 days prior to screening and throughout the study is prohibited.

Use of multivitamins (with the exception of megadose regimens) and/or occasional aspirin, acetaminophen, short acting antihistamine or decongestant use is acceptable for study participants provided none are taken within 24 hours of study drug administration.

All medication use will be documented on the case report form. Any medications used during the study must be approved by study unit personnel prior to administration.

7.0 STUDY PROCEDURES

7.1 Subject Informed Consent

Prior to any study-related activities, an IRB approved informed consent form must be signed and personally dated by the subject. The format and content of the informed consent form must be agreed upon by the Principal Investigator(s), appropriate IRB and the Sponsor. Appendix A contains the elements of informed consent.

The subject's original signed and personally dated informed consent form together with any subsequent IRB approved amended versions must be retained by the Investigator in the subject's file. A COPY of the original signed and dated informed consent form must be given to the subject.

7.2 Study Procedures for Safety Evaluations

A medical history and physical examination will be performed at the screening visit and at the post-study visit.

Vital signs (supine and standing blood pressure, pulse, and oral temperature) will be measured at all visits and on the PK profile days at pre-dose and approximately 2 hours post-dose.

7.3 Clinical Laboratory Tests and Results

Routine clinical laboratory tests will be performed at screening, Day 1, Day 8 and the post-study visit and include the following:

Blood Chemistry: sodium, potassium, chloride, blood urea nitrogen (BUN), creatinine, total bilirubin, uric acid, calcium, magnesium, carbon dioxide, Gamma GT, phosphorus, total protein, albumin, aspartate aminotransferase (AST) (or serum glutamyl-oxaloacetic transaminase (SGOT)), alanine aminotransferase

(ALT) or serum glutamic-pyruvic transaminase (SGPT), alkaline phosphatase, and lactate dehydrogenase (LDH);

Hematology: hemoglobin, hematocrit, red blood cell count, white blood cell count with differential and platelet count;

Urinalysis: color, pH, specific gravity, glucose, protein, ketones, and microscopic examination.

Special laboratory tests will include the following:

Drug and alcohol screen

Samples for drug and alcohol testing will be obtained at screening and prior to the two single doses of study drug.

A total of approximately 70 mL of blood will be obtained from each subject for the clinical laboratory tests over the duration of the study. All blood tests and urinalyses will be performed at a local laboratory.

All laboratory reports must be reviewed, initialed and dated by the Principal Investigator or a designee. Each abnormal test will be evaluated as clinically significant (CS) or not clinically significant (NCS). A legible copy of all reports must be filed with the subject's CRFs. All clinically significant abnormal laboratory tests post-treatment must be repeated. Any CS abnormal values that persist should be followed until they have resolved or the Investigator assesses them to be chronic or stable after consultation with the Sponsor.

7.4 Pharmacokinetic Evaluation

Prior to dosing on the administration days (Days 1 and 8), a PK blood sample for Skelaxin®(metaxalone) analysis will be obtained. Blood samples will also be obtained at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 16, 24 and 36 hours post-dose. A total of approximately 370 mL (37 samples) will be collected for Skelaxin®(metaxalone) PK analyses over a period of approximately three weeks.

Samples will be collected by venipuncture or indwelling catheter into appropriately labeled, negative pressure collection tubes (eg., vacutainer tubes). Samples for analysis of Skelaxin®(metaxalone) concentrations will be analyzed at Pracs Institute Laboratory. Details of sample handling are described in Appendix B.

A total of approximately 440 mL of blood will be drawn for clinical laboratory testing and PK analysis over the duration of the study (approximately five weeks).

7.5 12 Lead Electrocardiogram

A 12 lead electrocardiogram (ECG) will be performed at the screening visit and the post-study visit. The investigator will review the ECG for signs of cardiac disease, which, in his/her opinion, would exclude the subject from a research study.

All ECG recordings will be clearly identified with the subject's initials and number and will be signed and dated by the investigator (or designee). A copy of the ECG will be attached to the CRF and the investigator will retain the original with the source documents.

7.6 Other Requirements and Restrictions

7.6.1 Diet

Meals will be provided by the study unit during the period of confinement. Lunch, dinner, and a snack will be provided at approximately 1200 (4 hours post drug administration for subjects receiving Treatment B), 1800, and 2130 as applicable.

7.6.2 Alcohol, Caffeine, and Tobacco Use

Subjects will be asked to refrain from alcohol consumption from 24 hours prior to Day 1 to the completion of all PK blood draws. Caffeine intake will be restricted to no more than three cups of coffee, tea, or 12 ounce cans of soda per day. Subjects will also be asked to refrain from the use of tobacco for the duration of the study.

8.0 EVALUATIONS BY VISIT

The overall summary of evaluations by visit is given in the Schedule of Events at the end of the protocol synopsis section.

8.1 Screening Visit (Day -14 to Day -1)

Potential subjects will have a detailed oral presentation of the nature, purpose, risks, and requirements of this study and will receive written information prior to enrollment in the study. They will have an adequate opportunity to ask the investigator about any aspect of the study. After the volunteer has satisfied himself and is willing to participate in the study, he will be asked to sign the informed consent form (the original for the Clinical Unit and a copy for himself).

Screening procedures will be performed to establish eligibility for participation in the study as follows:

- Medical history;
- Concomitant medication review;
- Inclusion/exclusion criteria review;

- Physical examination including height, weight, sitting and standing blood pressure, pulse, and oral temperature;
- Blood and urine samples for hematology, chemistry, urinalysis, alcohol and drug screen as listed in section 7.3;
- 12 lead ECG;
- Instruct subjects to abstain from all drugs of abuse and alcohol intake and reduce caffeine intake to no more than three cups per days for at least 24 hours prior to planned study drug administration and throughout the study.

8.2 Day –1 (Subject to arrive at study unit in the evening for overnight stay)

- Subjects will report to the study unit in the evening prior to the first study drug administration;
- Review subject eligibility prior to dosing on Day 1;
- Check that subjects reduced caffeine intake to no more than three cups per day for at least 24 hours prior to planned study drug administration and remind them to continue this throughout the study;
- Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature);
- Obtain sample for drug abuse screen and perform alcohol screen;
- Perform a concomitant medication review;
- Provide snack to subject;
- Instruct subject to fast for 10 hours.

8.3 Day 1 (Study drug administration, PK sampling, and overnight stay)

Pre-dose

- Review drug and alcohol screen results. They must be negative for continued participation;
- Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature);
- Obtain blood and urine samples for clinical laboratory tests and pre-dose PK sample for Skelaxin®(metaxalone) within 30 - 45 minutes prior to study drug administration.

Study Drug Administration

Breakfast will be given to the subjects receiving Treatment A 30 minutes prior to dosing and eaten within a 15 minute period. The dose of study drug will be administered to the subjects 15 minutes after the breakfast has been finished.

Administer the single dose of Skelaxin®(metaxalone) according to the randomization scheme and according to the specific instructions for administration (i.e. Treatment A with food and Treatment B without food).

Post-Study Drug Administration

- Obtain PK blood samples at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12 and 16 hours post-study drug administration;
- Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) two hours post-study drug administration;
- Observe subjects and ask subjects about any adverse events particularly CNS related such as dizziness, confusion, and somnolence;
- Lunch will be served approximately 4 hours after study drug administration.

8.4 Day 2

- Obtain PK blood samples at 24, 30, and 36 hours post-study drug administration;
- Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) prior to the 24 hour blood sample;
- Inquire about adverse events and any concomitant medications taken;
- Remind subject about next study visit on Day 7.

8.5 Day 7 (Subject to arrive at study unit in the evening for overnight stay)

- Subjects will report to the study unit in the evening prior to the second study drug administration;
- Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature);
- Obtain sample for drug abuse screen and perform alcohol screen;
- Perform an adverse event assessment;
- Perform a concomitant medication review;
- Provide snack to subject;
- Instruct subject to fast for 10 hours.

8.6 Day 8 (Study drug administration, PK sampling, and overnight stay)

Pre-dose

- Review drug and alcohol screen results. They must be negative for continued participation;
- Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature);
- Obtain blood and urine samples for clinical laboratory tests and pre-dose PK sample for Skelaxin®(metaxalone) within 30 – 45 minutes prior to study drug administration.

Study Drug Administration

Breakfast will be given to the subjects receiving Treatment A 30 minutes prior to dosing and eaten within a 15 minute period. The dose of study drug will be administered to the subjects 15 minutes after the breakfast has been finished.

Administer the single dose of Skelaxin®(metaxalone) according to the randomization scheme and according to the specific instructions for administration (i.e. Treatment A with food and Treatment B without food).

Post-Study Drug Administration

- Obtain PK blood samples at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12 and 16 hours post-study drug administration;
- Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) two hours post-study drug administration;
- Observe subjects and ask subjects about any adverse events particularly CNS related such as dizziness, confusion, and somnolence;
- Lunch will be served approximately 4 hours after study drug administration.

8.7 Day 9

- Obtain PK blood samples at 24 and 36 hours post-study drug administration;
- Obtain vital signs (supine and standing blood pressure, pulse, and oral temperature) prior to the 24 hour blood sample;
- Inquire about adverse events and any concomitant medications taken;
- Remind subject about Post-Study Visit.

8.8 Post-Study Visit

- Perform physical examination;
- Obtain vital signs (lying and standing blood pressure, pulse, and oral temperature);
- Obtain blood and urine samples for hematology, chemistry, and urinalysis;
- Obtain blood sample for Skelaxin®(metaxalone) PK analysis;
- 12 lead ECG;
- Inquire about adverse events and any concomitant medications taken.

9.0 WITHDRAWAL AND REPLACEMENT OF SUBJECTS

9.1 Criteria for Subject Withdrawal

Subjects may be discontinued or withdrawn from the study for any of the following reasons, which must be recorded on the appropriate CRF:

- At the patient's request
- At the discretion of the Investigator, if deemed appropriate, for any reason

- At the discretion of the Sponsor, if deemed appropriate, for any reason

10.0 ADVERSE EVENTS/SERIOUS ADVERSE EVENTS AND REPORTING

10.1 Adverse Events—Definition

An adverse event is any undesirable event that occurs to a participant during the course of a study (or a reasonable time after study termination), whether or not that event is considered study drug-related. Examples include:

- Any treatment emergent signs and symptoms (events that are marked by a change from the subject's baseline/entry status [e.g., an increase in severity or frequency of pre-existing abnormality or disorder])
- All reactions from study drug, an overdose, abuse of drug, withdrawal phenomena, sensitivity or toxicity to study drug.
- Apparently unrelated illnesses.
- Injury or accidents (e.g., for a fall secondary to dizziness, record "dizziness" as the first event and record the "fall" as the second event. Please note in the comment/narrative section that the fall occurred secondary to the dizziness and record information about the consequence of the fall as part of the outcome information;
- Extensions or exacerbations or symptomatology, subjective subject-reported events, new clinically significant abnormalities in clinical laboratory, physiological testing or physical examination.

All adverse events, whether or not related to the study drug, and whether non-serious or unexpected must be fully and completely documented on the Adverse Event page of the CRF and in the subject's medical notes. The following attributes must be assigned: description; dates of onset and resolution; severity; assessment of relatedness to study drug (either related or not related); and action taken. The Investigator may be asked to provide follow up information.

In the event that a subject is withdrawn from the study because of an adverse event, it must be recorded on the CRF as such. The subject should be followed for at least 30 days after the last Skelaxin®(metaxalone) dose and treated by the Investigator until the abnormal parameter or symptom has resolved or stabilized.

The Investigator must report all directly observed adverse events and all spontaneously reported adverse events. At each visit the Investigator will ask the subject a non-specific question (e.g. "Have you noticed anything different since your last visit?") to assess whether any adverse events have been experienced since the last report or visit. Adverse events will be identified and documented on the Adverse Event page of the CRF in appropriate medical

terminology. The severity and the relationship to the study drug will be determined and reported on the CRF (see below).

Note that any intermittent or as needed (prn) use of medication (and specifically any newly prescribed medication) during the course of a study may indicate the occurrence of an adverse event that may need to be recorded on both the Adverse Event page of the CRF and the Concomitant Medication page.

10.2 Adverse Events—Severity Rating

The severity of each adverse event should be characterised and then classified into one of three clearly defined categories as follows:

- Mild – the adverse event does not interfere in a significant manner with the subject's normal functioning level. It may be an annoyance.
- Moderate – the adverse event produces some impairment of functioning, but is not hazardous to health. It is uncomfortable or an embarrassment.
- Severe – the adverse event produces significant impairment of functioning or incapacitation and is a definite hazard to the subject's health.

These three categories are based on the Investigator's clinical judgement, which in turn depends on consideration of various factors such as the subject's reports, the physician's observations and the physician's prior experience. The severity of the adverse event should be recorded in the appropriate section of the Adverse Event page of the CRF.

10.3 Adverse Events—Causality Rating

An adverse event will be considered 'not related' to the use of the product if any of the following tests are met:

- An unreasonable temporal relationship between administration of the product and the onset on the AE (e.g. the event occurred either before, or too long after administration of the product for it to be considered product-related)
- A causal relationship between the product and the AE is biologically implausible (e.g. death as a passenger in an automobile accident)
- A clearly more likely alternative explanation for the AE is present (e.g. typical adverse reaction to a concomitant drug and/or typical disease-related event)

Individual adverse event reports will be considered 'related' to the use of the product if the 'not related' criteria are not met.

Associated with the use of the drug' means that there is 'a reasonable possibility' i.e. there are facts, evidence or arguments to suggest that the event may have been caused by the product under investigation.

10.4 Serious Adverse Events and Unexpected Adverse Events

In addition to the severity rating, each adverse event is to be classified by the Investigator as "serious" or "not serious". A serious adverse event is one that:

- is fatal
- is life-threatening
- is permanently [or significantly] disabling.
- requires hospitalization
- prolongs existing hospitalization
- is a congenital anomaly or birth defect [in an offspring]

Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above.

Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization; or development of drug dependency or drug abuse.

Any adverse event that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e. it does not include a reaction that, had it occurred in a more severe form, might have caused death.

Disability is a substantial disruption of a person's ability to conduct normal life functions.

A serious adverse event may also include any other event that the Investigator or medical monitor judges to be serious, or that suggests a significant hazard, contraindication, side effect or precaution.

In addition, the following events should also be considered serious and reported according to the directions in the next Section (10.5):

- A new diagnosis of cancer or a significant change of status in a subject's baseline of cancer
- An overdose, whether or not there are any clinical sequelae
- Pregnancy

Any subjects that become pregnant during the study must be withdrawn from treatment, and those who have received at least one dose of study drug will be followed to term.

10.5 Serious Adverse Events—Reporting

The reporting of Serious Adverse Events (SAEs) by Elan to the Regulatory Authorities is a regulatory requirement. Each Regulatory Authority has established a timetable for reporting SAEs based upon established criteria. Likewise, it is the responsibility of the Principal Investigator to report SAEs to their IRB.

Do **not** delay in the reporting of a suspected SAE in order to obtain additional information. Any additional information, if collected, can be reported to the Sponsor as a follow-up to the initial report. SAEs will be reported using the SAE forms provided as part of the subjects CRF. Please remember to give details of the subject initials and identification number and ensure the narrative is comprehensive and includes a chronology and assessment of the event.

The process for reporting a serious adverse event is as follows:

- Complete an adverse event case report form
- Complete a serious adverse event form
- The narrative should be comprehensive and include a chronology and an assessment of the event.
- Complete the FAX cover sheet.
- Call Elan and ask for your study monitor, the study manager, or the medical monitor on call (see details that follow)
- Fax the cover sheet and the serious adverse event form to the appropriate contact

Follow up information on a previously reported SAE should be processed using a new set of SAE forms. Follow up information includes additions, deletions, and

corrections to the initial report. Previously signed, dated and faxed forms should not be altered to provide follow up SAE information of any type. Please remember that the following must be done when providing follow-up information:

- Tick the box that indicates follow up information is being provided
- Fill out the dates on each page of the form that indicates this is a follow up report
- Restate the event as it appears on the initial report. If the event has changed, indicate, with parentheses, what the event was previously per the example below:

SERIOUS ADVERSE EVENT
Diagnosis or Sign/Symptom

Myocardial Infarction
(previously chest pain)

All SAEs must be reported immediately (within 24 hours of discovery) by fax to the following number: (877) 352-6237. During working hours (9 am to 5 pm) SAE related calls should first be directed to:

Contact: Janice K. Gross, R.N., B.S.

Office Tel No.: (650) 794-5760

or

Contact: Jaymin Shah, Ph.D.

Office Tel No.: (650) 877-7457

In the event that this person cannot be reached, or if the call is outside working hours, or requires medical advice, contact:

Contact: Global Safety Surveillance

Office Tel No.: (877) 352-6477

It is the Investigator's responsibility to notify the responsible IRB regarding new and significant safety information. At a minimum, events identified by Elan to require expedited reporting as serious, unexpected, and possibly related to study drug, must be brought to the attention of the responsible IRB. It is the Investigator's responsibility to provide any additional information to the IRB in accordance with specific agreements.

Subjects in this study will be followed until minimum 30 days from last dose for any SAEs and/or unexpected events. These events should continue to be reported within 24 hours of discovery, particularly life-threatening or fatal events, and the Investigator should continue to provide reports to the IRB, as required. In the event of any SAE (other than death), the subject will be instructed to contact the Investigator (or designee) about any event that is unusual or unexpected

using the telephone number provided in the subject information sheet. All subjects experiencing an SAE will be seen by the Investigator or designee as soon as is feasible following the report of the SAE.

11.0 STATISTICAL CONSIDERATIONS

11.1 Statistical methods

11.1.1 Comparisons of Interest

The primary goal is to evaluate the bioavailability of 400 mg of the current marketed drug Skelaxin®(metaxalone) administered to healthy volunteers with and without food.

11.1.2 Sample Size Determination

This is a descriptive study to determine the bioavailability of Skelaxin®(metaxalone) when administered with and without food. Due to the descriptive nature of the study, no power calculation was done.

11.1.3 Subject Population/Data Sets to Be Evaluated

A total of approximately 44 healthy subjects will be evaluated.

11.2 Statistical analyses

11.2.1 Demography

Demographic characteristics of the subjects will be summarized by type of variable. Categorical data (eg. gender and race) will be summarized by counts, percentages and continuous variables (eg. age, and weight by mean, standard deviation, median, minima, maxima, and number of subjects, as appropriate.

11.2.2 Pharmacokinetic Analysis

All pharmacokinetic parameters will be analyzed by non-compartmental methods. The following PK parameters will be calculated for the 2 PK profiles:

- T_{max} – time to maximum concentration;
- C_{max} – observed maximum concentration;
- Kel – slope of the terminal linear portion of the concentration-time curve;
- $T_{1/2}$ – half life of metaxalone calculated as $0.693/Kel$
- $AUC_{(last)}$ – area under the curve to last quantifiable concentration as measured by the trapezoidal rule;
- $AUC_{(inf)}$ – the AUC value extrapolated to infinity calculated as:
$$AUC_{(inf)} = AUC_{last} + C(t)_{last}/Kel$$

Where C(t) is the last measurable concentration

All statistical analyses will be performed using SAS® version 6.08 or higher. The PK parameters between the two treatments will be compared using an appropriate ANOVA model that includes term for treatment, sequence, and period effect. Ninety percent confidence interval will be computed for the C_{max} and AUC values of the fed treatment with fasting as a reference treatment.

11.2.3 Safety Analysis

All subjects who receive study treatment will be included in the safety analysis.

All adverse events will be recorded. Adverse events will be coded using the COSTART classification to give a preferred term and primary body system for each event. Proportions of subjects with adverse events will be presented by dose. Tables of adverse events will be presented by body system and also by preferred term. These tables will also include overall totals for adverse events within each body system. Counting will be done by subject and not event.

A table of counts and percentages will be made for subjects with serious adverse events or adverse events that lead to withdrawal from the study.

Treatment emergent and non-treatment emergent events (events that occur prior to the initial dose level of metaxalone) will be presented separately. Treatment emergent adverse events are defined as adverse events that had an onset day on or after the day of the first dose of metaxalone or worsening of an event which was present at baseline. Adverse events that have missing onset dates will be considered treatment emergent.

11.2.4 Withdrawals

The number and percentage of subjects who withdraw from the study and their reasons for withdrawal will be tabulated by dose. The distribution of withdrawals and reasons will be displayed at each visit.

11.2.5 Deaths

All deaths will be listed.

12.0 DATA RECORDING, RETENTION AND MONITORING

12.1 Case Report Forms (CRFs)

CRFs will be provided for each subject. The participants of the study will not be identified by name on any study documents to be collected by the Sponsor, but will be identified by a Subject Identification Number and initials.

All clinical information requested in this protocol will be recorded on the CRFs provided by Sponsor using legible entries with a black/blue ball-point pen. If an

error is made, a single line will be drawn through the error and the correct response will be written adjacent to the error, initialed and dated.

CRFs must be reviewed and verified for accuracy by the Principal Investigator and signed-off before collection by either Elan. A copy (or original) of the CRF will remain at the Investigator's site at the completion of the study.

12.2 Retention and Availability of Records

The Investigator must make study data accessible to the monitor, other authorized representatives of Sponsor and/or designee and Regulatory Agency (e.g., FDA, HPB, MCA others) inspectors upon request. A file for each subject must be maintained that includes the signed Informed Consent form and your copies of all source documentation related to that subject. The Investigator must ensure the reliability and availability of source documents from which the information on the CRF was derived.

Investigators are required to maintain all study documentation, including copies of CRFs, Informed Consent forms and adequate records for the receipt and disposition of all study medications, for a period of two years following the FDA or other regulatory approval date of the drug, or until two years after the drug investigational program is discontinued unless a longer period is required by applicable law or regulation. Only Sponsor can notify an Investigator when any records may be discarded.

Subject identity information will be maintained for 15 years unless a longer period is required by applicable law or regulation.

12.3 Monitoring and Compliance

The Sponsor and/or designee representative and regulatory authority inspectors are responsible for contacting and visiting the Investigator for the purpose of inspecting the facilities and, upon request, inspecting the various records of the trial (e.g. CRFs and other pertinent data) provided that subject confidentiality is respected.

The Elan and/or designee monitor is responsible for inspecting the case report forms at regular intervals throughout the study to verify adherence to the protocol; completeness, accuracy, and consistency of the data; and adherence to local regulations on the conduct of clinical research. The monitor should have access to subject medical records and other study-related records needed to verify the entries on the CRFs.

The Investigator agrees to cooperate with the monitor to ensure that any problems detected in the course of these monitoring visits are resolved.

In accordance with ICH GCP and the Sponsor and/or its designee audit plans, this study may be selected for audit. Inspection of site facilities (e.g. pharmacy, drug storage areas, laboratories etc) and review of study related records will occur in order to evaluate the trial conduct and compliance with the protocol, ICH GCP, and applicable regulatory requirements.

12.4 Subject Confidentiality

The Investigator must ensure that each subject's anonymity is maintained as described below. On the CRFs or other documents submitted to the Sponsor and/or its designee, subjects must be identified by their initials and a Subject Identification number only. Documents that are not for submission to the Sponsor and/or its designee (e.g. signed informed Consent forms) should be kept in strict confidence by the Investigator in compliance with Federal regulations or other applicable laws or ICH GCP Guidelines. The Investigator and institution must permit authorized representatives of the Sponsor and/or its designee, of the regulatory agency(s), and the IRB direct access to review the subject's original medical records for verification of study-related procedures and data. Direct access includes examining, analyzing, verifying, and reproducing any records and reports that are needed for the evaluation of the study. The Investigator is obligated to inform the subject in the informed consent that his/her study-related records will be reviewed by the above named representatives.

13.0 ETHICAL AND LEGAL ISSUES

13.1 Ethical Conduct of the Study

The study will conform to Good Clinical Practice Guidelines and to the Declaration of Helsinki 1964, as modified by the 42nd World Medical Assembly, Somerset West, S Africa, 1996 (Appendix C).

13.2 Ethics Committee Approval

The Principal Investigator at each site is responsible for obtaining IRB approval for the final protocol, sponsor-approved informed consent, and any advertisements to recruit subjects at the next available meeting. Written approval of these documents must be obtained from the committee before any subject is enrolled at a center.

The Principal Investigator is also responsible for the following interactions with the IRB:

- Obtaining IRB approval for any protocol amendments and Informed Consent form revisions before implementing the changes;
- Providing the IRB with any required information before or during the study;
- Submitting progress reports to the IRB, as required, during the conduct of the study; requesting re-review and approval of the study, as needed; providing copies of all IRB re-approvals and relevant communication to Elan and/or designee;
- Notifying the IRB of all serious and unexpected adverse events related to the study medication reported by Elan and/or designee, as required.

13.3 Subject Informed Consent

The Investigator's draft Informed Consent must be reviewed by the Sponsor prior to IRB submission for approval. An IRB/IEC-approved copy of the Informed Consent will be forwarded to the Sponsor.

The Informed Consent form documents the study-specific information the Investigator provides to the subject and the subject's agreement to participate. Among other things, the Investigator will fully explain in layman's terms the nature of the study, along with the aims, methods, anticipated benefits, potential risks and any discomfort participation may entail (see Appendix B for the Element of Informed Consent). The Informed Consent form must be appropriately signed and dated before entering the study. The original and any amended signed and dated Informed Consent form(s) must be retained in the subject's file at the study site; and a copy must be given to the subject.

13.4 Protocol Amendments and Study Termination

Protocol amendments must be made only with the prior approval of Elan and/or designee. Agreement from the Investigator must be obtained for all protocol amendments and amendments to the informed consent document. The IRB must be informed of all amendments and give approval for any amendments likely to affect the safety of the subjects or the conduct of the trial. The Investigator must send a copy of the approval letter from the IRB to Elan and/or designee.

Both Elan and the Investigator reserve the right to terminate the study, according to the study contract. The Investigator should notify the IRB in writing of the trial's completion or early termination and send a copy of the notification to Elan and/or designee.

14.0 INVESTIGATORS RESPONSIBILITIES

In signing this protocol and the FDA Form 1572 the Investigator agrees to:

- i. Conduct the study in accordance with the relevant, current protocol(s) and only make changes after notifying the Sponsor, except when to protect the safety, rights or welfare of the subjects.
- ii. Comply with the International Conference on Harmonisation Tripartite Guideline on Good Clinical Practice plus appropriate FDA CFRs.
- iii. Personally conduct or supervise the described investigation.
- iv. Inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes.
- v. Ensure that the requirements relating to obtaining Informed Consent and IRB review and approval have been met.
- vi. Report to the Sponsor adverse experiences that occur in the course of the investigation(s) as specified in Section 10.
- vii. Have read and understand the Investigator's Brochure, including potential risks and side effects of the drug.
- viii. Ensure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
- ix. Maintain adequate and accurate records and make these available for inspection by the Sponsor and/or its designee, the FDA or any agency authorized by law, as defined in Section 12.
- x. Ensure that an IRB complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation.
- xi. Promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others.
- xii. Not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
- xiii. Comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements.

15.0 PUBLICATION

All publication rights are delineated in the Clinical Study Agreement.

16.0 REFERENCES

1. Monographs from Physician's Desk Reference. Medical Economics Company: Montvale, NJ, 2001.

LIST OF APPENDICES

- A. Elements of Informed Consent
- B. Pharmacokinetic Samples
- C. Declaration of Helsinki

APPENDIX A: ELEMENTS OF INFORMED CONSENT

Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

- That the trial involves research;
- The purpose of the trial;
- The trial treatment(s) and the probability for random assignment to each treatment;
- The trial procedures to be followed including all invasive procedures;
- The subject's responsibilities;
- Those aspects of the trial that are experimental;
- The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant;
- The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this;
- The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks;
- The compensation and/or treatment available to the subject in the event of trial-related injury;
- The anticipated prorated payment, if any, to the subject for participating in the trial;
- The anticipated expenses, if any, to the subject for participating in the trial;
- That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled;
- That the monitor(s), the auditor(s), the IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written Informed Consent Form, the subject or the subject's legally acceptable representative is authorizing such access;
- That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly

available. If the results of the trial are published, the subject's identity will remain confidential;

- That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial;
- The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury;
- The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated;
- The expected duration of the subject's participation in the trial;
- The approximate number of subjects involved in the trial.

APPENDIX B: PHARMACOKINETIC EVALUATION

1. PK samples for Skelaxin®(metaxalone)

The Skelaxin®(metaxalone) PK assay will be performed by Pracs Institute Laboratory. The collection procedure will be as follows:

A blood sample will be collected into a 10 mL EDTA vacutainer. Samples will then be centrifuged at 2400 rpm at 4°C for 15 minutes.

Plasma samples will be transferred by pipette into 2 polypropylene tubes, frozen and stored at approximately -20°C. All plasma samples (microtubes) must be stored in an approximately -20°C freezer prior to analysis.

APPENDIX C: DECLARATION OF HELSINKI

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975, 35th WMA General Assembly, Venice, Italy, October 1983, 41st WMA General Assembly, Hong Kong, September 1989, 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.

A. INTRODUCTION

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.
2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.
3. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.
5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.
7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.
13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.
14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the

principles enunciated in this Declaration.

15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.
17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.
19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
20. The subjects must be volunteers and informed participants in the research project.
21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the

consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.
24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.
25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.
26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.
27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.
29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.
30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.
32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

**CLINICAL RESEARCH PROTOCOL
AN151607-101**

**BIOAVAILABILITY STUDY OF SKELAXIN® (METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS**

Date: July 3, 2001

Sponsor: Elan Pharmaceuticals, Inc.
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**ELAN PHARMACEUTICALS, INC.
CLINICAL RESEARCH PROTOCOL
AN151607-101**

**BIOAVAILABILITY STUDY OF SKELAXIN®(METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS**

Protocol Date: July 3, 2001

Prepared by:

Rebecca E. Tupper
Rebecca E. Tupper
Clinical Research Associate

5 July 2001
Date

Approved by:

Jaymin Shah
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Kent Shellenberger
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Vice President, Clinical Affairs

3 July 01
Date

**CONFIDENTIALITY AND INVESTIGATOR STATEMENT
ELAN PHARMACEUTICALS, INC.
CLINICAL RESEARCH PROTOCOL
AN151607-101**

JULY 3, 2001

**BIOAVAILABILITY STUDY OF SKELAXIN®(METAXALONE) 400 MG
ADMINISTERED WITH AND WITHOUT FOOD TO HEALTHY VOLUNTEERS**

The information contained in this document and all information provided to you related to metaxalone ("drug") are the confidential and proprietary information of Elan Pharmaceuticals, Inc. (Sponsor) and except as may be required by federal, state or local laws or regulations, may not be disclosed to others without prior written permission of Sponsor. The Principal Investigator may, however, disclose such information to supervised individuals working on the Drug, provided such individuals agree to be bound to maintain the confidentiality of such Drug information.

I agree to abide by the statement of confidentiality.

I agree to conduct the study according to this protocol and have read and agree to comply with the Investigator's obligations (Section 14). Any changes in procedure will only be made if necessary to protect the safety, rights or welfare of subjects.

I agree to comply with the current International Conference on Harmonisation Tripartite Guideline on Good Clinical Practice plus appropriate FDA CFRs.

I agree to conduct the study in person or to supervise the study.

I agree to ensure that all who assist me in the conduct of the study have access to the study protocol and any amendments and are aware of their obligations.

Principal Investigator Signature

Date

Investigator send signed original to Elan. Keep copy for files.

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PROTOCOL SYNOPSIS

Title	Bioavailability Study of Skelaxin® (metaxalone) 400 mg Administered With and Without Food to Healthy Volunteers
Study Phase	I
Indication	Muscle Pain
Primary Objective	To evaluate the effect of food on the bioavailability of Skelaxin® (metaxalone) 400 mg in healthy volunteers
Study Design	Single center, single dose, open-label, two-period, randomized, crossover trial in healthy subjects
Number of Sites And Subjects	44 subjects to achieve 42 evaluable subjects at one site
Estimated Study Duration	Approximately 32 days
Summary of Subject Eligibility Criteria	<p><u>Inclusion:</u> Agreed to voluntarily participate and sign informed consent document; healthy volunteers ages 18 – 55; within 20% of ideal body weight.</p> <p><u>Exclusion:</u> Abnormalities on physical examination or clinical laboratory tests; history of clinically meaningful abnormalities or drug/alcohol addiction or abuse; history of drug allergies, allergic response to metaxalone or use of drugs which could affect metaxalone metabolism; known to be positive for HIV, hepatitis B or C; clinically significant illness within 4 weeks of screening; use of tobacco products; females who are pregnant or breastfeeding; blood donation within 30 days of screening or plasma donation within 14 days of screening; use of prescribed medication within 14 days of screening or non-prescribed medications within 3 days prior to screening; participated in clinical trial within 30 days; considered to be unsuitable for participation.</p>

Subject 12

Figure 3.10a
Plasma Concentrations (0 - 36 hours)

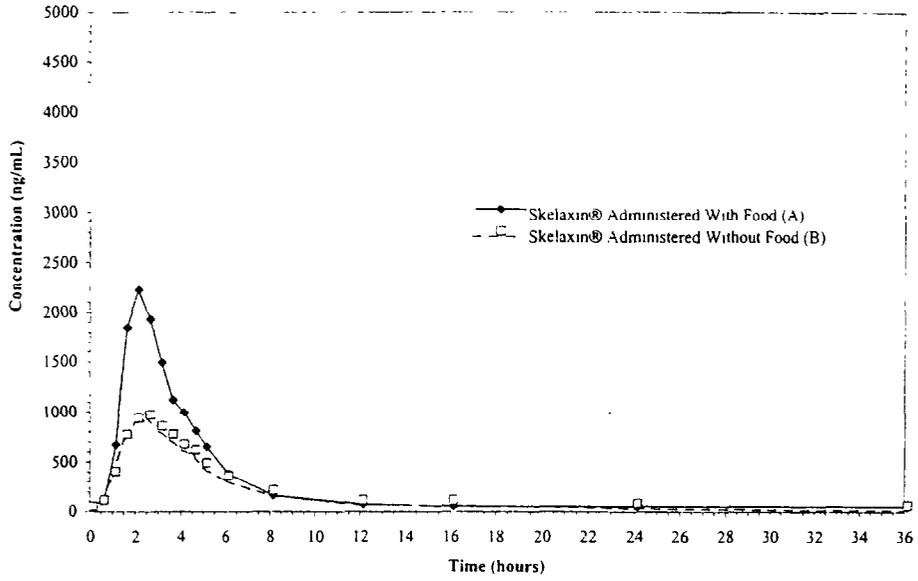
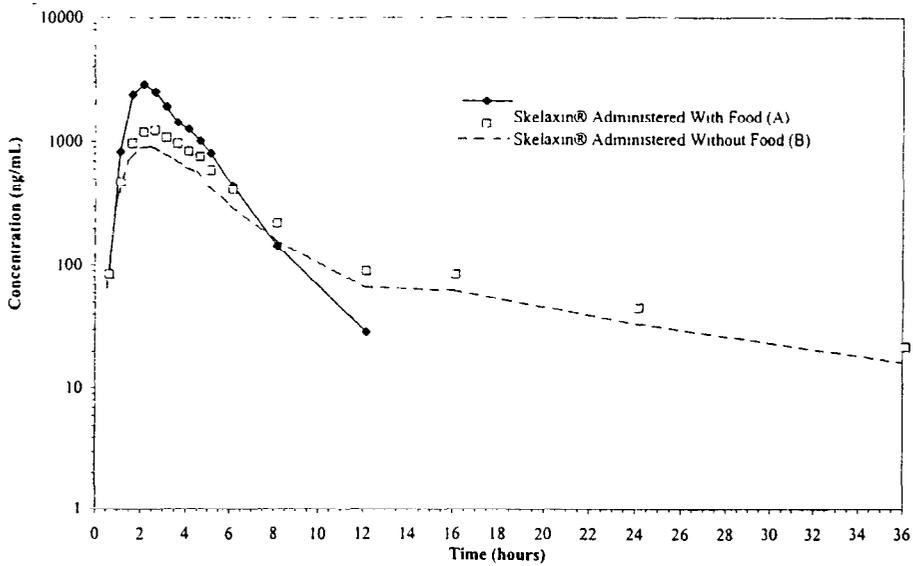


Figure 3.10b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 13

Figure 3.11a
Plasma Concentrations (0 - 36 hours)

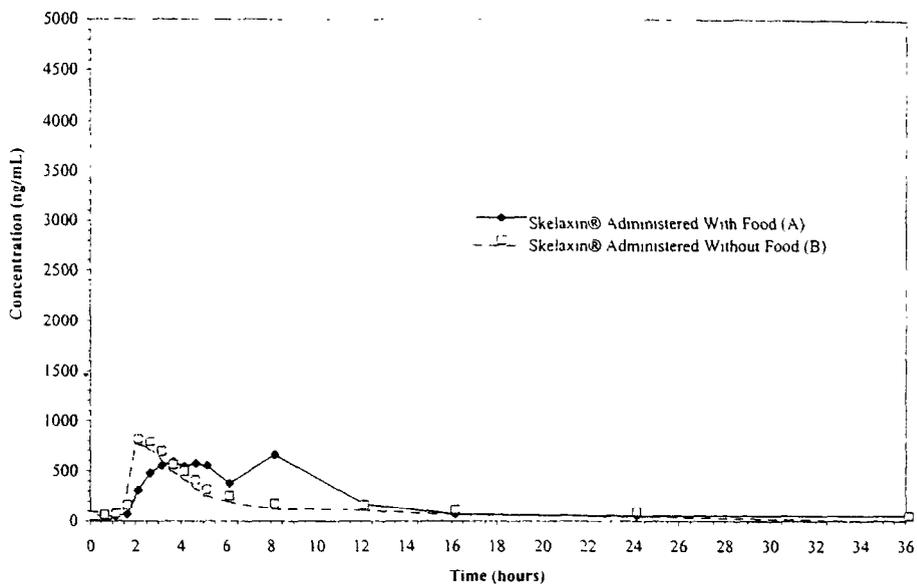
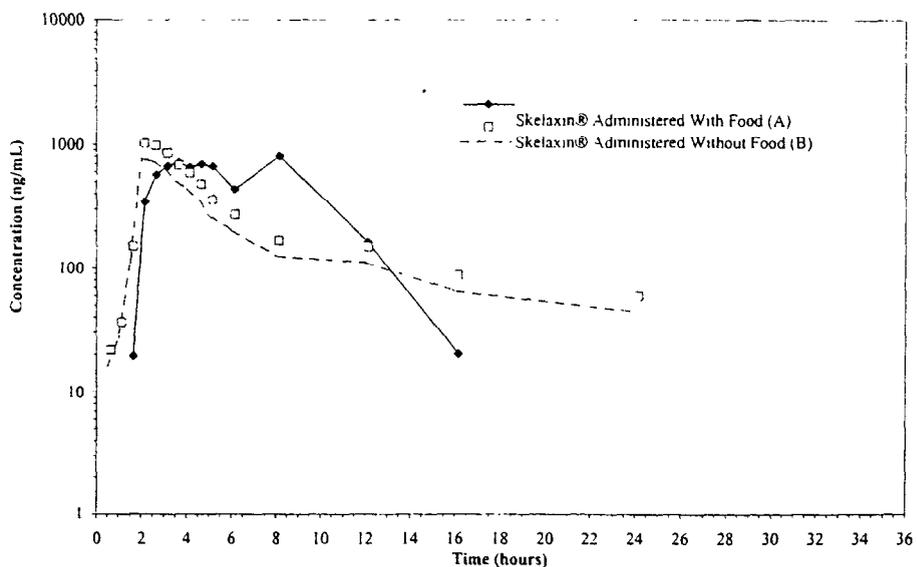


Figure 3.11b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 14

Figure 3.12a
Plasma Concentrations (0 - 36 hours)

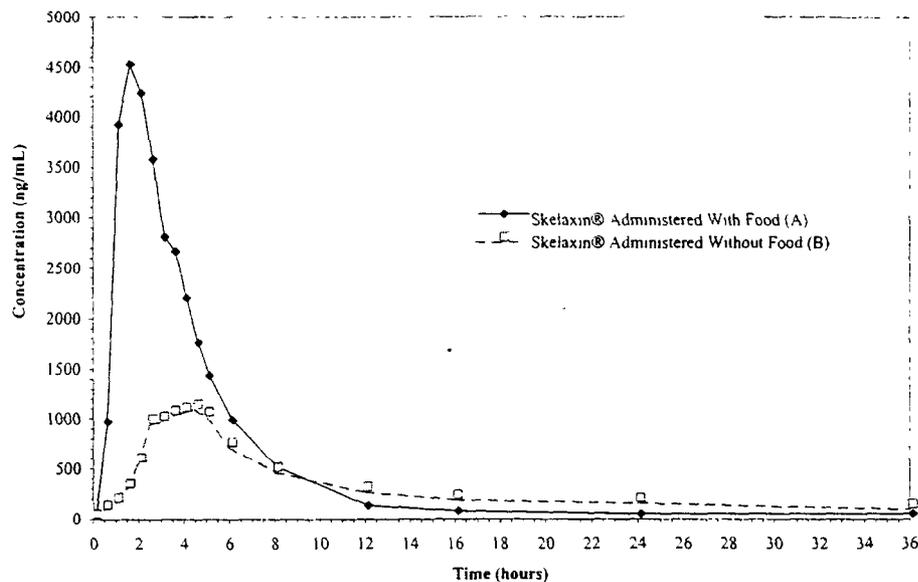
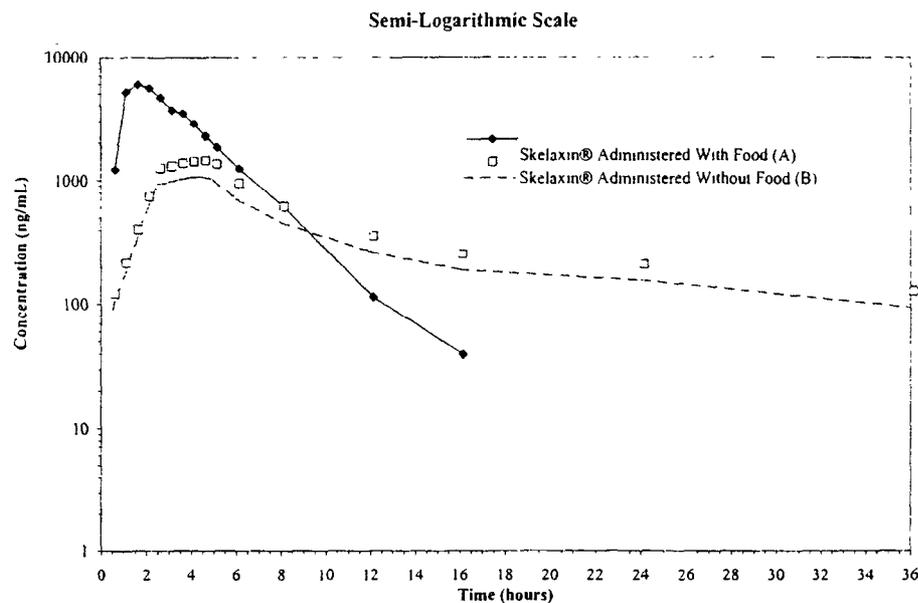


Figure 3.12b
Plasma Concentrations (0 - 36 hours)



Subject 15

Figure 3.13a
Plasma Concentrations (0 - 36 hours)

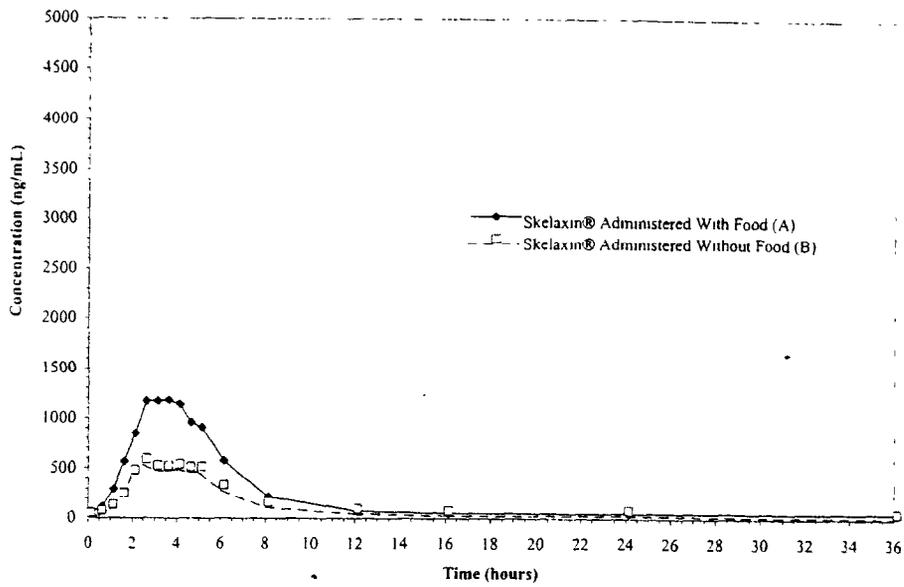
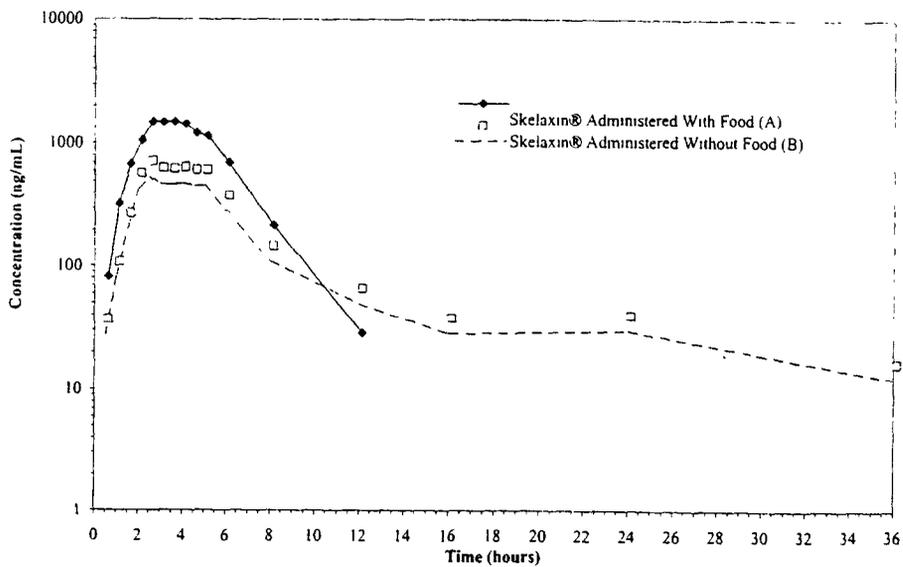


Figure 3.13b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 16

Figure 3.14a
Plasma Concentrations (0 - 36 hours)

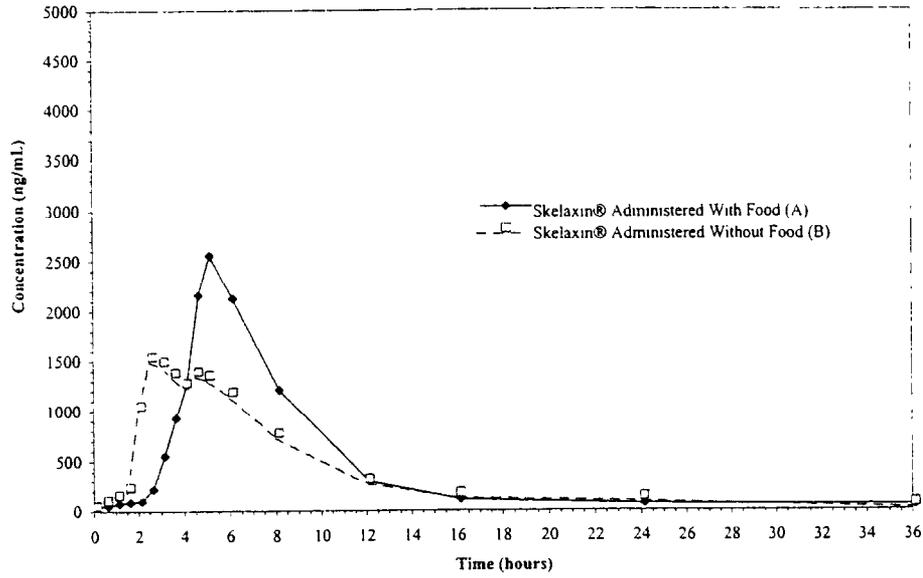
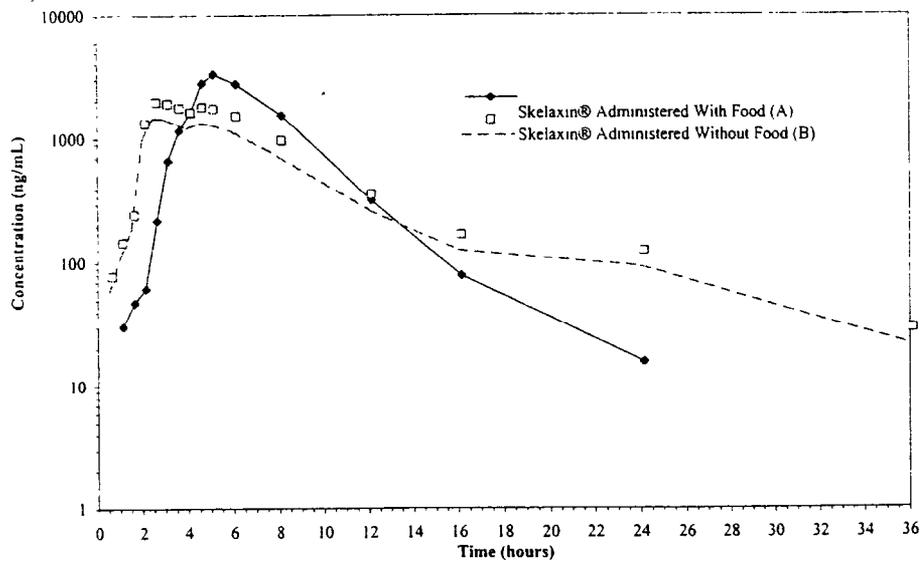


Figure 3.14b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 17

Figure 3.15a
Plasma Concentrations (0 - 36 hours)

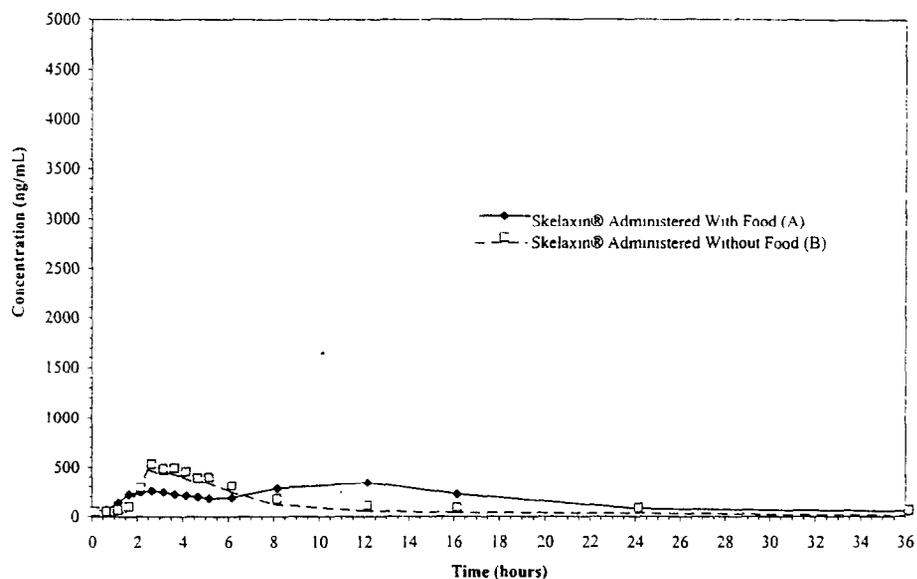
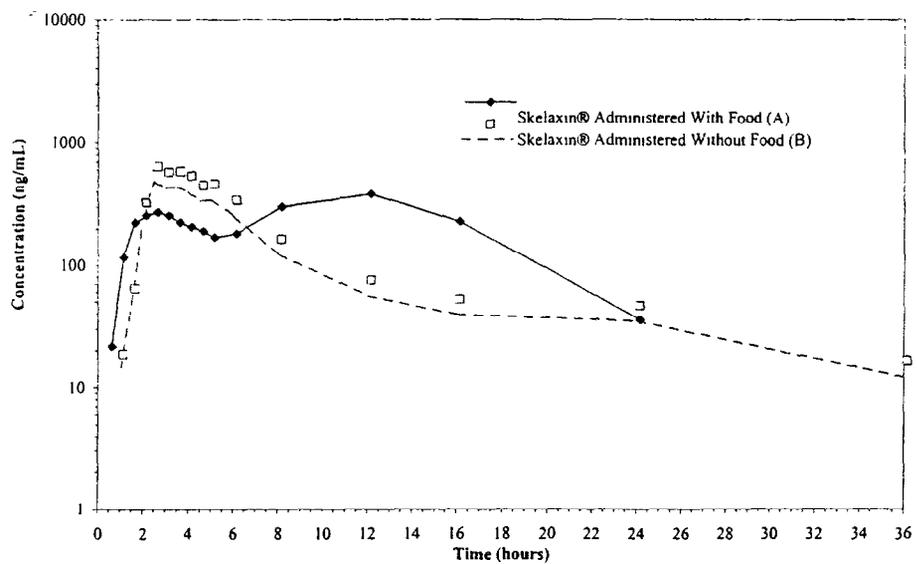


Figure 3.15b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 18

Figure 3.16a
Plasma Concentrations (0 - 36 hours)

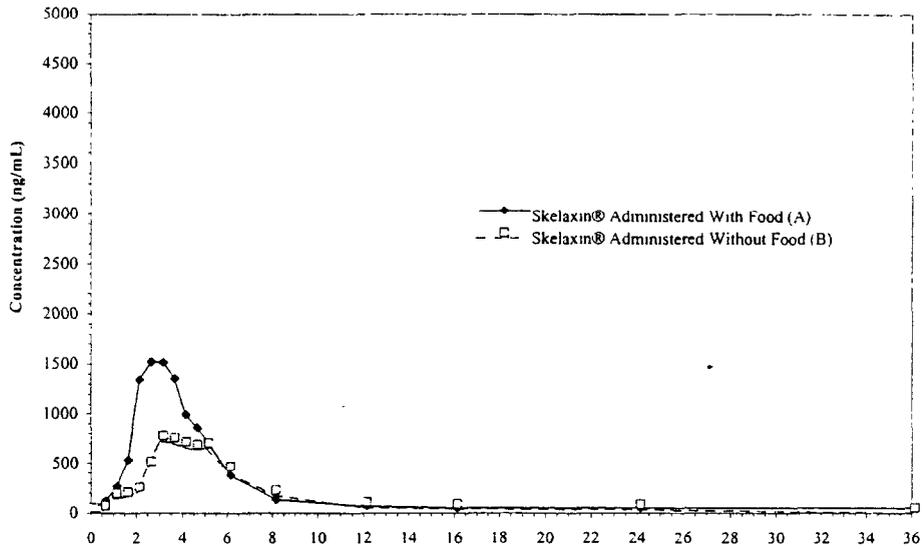
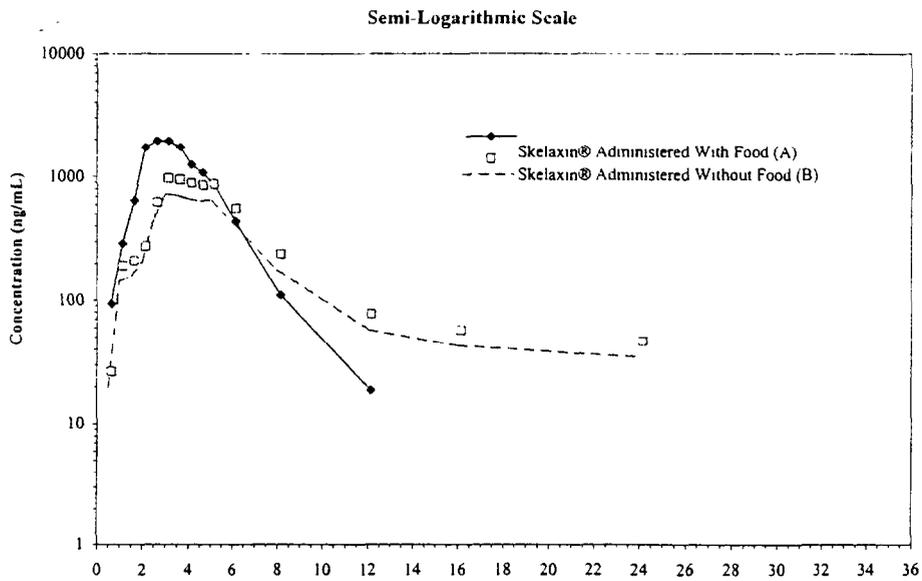


Figure 3.16b
Plasma Concentrations (0 - 36 hours)



Subject 19

Figure 3.17a
Plasma Concentrations (0 - 36 hours)

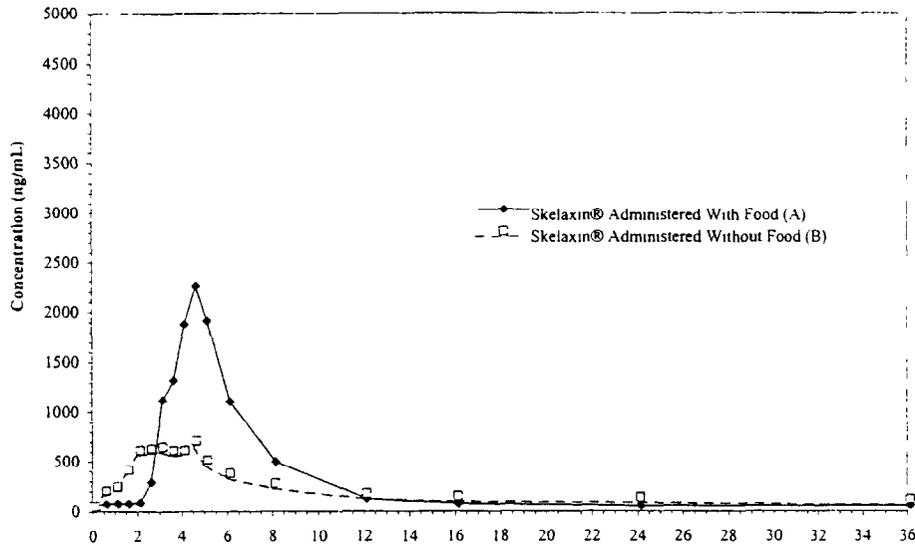
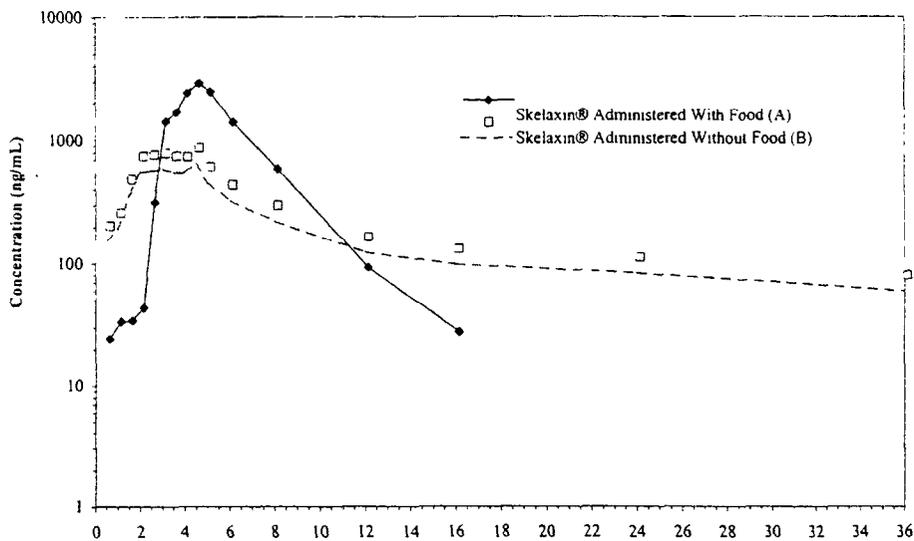


Figure 3.17b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 20

Figure 3.18a
Plasma Concentrations (0 - 36 hours)

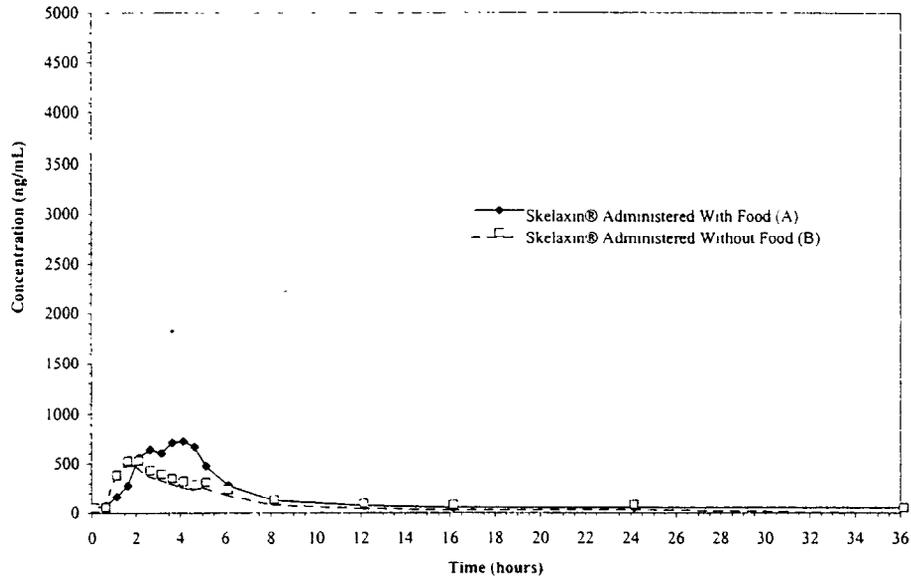
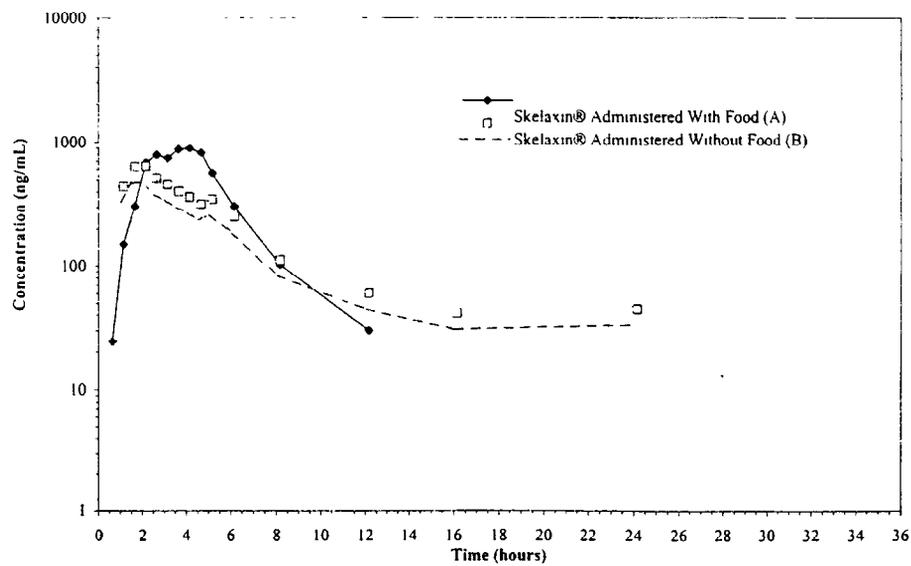


Figure 3.18b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 21

Figure 3.19a
Plasma Concentrations (0 - 36 hours)

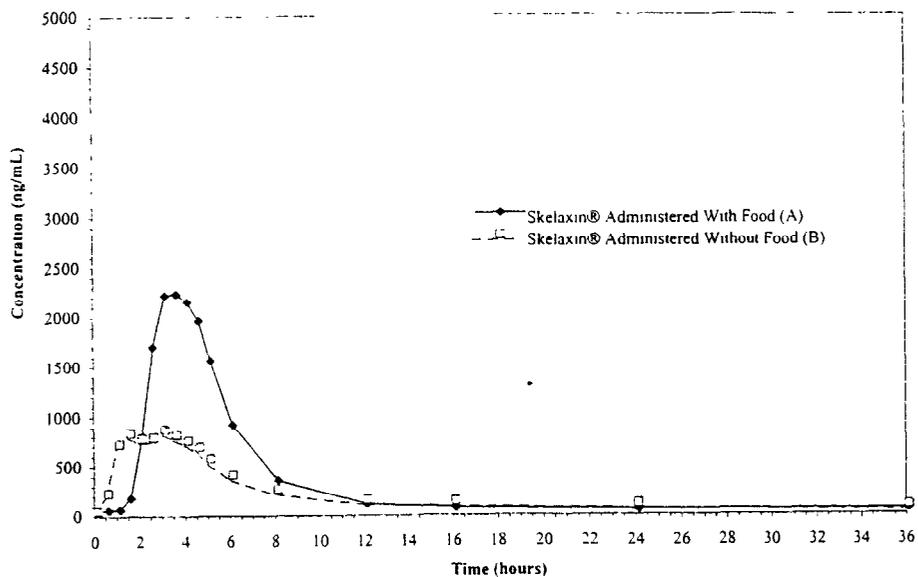
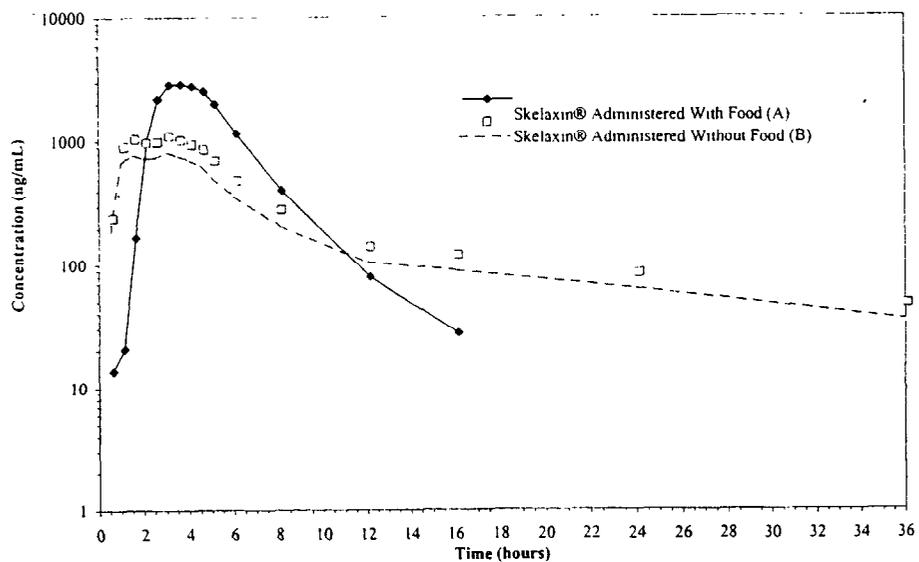


Figure 3.19b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 22

Figure 3.20a
Plasma Concentrations (0 - 36 hours)

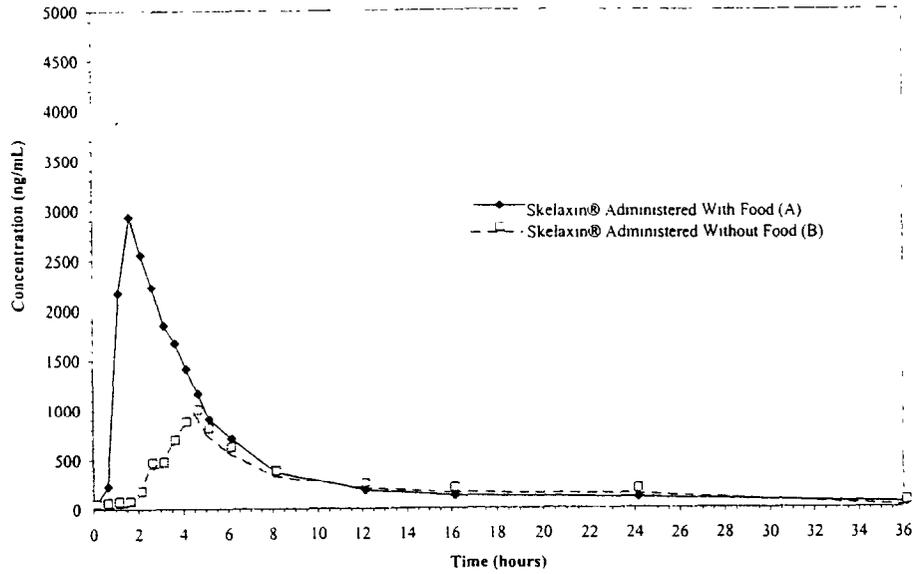
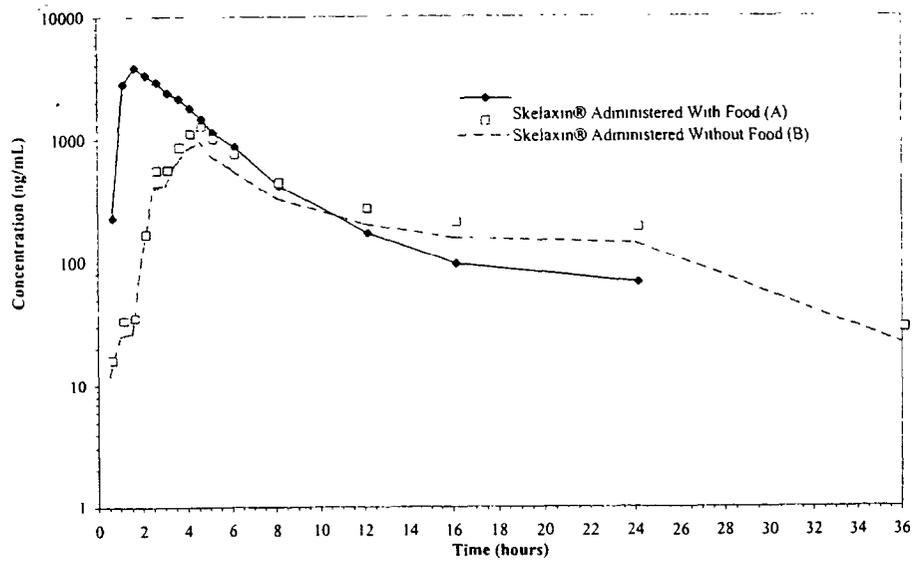


Figure 3.20b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 23

Figure 3.21a
Plasma Concentrations (0 - 36 hours)

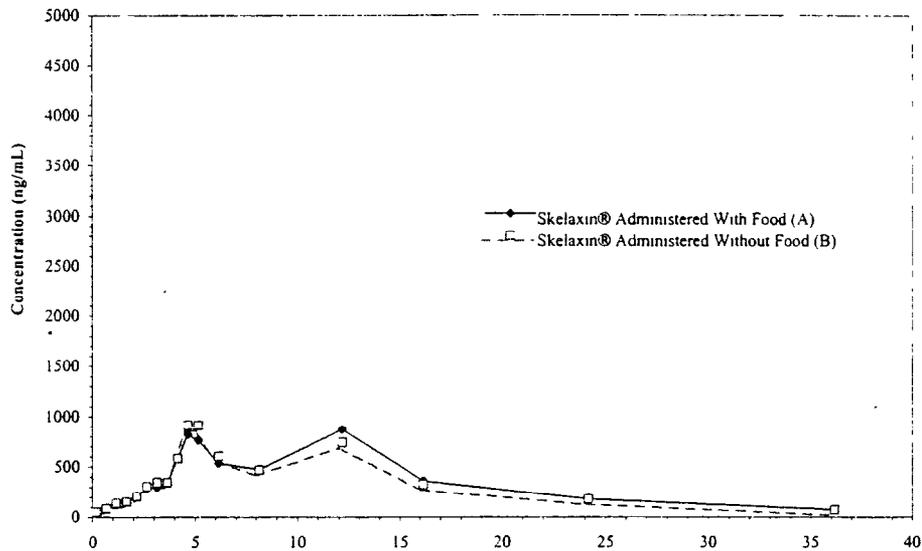
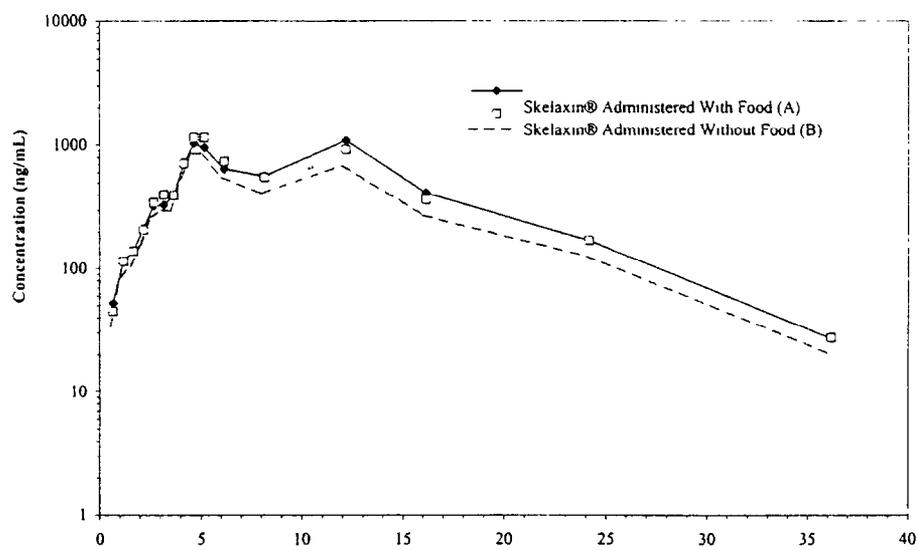


Figure 3.21b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 24

Figure 3.22a
Plasma Concentrations (0 - 36 hours)

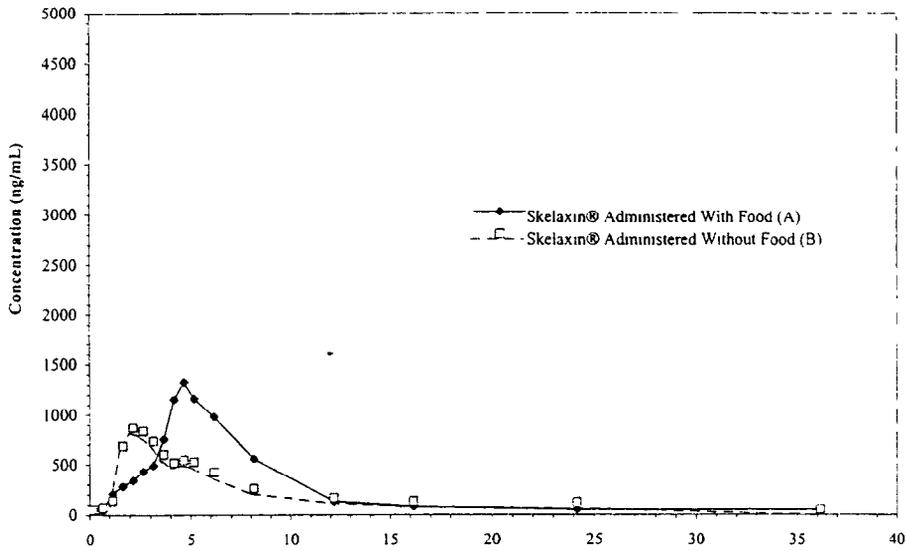
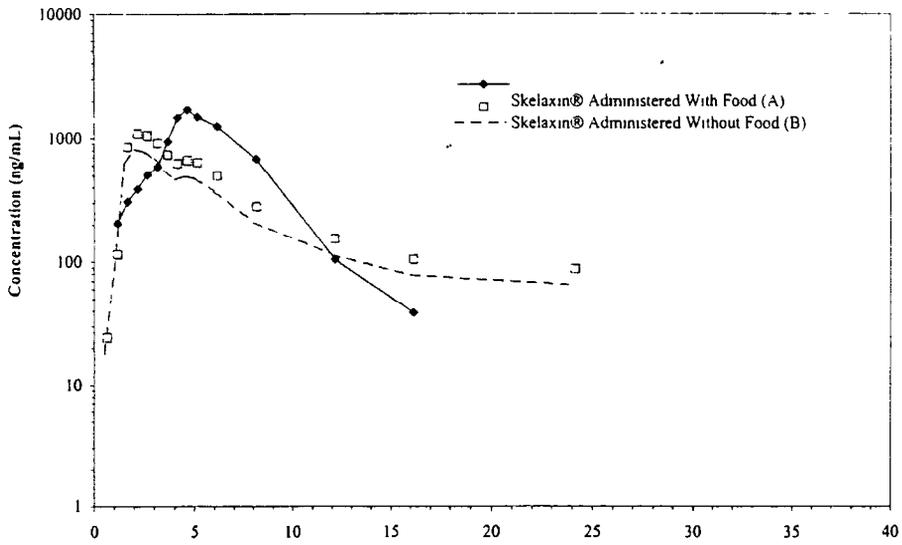


Figure 3.22b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 25

Figure 3.23a
Plasma Concentrations (0 - 36 hours)

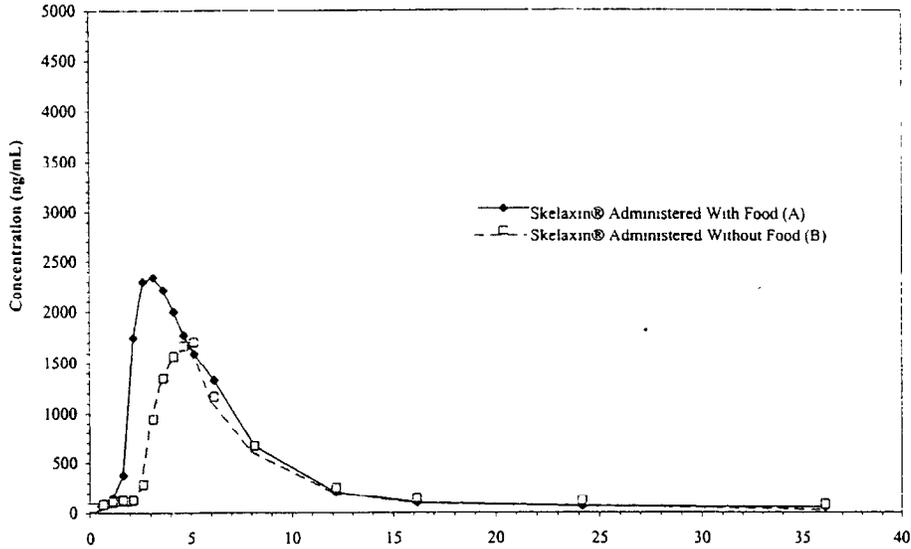
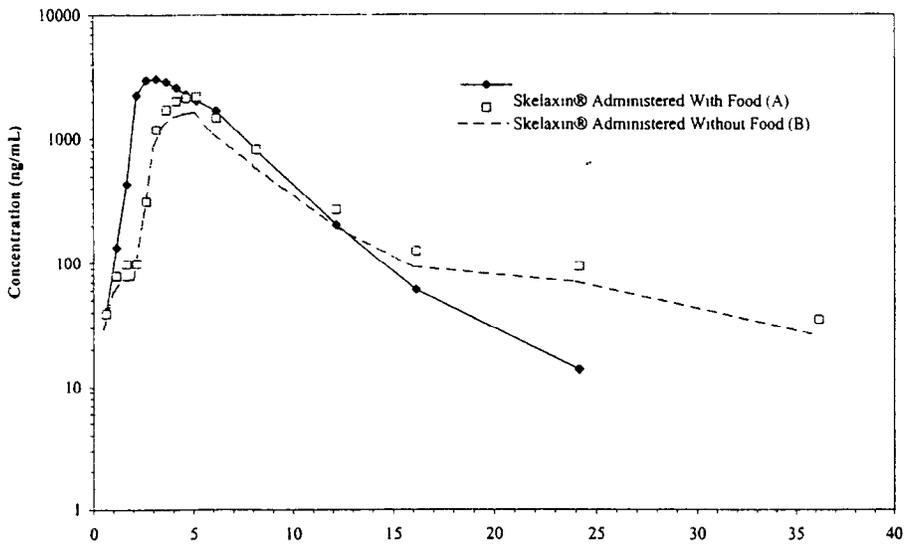


Figure 3.23b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 26

Figure 3.24a
Plasma Concentrations (0 - 36 hours)

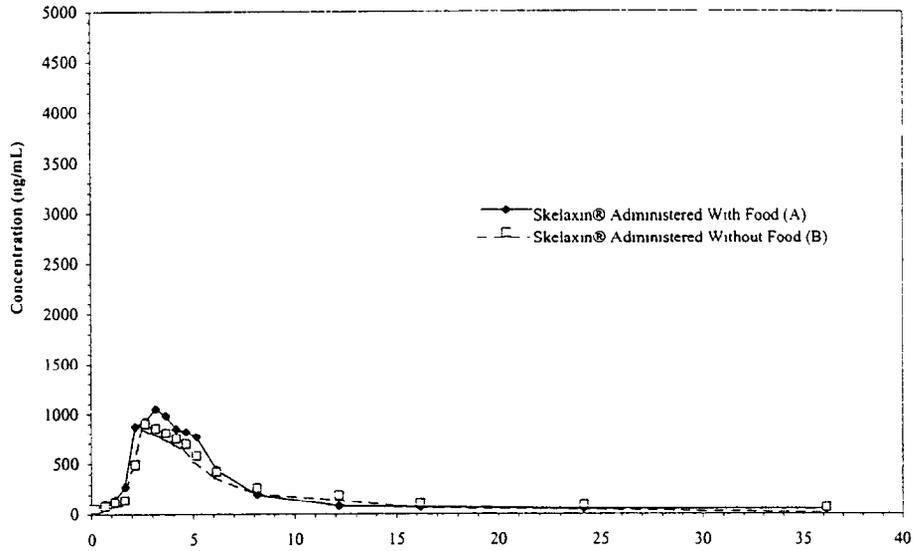
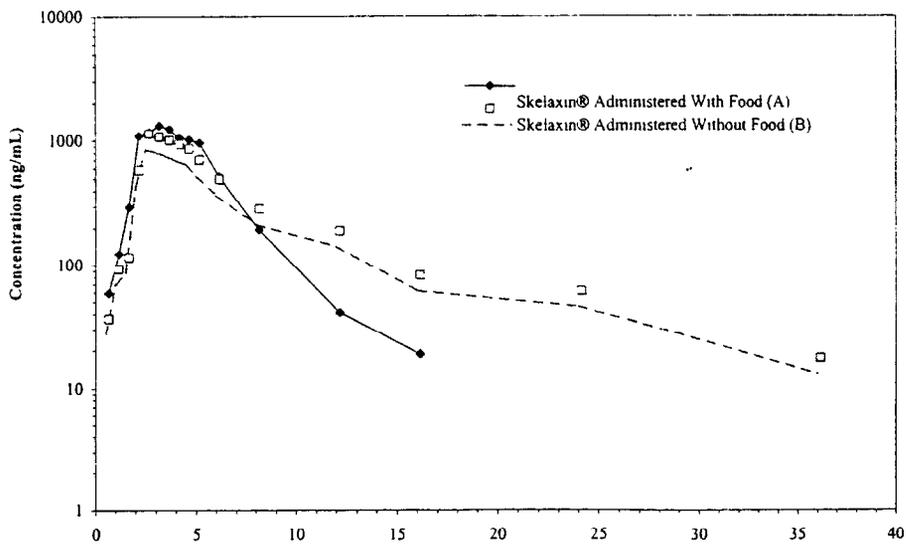


Figure 3.24b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 27

Figure 3.25a
Plasma Concentrations (0 - 36 hours)

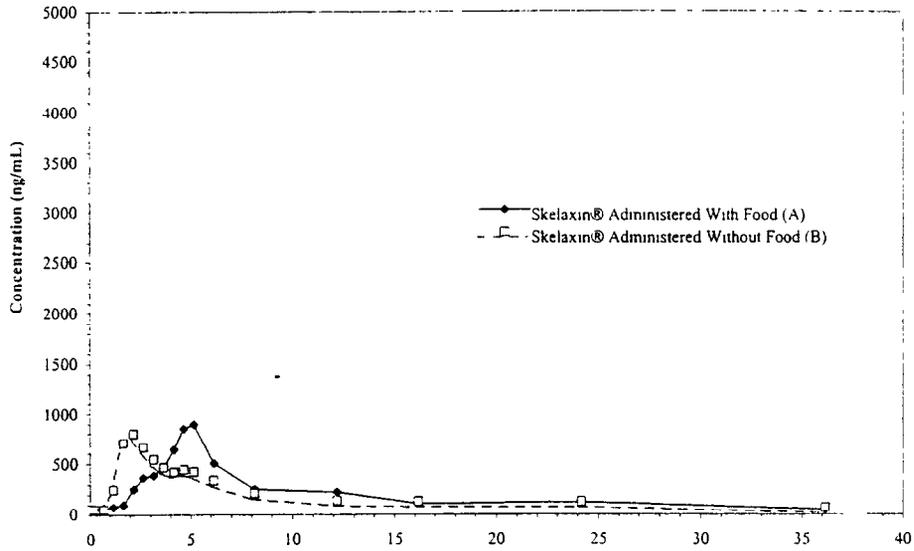
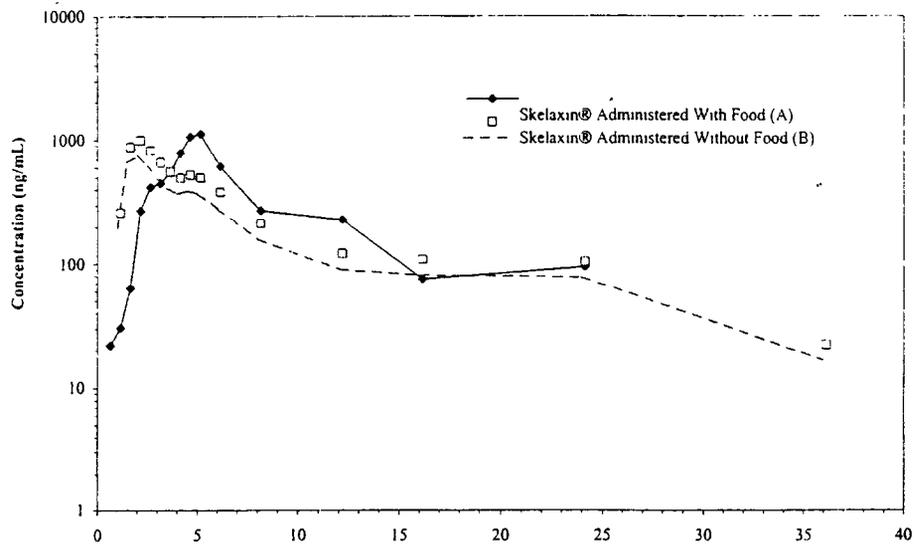


Figure 3.25b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 28

Figure 3.26a
Plasma Concentrations (0 - 36 hours)

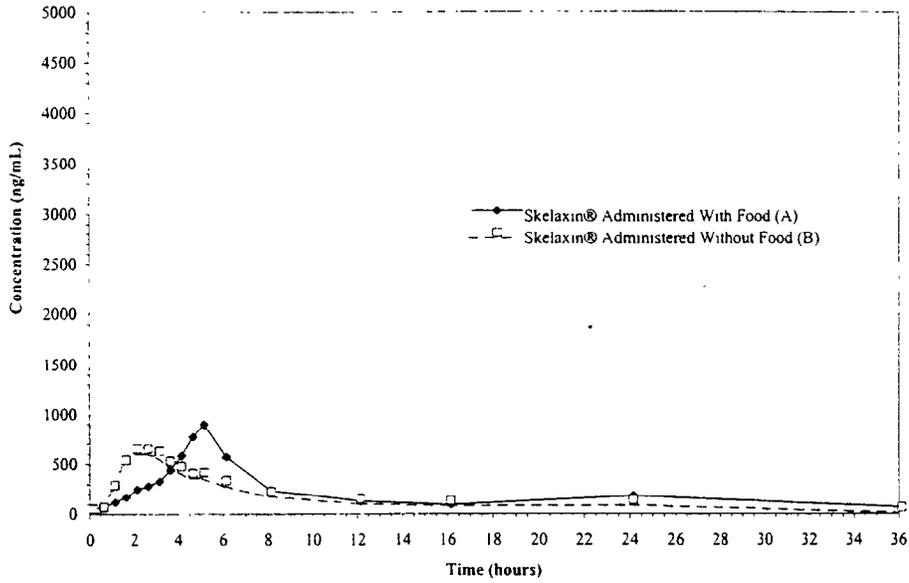
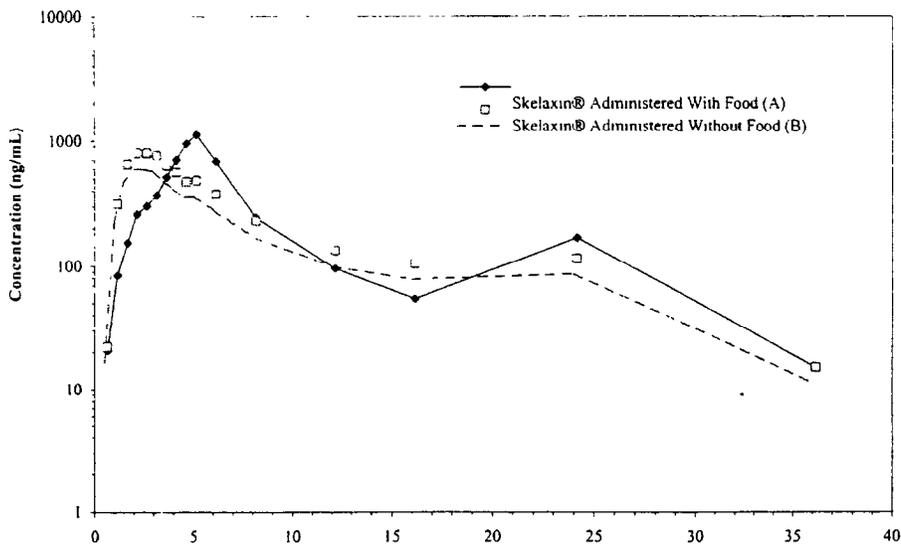


Figure 3.26b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 29

Figure 3.27a
Plasma Concentrations (0 - 36 hours)

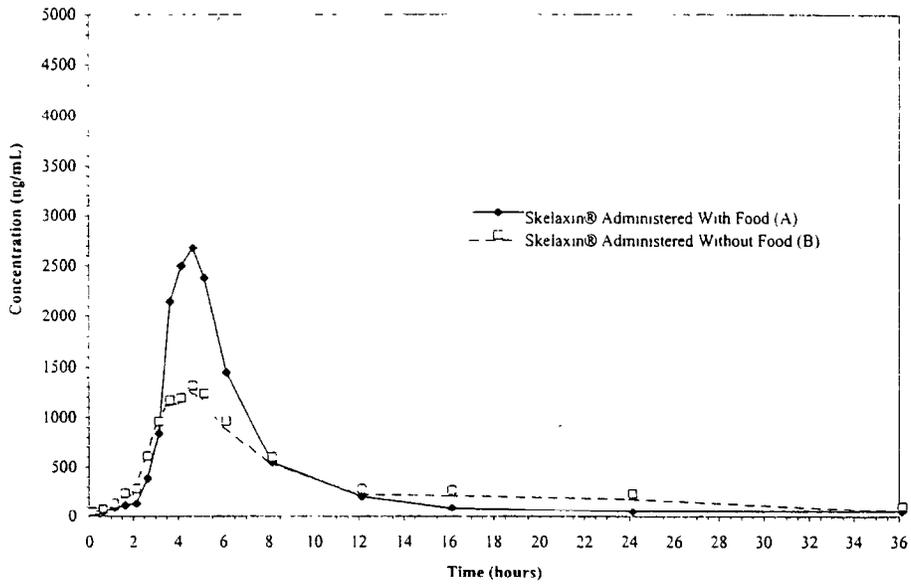
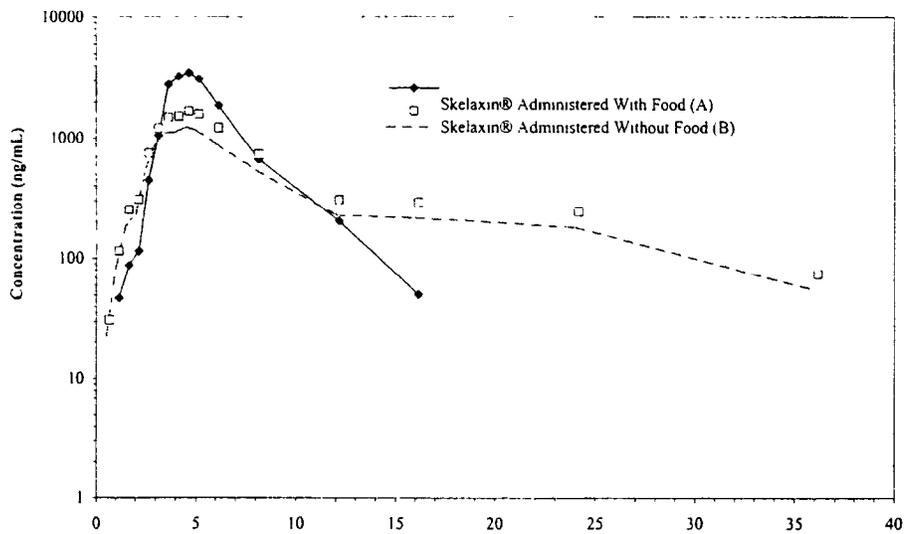


Figure 3.27b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 30

Figure 3.28a
Plasma Concentrations (0 - 36 hours)

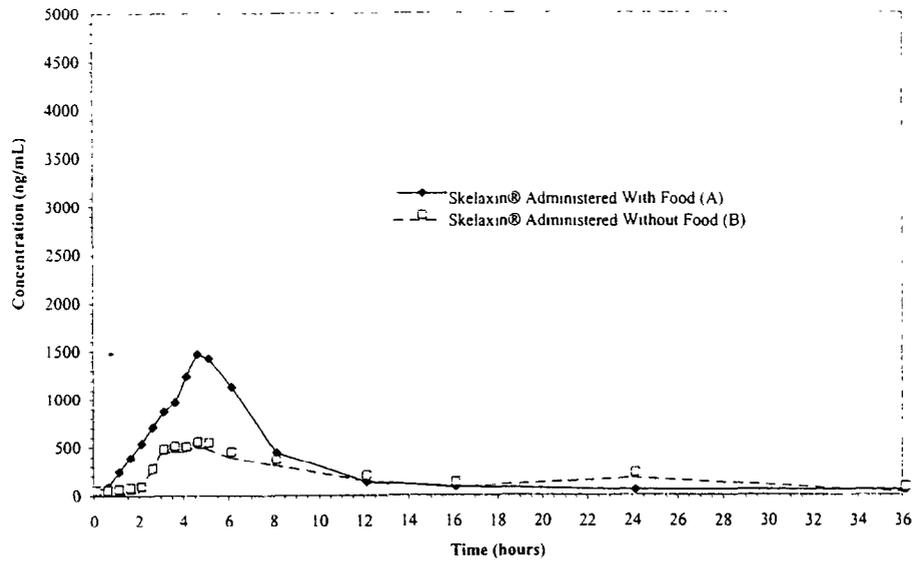
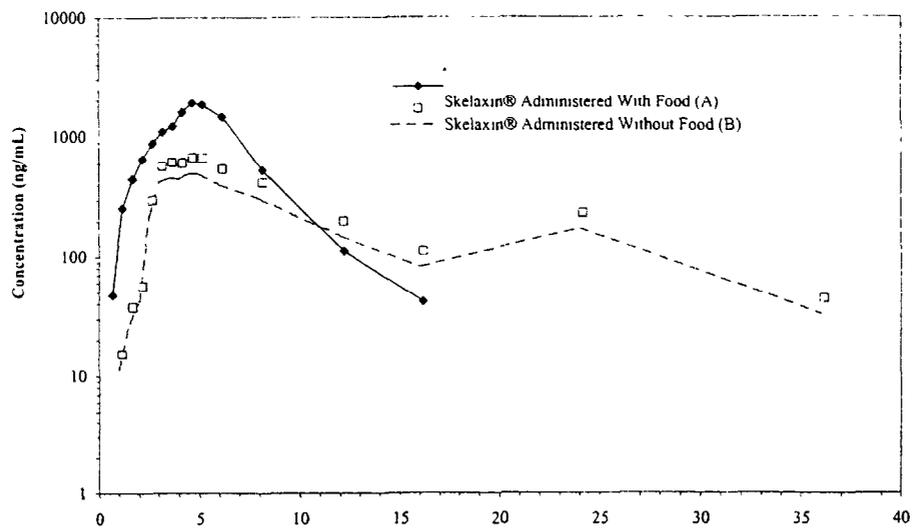


Figure 3.28b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 31

Figure 3.29a
Plasma Concentrations (0 - 36 hours)

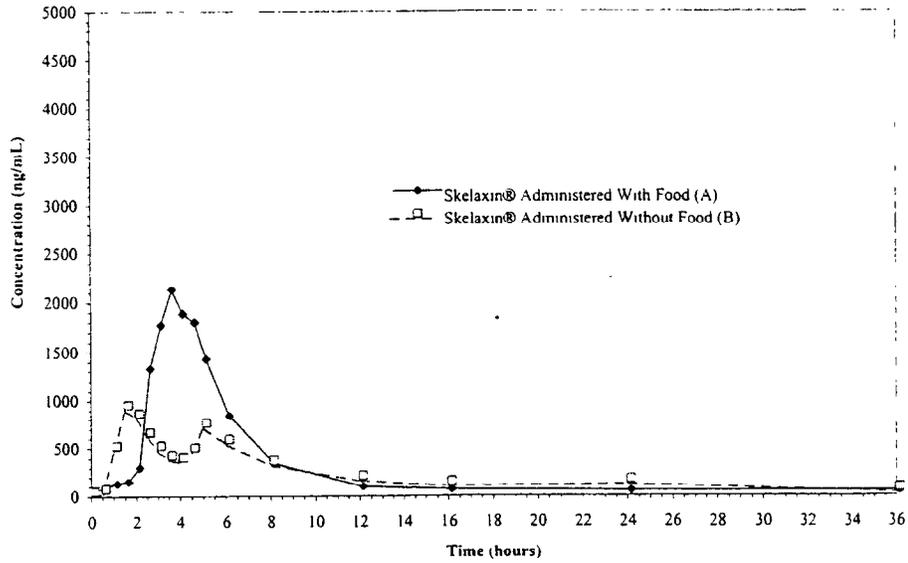
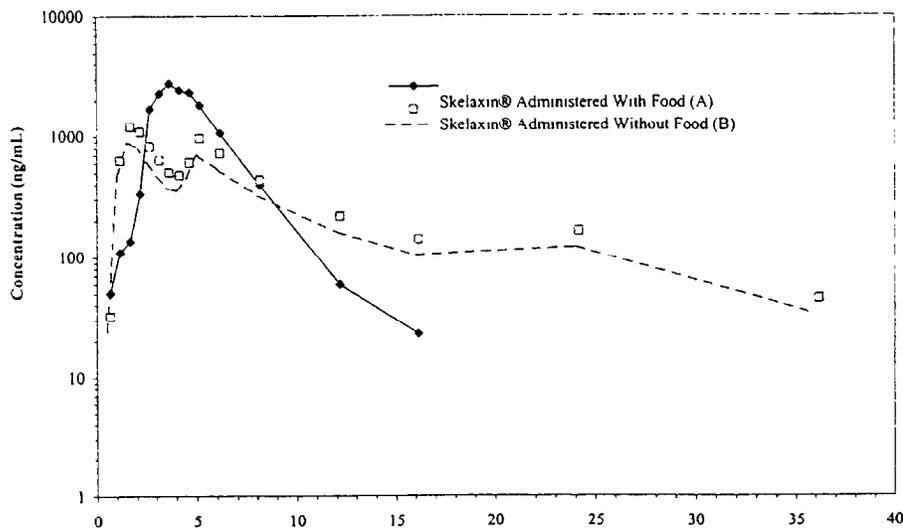


Figure 3.29b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 32

Figure 3.30a
Plasma Concentrations (0 - 36 hours)

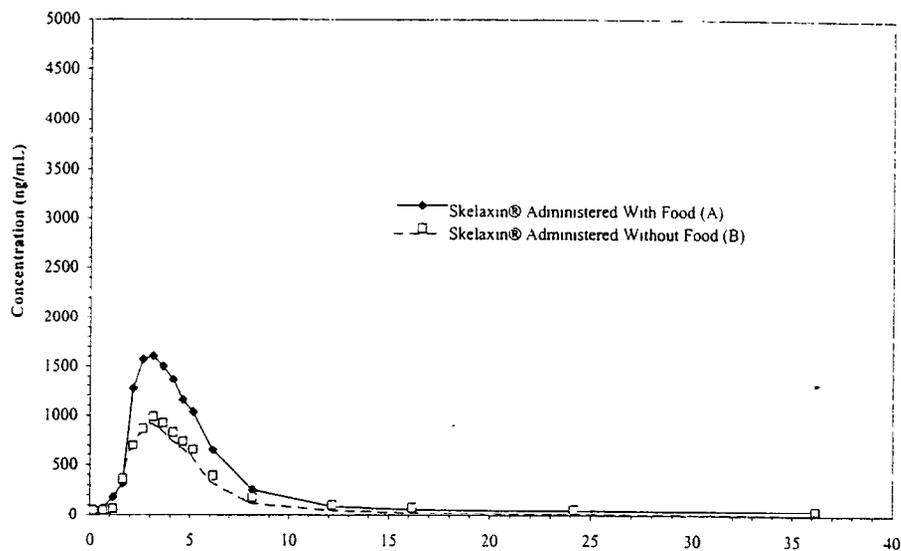
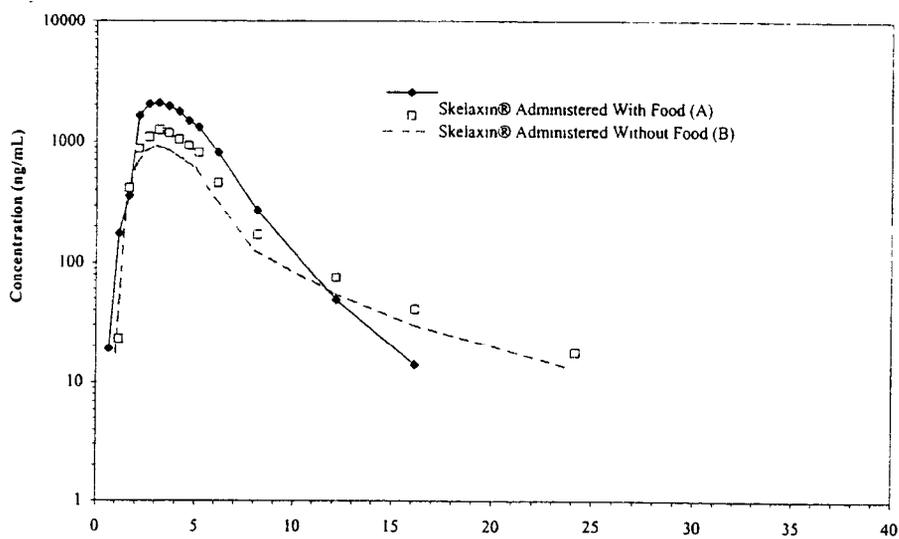


Figure 3.30b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 33

Figure 3.31a
Plasma Concentrations (0 - 36 hours)

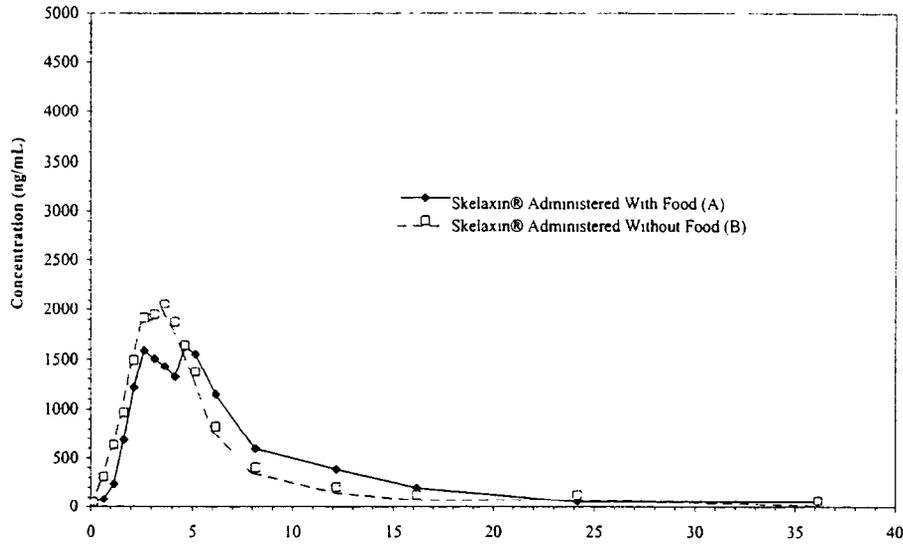
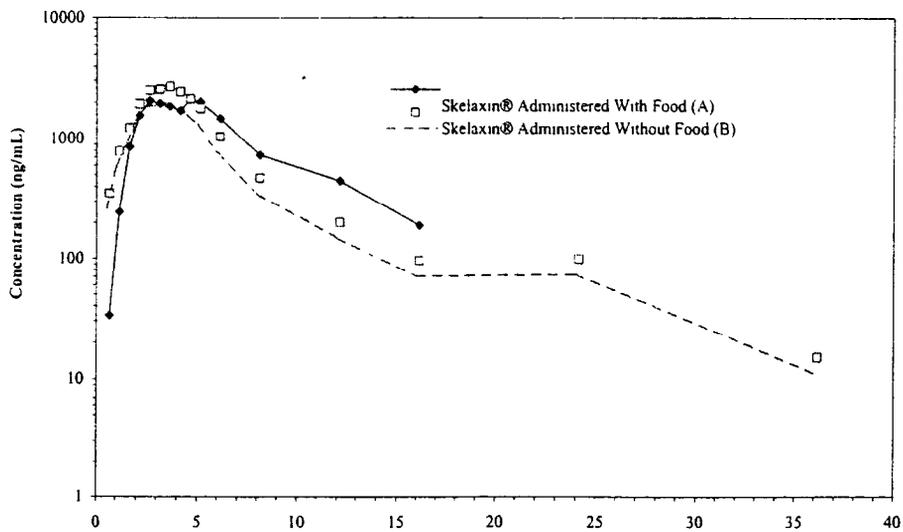


Figure 3.31b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 34

Figure 3.32a
Plasma Concentrations (0 - 36 hours)

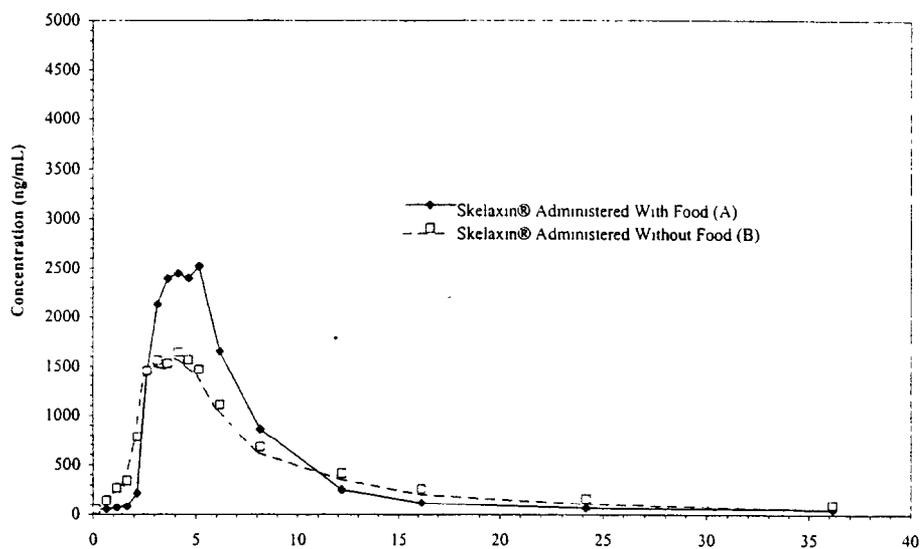
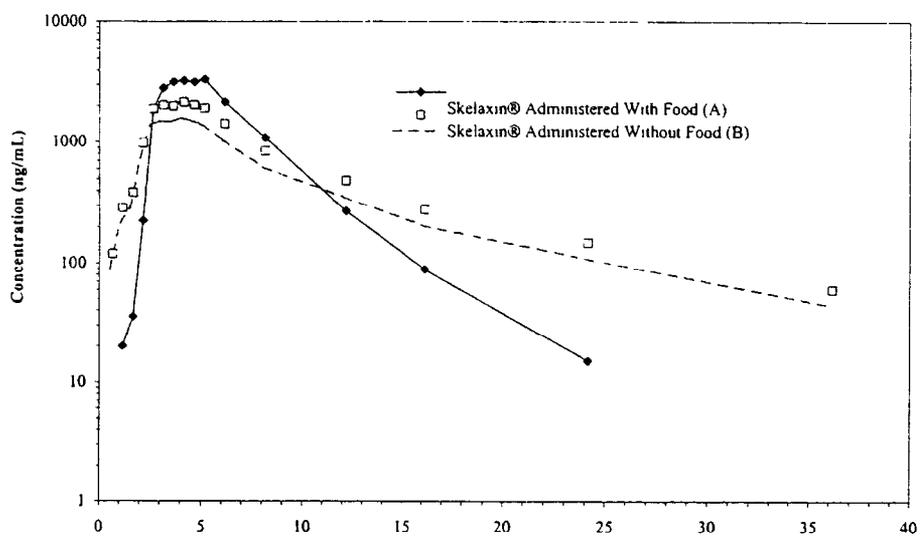


Figure 3.32b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 35

Figure 3.33a
Plasma Concentrations (0 - 36 hours)

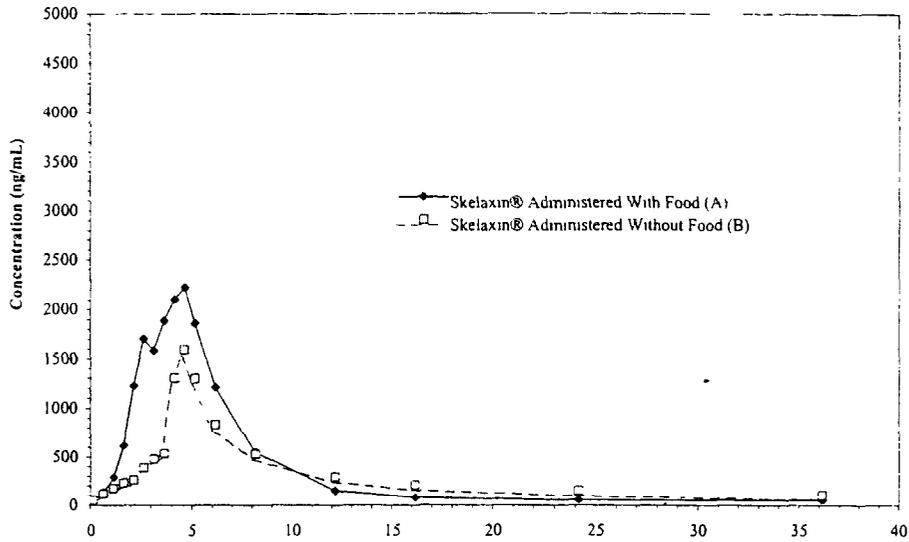
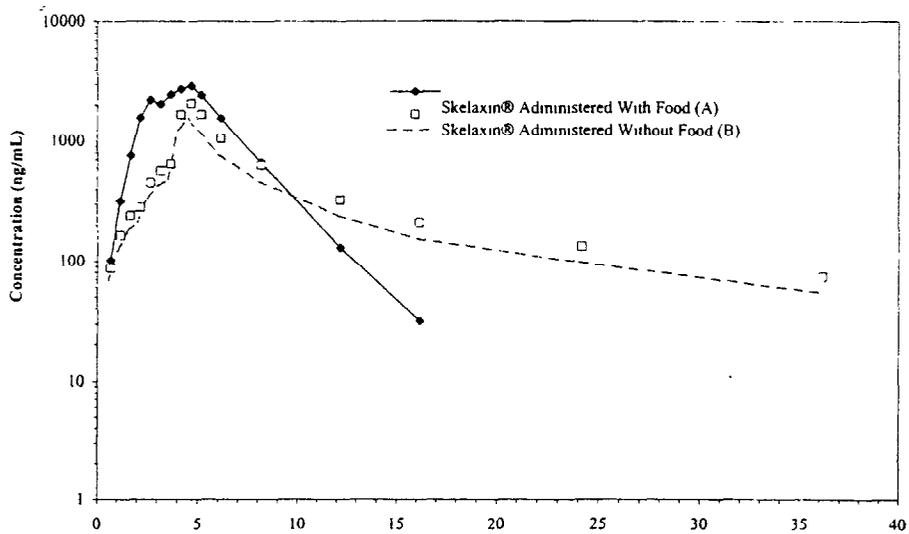


Figure 3.33b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 36

Figure 3 34a
Plasma Concentrations (0 - 36 hours)

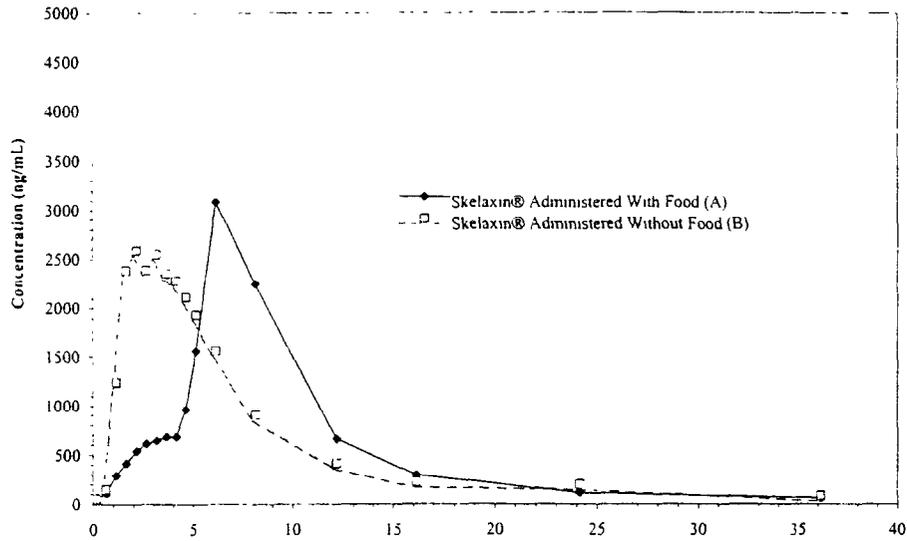
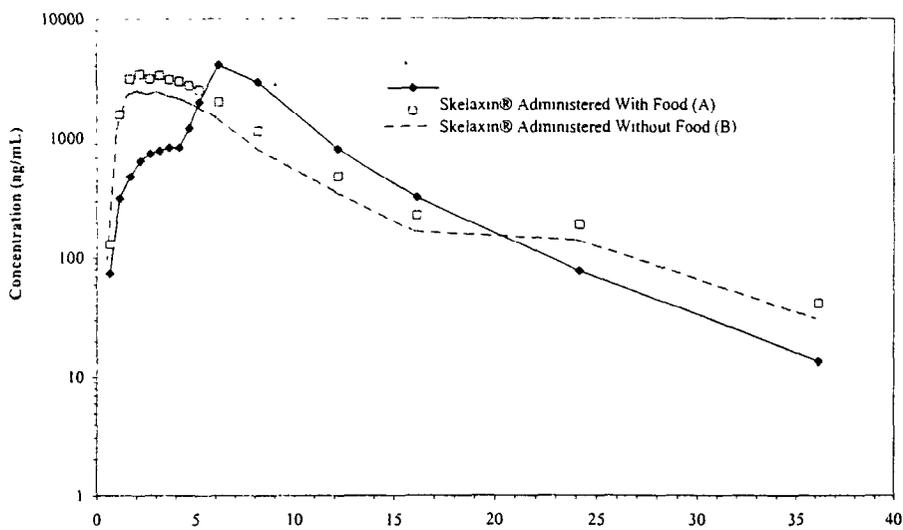


Figure 3 34b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 37

Figure 3.35a
Plasma Concentrations (0 - 36 hours)

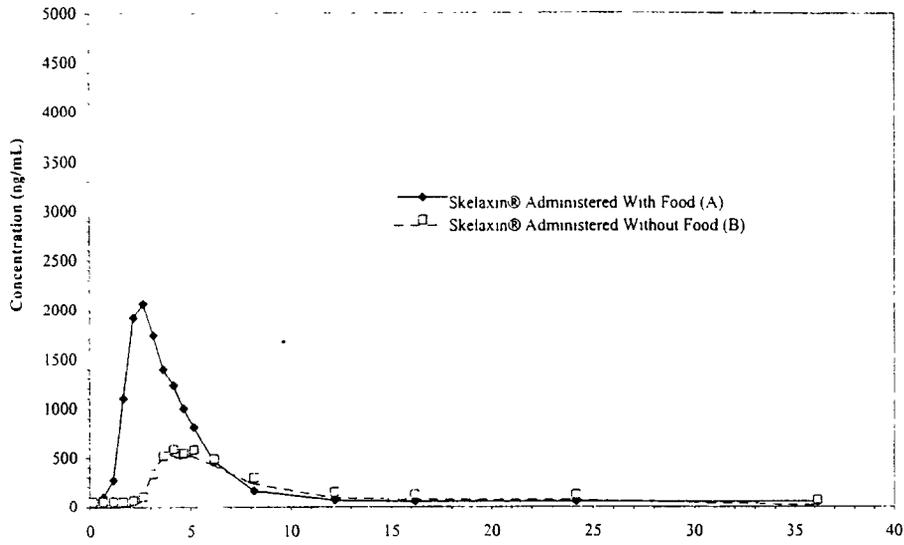
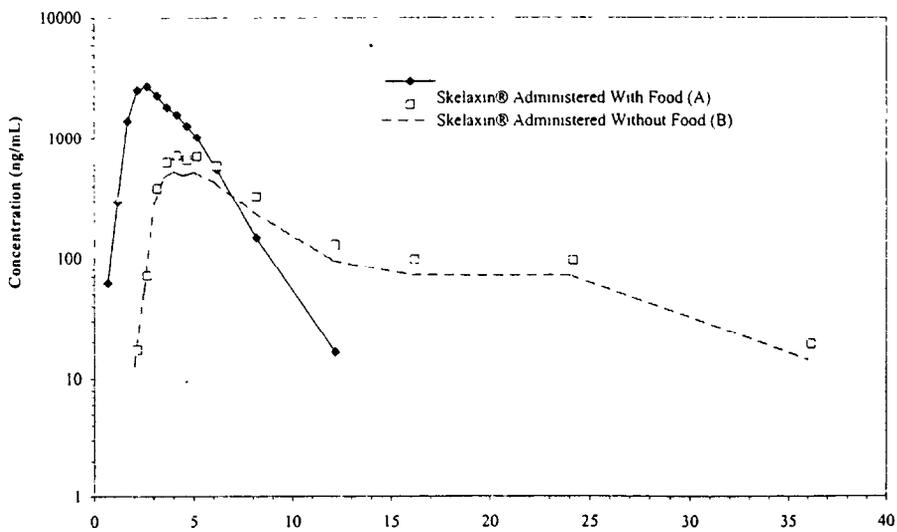


Figure 3.35b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 38

Figure 3.36a
Plasma Concentrations (0 - 36 hours)

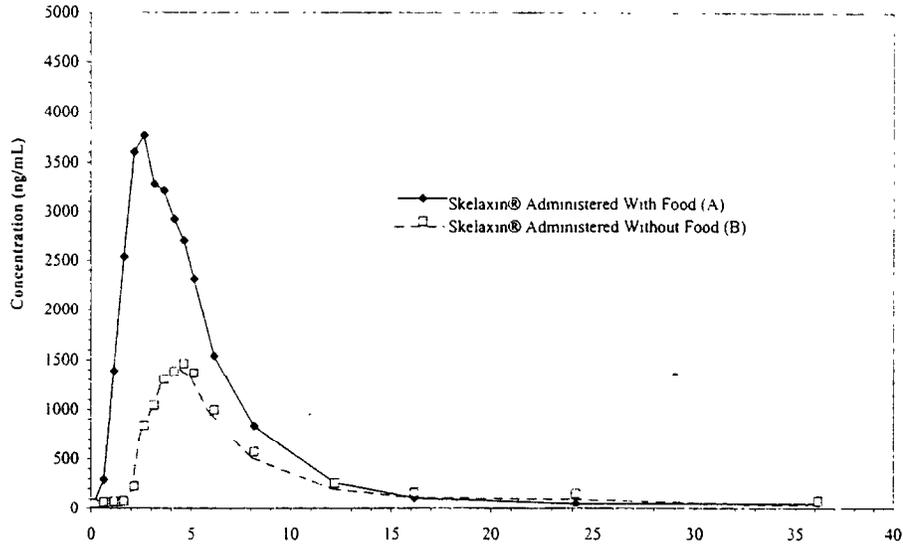
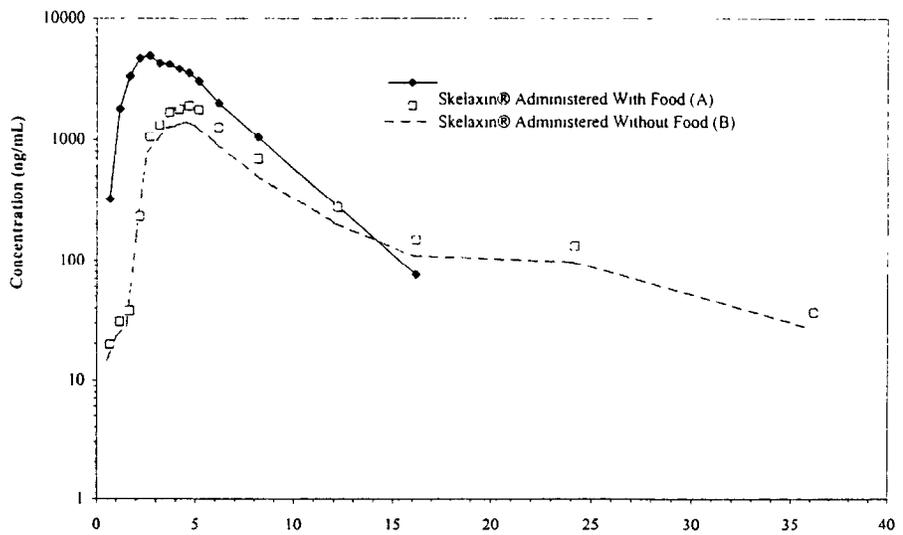


Figure 3.36b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 39

Figure 3.37a
Plasma Concentrations (0 - 36 hours)

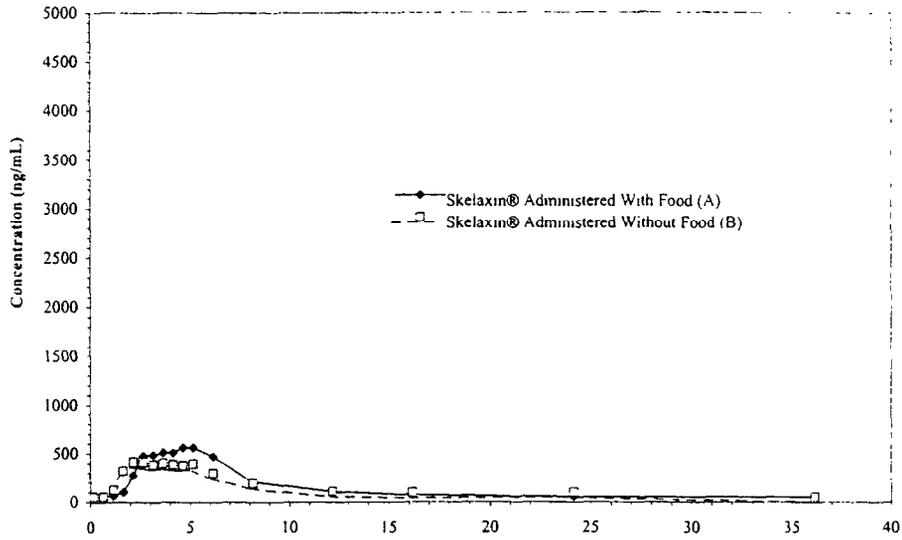
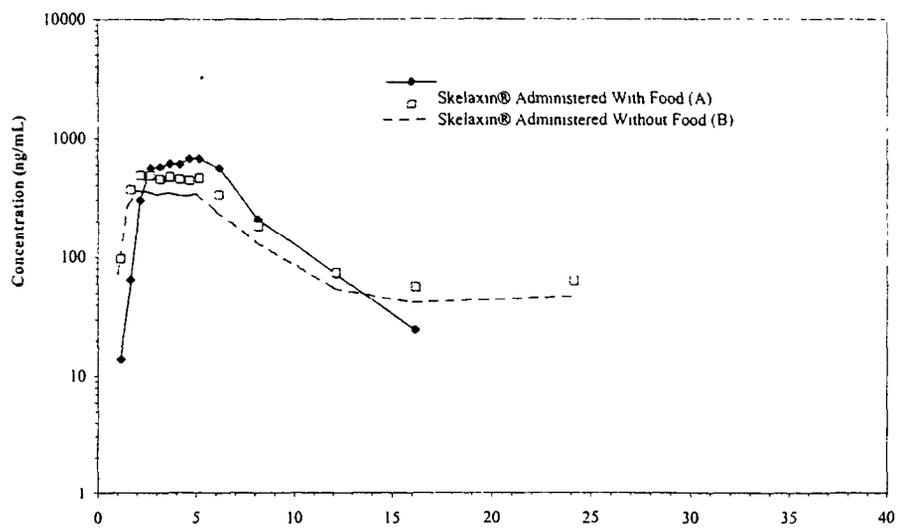


Figure 3.37b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 40

Figure 3.38a
Plasma Concentrations (0 - 36 hours)

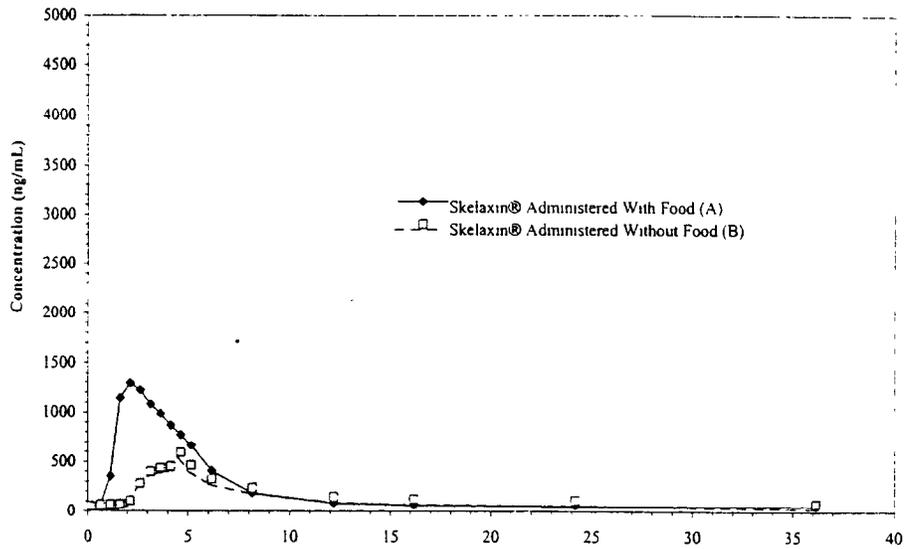
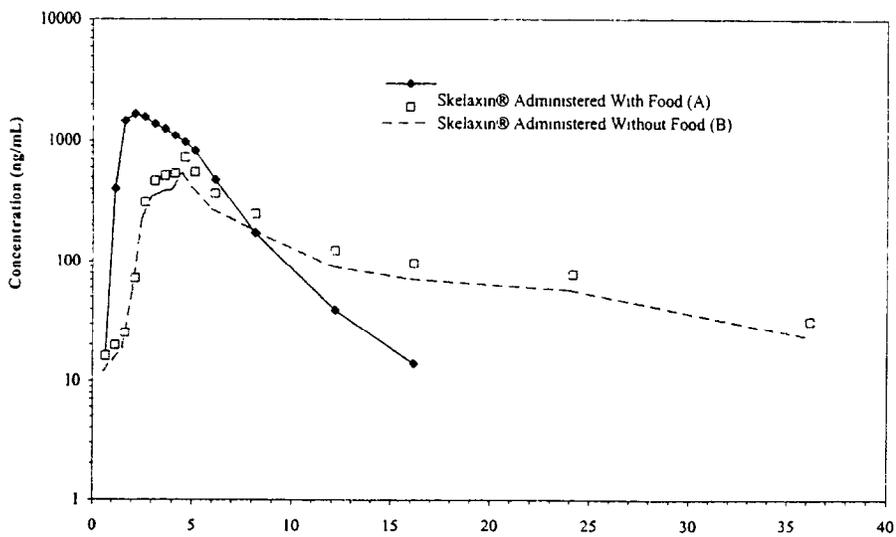


Figure 3.38b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 41

Figure 3.39a
Plasma Concentrations (0 - 36 hours)

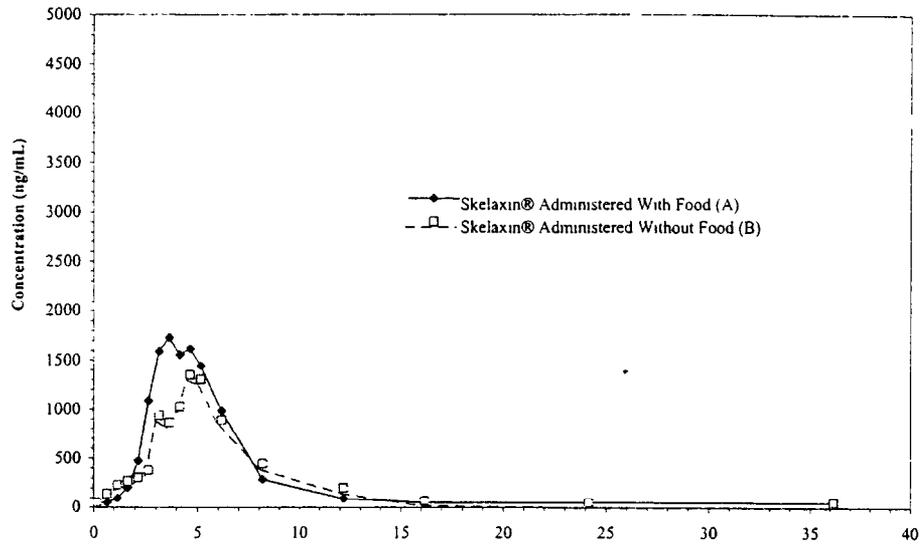
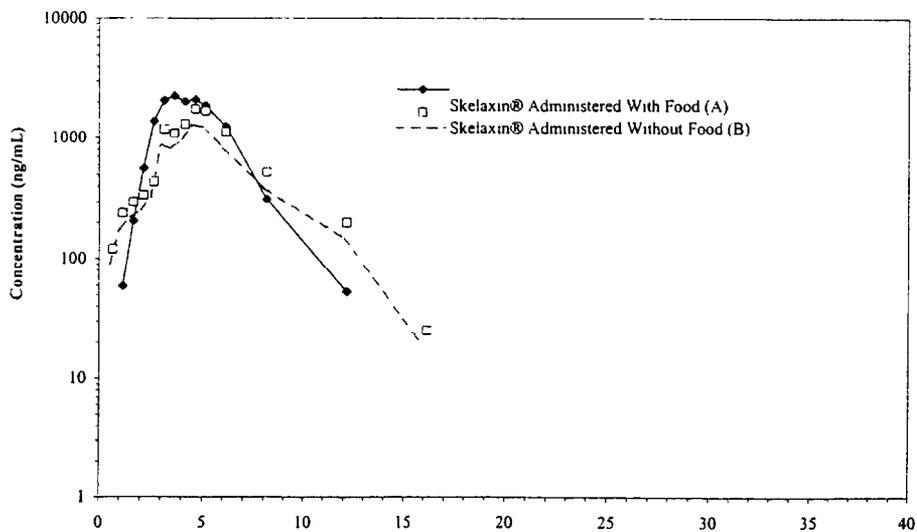


Figure 3.39b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



Subject 42

Figure 3.40a
Plasma Concentrations (0 - 36 hours)

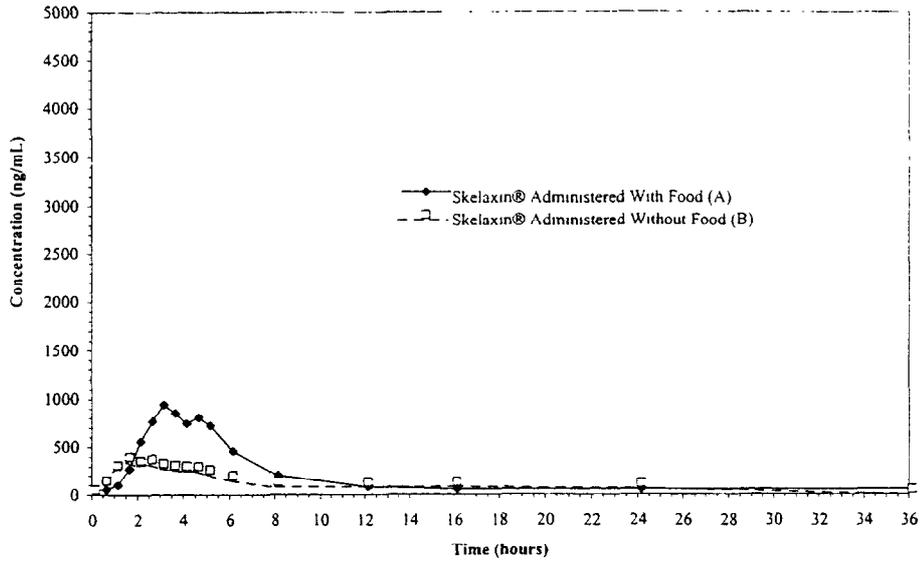
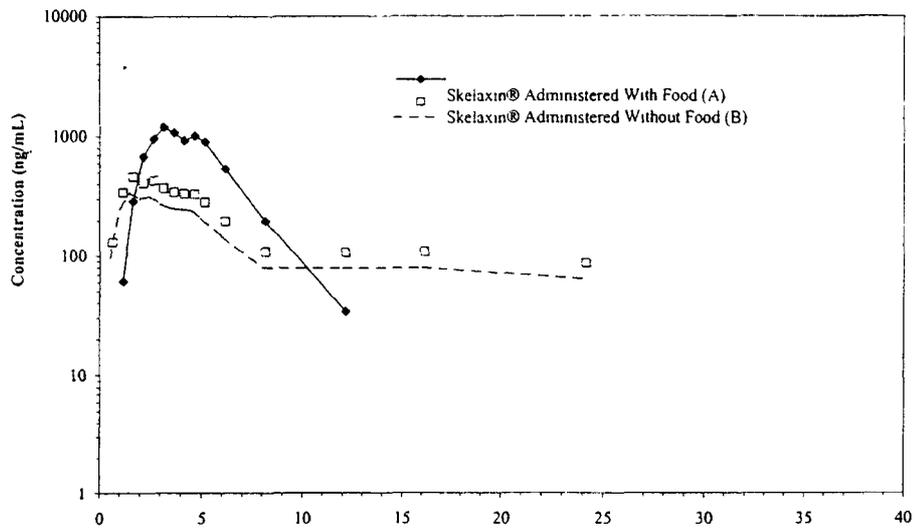


Figure 3.40b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 43

Figure 3.41a
Plasma Concentrations (0 - 36 hours)

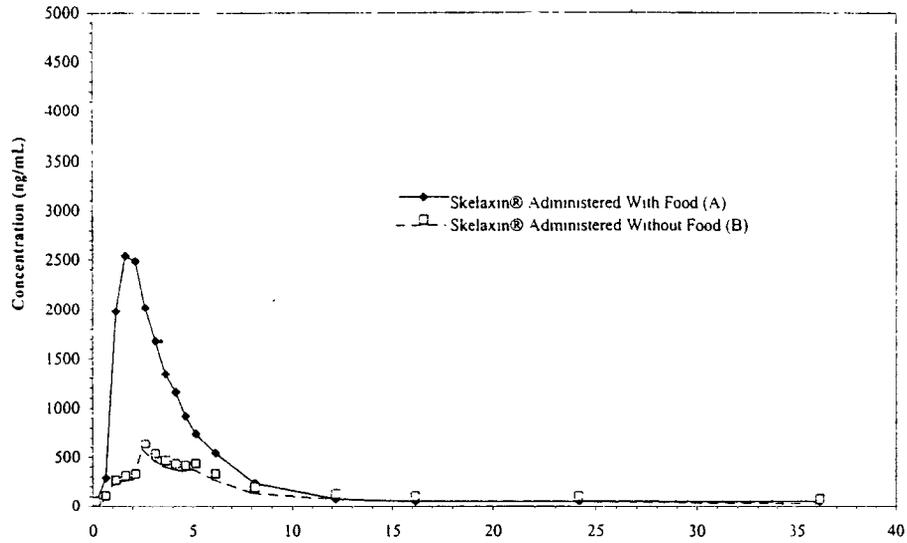
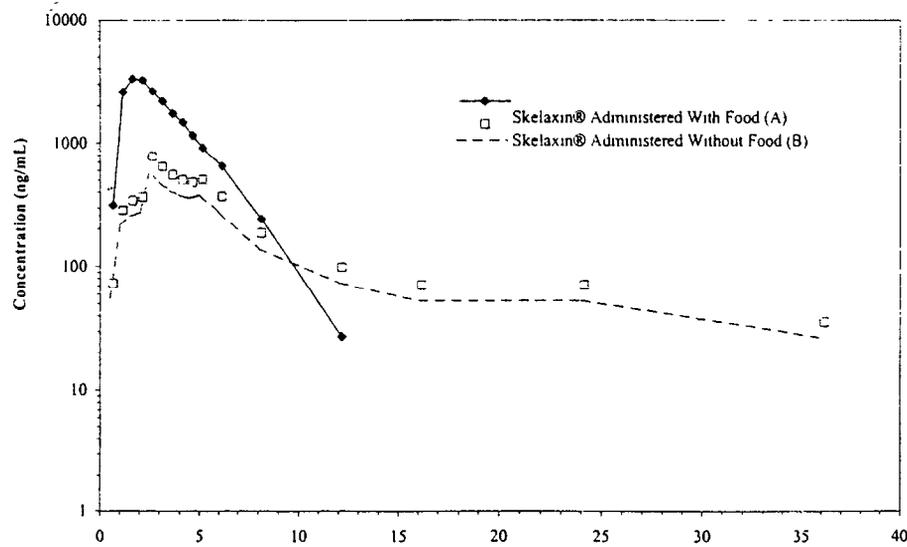


Figure 3.41b
Plasma Concentrations (0 - 36 hours)
Semi-Logarithmic Scale



Subject 44

Figure 3.42a
Plasma Concentrations (0 - 36 hours)

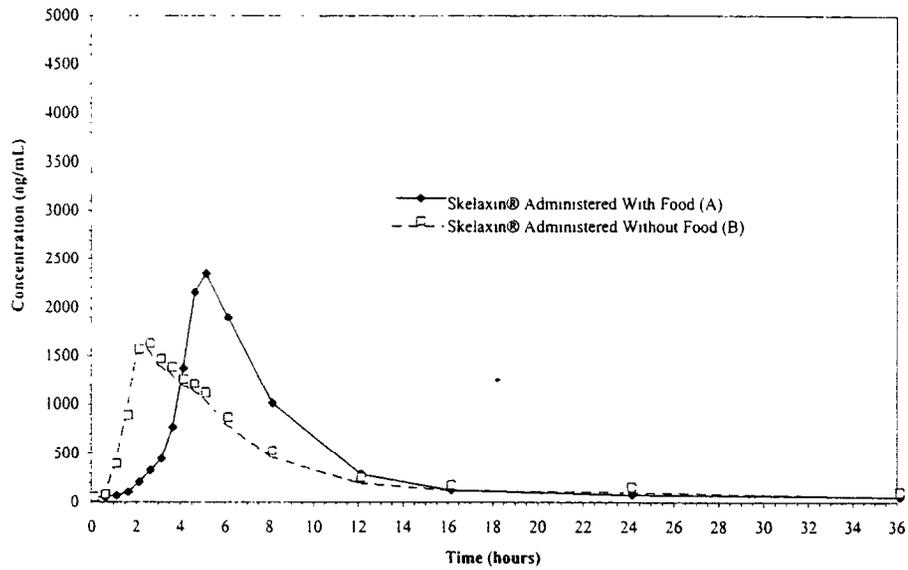
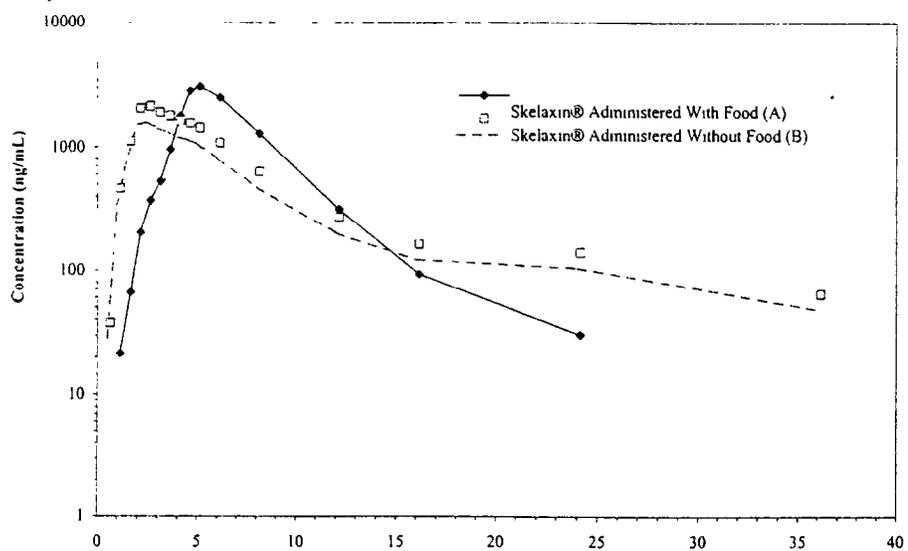


Figure 3.42b
Plasma Concentrations (0 - 36 hours)

Semi-Logarithmic Scale



SECTION 17.2.6

Individual Adverse Event Listings

Adverse Events Summary by Subject

Study Period I = July 21-22, 2001
 Study Period II = July 28-29, 2001

Subject No.	Init.	Event	Onset	Resolution		Frequency of Event	Serious	Intensity	Relationship to Study Drug	
				(Date)	(Military Time)					
06	BAZ	Cold Sore Top Right Lip	07-26-01	2100	07-29-01	0630	2	No	1	2
12	CMP	Headache	07-28-01	0945	07-28-01	1315	2	No	1	1
15	WLE	Headache	07-21-01	1200	07-22-01	0200	2	No	1	1
17	CDD	Headache	07-21-01	0900	07-21-01	1000	2	No	1	1
17	CDD	Pain Chest	07-21-01	1100	07-21-01	1200	2	No	1	1
17	CDD	Headache	07-28-01	0950	07-28-01	1600	2	No	1	1
20	CRG	Pain Abdo (Stomachache)	07-21-01	2100	07-21-01	2300	2	No	1	1
22	TMF	Dyspepsia (Heartburn)	07-21-01	0955	07-21-01	1223	2	No	1	1
26	JLP	Stomatitis Ulcer (Canker Sore)	07-18-01	0800	07-21-01	1600	2	No	1	2
33	DMT	Headache	07-21-01	1300	07-21-01	2100	2	No	1	1
33	DMT	Nausea	07-28-01	1400	07-28-01	2100	2	No	1	1
34	ACT	Headache	07-28-01	1200	07-28-01	1500	2	No	1	1
34	ACT	Vomit (Vomited)	07-28-01	1418	07-28-01	1419	2	No	1	1
35	AMK	Headache	07-21-01	1915	07-21-01	2000	2	No	1	1
35	AMK	Headache	07-21-01	2215	07-22-01	0015	2	No	1	1
36	DLJ	Headache	07-22-01	0600	07-24-01	1800	2	No	1	2
38	THP	Headache	07-21-01	1200	07-22-01	0600	2	No	1	1
43	KAO	Pain Abdo (Stomachache)	07-28-01	0520	07-28-01	1630	2	No	1	2

Adverse Events Summary

Subject No.	Init.	Event	Onset		Resolution		Frequency of Event	Serious	Intensity	Relationsh to Study Drug
			(Date)	(Military Time)	(Date)	(Military Time)				
06	BAZ	Cold Sore Top Right Lip	07-26-01	2100	07-29-01	0630	2	No	1	2
22	TMF	Dyspepsia (Heartburn)	07-21-01	0955	07-21-01	1223	2	No	1	1
12	CMP	Headache	07-28-01	0945	07-28-01	1315	2	No	1	1
15	WLE	Headache	07-21-01	1200	07-22-01	0200	2	No	1	1
17	CDD	Headache	07-21-01	0900	07-21-01	1000	2	No	1	1
17	CDD	Headache	07-28-01	0950	07-28-01	1600	2	No	1	1
33	DMT	Headache	07-21-01	1300	07-21-01	2100	2	No	1	1
34	ACT	Headache	07-28-01	1200	07-28-01	1500	2	No	1	1
35	AMK	Headache	07-21-01	1915	07-21-01	2000	2	No	1	1
35	AMK	Headache	07-21-01	2215	07-22-01	0015	2	No	1	1
36	DLJ	Headache	07-22-01	0600	07-24-01	1800	2	No	1	2
38	THP	Headache	07-21-01	1200	07-22-01	0600	2	No	1	1
33	DMT	Nausea	07-28-01	1400	07-28-01	2100	2	No	1	1
20	CRG	Pain Abdo (Stomachache)	07-21-01	2100	07-21-01	2300	2	No	1	1
43	KAO	Pain Abdo (Stomachache)	07-28-01	0520	07-28-01	1630	2	No	1	2
17	CDD	Pain Chest	07-21-01	1100	07-21-01	1200	2	No	1	1
26	JLP	Stomatitis Ulcer (Canker Sore)	07-18-01	0800	07-21-01	1600	2	No	1	2
34	ACT	Vomit (Vomited)	07-28-01	1418	07-28-01	1419	2	No	1	1

EVENT: The general description in parenthesis is at the request of the PRACS IRB to avoid the occasional

ONSET/RESOLUTION: Date in calendar time and hours and minutes recorded in military time

FREQUENCY OF EVENT:

- 1 = Intermittent
- 2 = Continual

SERIOUS:

Any adverse event that results in death, is life threatening, results in a persistent or significant disability, prolongs inpatient hospitalization, or results in a congenital anomaly/birth defect.

INTENSITY:

- 1 = MILD - Events are usually transient, requiring no special treatment and do not interfere with the subject's usual daily activities.
- 2 = MODERATE - Events traditionally introduce a low level of inconvenience or concern to the subject, but are usually ameliorated by simple therapeutic measures.
- 3 = SEVERE - Events interrupt a subject's usual daily activity and traditionally require systematic drug therapy.

RELATIONSHIP TO STUDY DRUG:

- 1 = Related
- 2 = Unrelated

OUTCOME:

- 1 = Resolved
- 2 = Hospitalized
- 3 = Death
- 4 = Improved/Worsened
- 5 = Insufficient Follow-up

COUNTER MEASURES:

- 1 = None
- 2 = Drug Discontinued Permanently
- 3 = Drug Discontinued and Restarted
- 4 = Dose Reduced
- 5 = Therapy Required
- 6 = Other

STUDY DRUG. Randomization Code

Treatment A (With Food) - SKELAXIN® 400 mg Tablets
[West-Ward Pharmaceutical Corp., Manufactured for Elan Pharmaceuticals Inc.; Lot No. SKLWW263F, Exp. Date: FEB03]

Treatment B (Without Food) - SKELAXIN® 400 mg Tablets
[West-Ward Pharmaceutical Corp., Manufactured for Elan Pharmaceuticals Inc.; Lot No. SKLWW263F, Exp. Date: FEB03]

SECTION 17.2.7

Listing of Individual Laboratory Measurements

CBC Results

Chart Number	Subject Number	Subject Initials	Draw Date	WBC	RBC	HCT	PLT	HGB	NEUT	EOS	LY
104248	01	ANJ	07/09/2001	6.4	4.63	39.7	284	13.4	69.5	1.4	
104248	01	ANJ	07/21/2001	6.6	4.58	39.6	259	13.1	59.6	2.1	
104248	01	ANJ	07/28/2001	6	4.54	38.4	261	12.9	55.4	2.6	
100515	02	RAW	07/19/2001	6.4	5.52	49.2	361	17.1	60.6	1.9	
100515	02	RAW	07/21/2001	6.3	5.63	50.9 H	337	17.6 H	54.8	3.9	
100515	02	RAW	07/28/2001	5.1	5.42	48.5	323	16.6	53.4	4.3 H	
100515	02	RAW	07/29/2001	7	5.24	46.9	347	16.3	58.6	2.9	
104659	03	TLS	07/09/2001	7.2	4.2	38	213	13.1	57.2	2.5	
104659	03	TLS	07/21/2001	6.1	4.2	38.5	202	13	55.6	2.5	
104659	03	TLS	07/28/2001	6.2	3.89	35.4	203	12.2	60.7	2.5	
104659	03	TLS	07/29/2001	8	3.79 L	33.9	213	11.6	62.3	1.7	
104492	04	KRE	07/10/2001	7.4	5.42	47.3	382	15.9	61.2	2.4	
104492	04	KRE	07/21/2001	7.7	5.35	49	361	15.7	63.8	3	
104492	04	KRE	07/28/2001	6.4	5.4	48	365	16	49.5 L	4.1 H	
104492	04	KRE	07/29/2001	9.2	5.15	45.6	358	15.6	56.5	2	
98555	05	SAP	07/10/2001	6.2	5.05	42.9	246	15.2	58.1	3.9	
98555	05	SAP	07/21/2001	5	5.02	44.5	230	14.9	41.7 L	4.5 H	
98555	05	SAP	07/28/2001	5.1	4.73	41.8	207	14.4	47.0 L	3.7	
98555	05	SAP	07/29/2001	6.8	5	43.7	271	15	54.9	3.1	
104752	06	BAZ	07/19/2001	3.6 L	4.94	45.5	223	15.5	56	2.2	
104752	06	BAZ	07/21/2001	3.5 L	4.99	46.2	214	15.9	59.3	2.8	
104752	06	BAZ	07/28/2001	4.4 L	4.67	42.9	217	14.6	58.9	2.7	
104752	06	BAZ	07/29/2001	8	4.91	45.3	238	15.6	79.5 H	0.9	
95514	07	CRT	07/19/2001	3.8 L	5.31	47.5	197	15.9	50.8	1.6	
95514	07	CRT	07/21/2001	5.5	5.33	48.4	175	16.4	35.5 L	2.6	!
95514	07	CRT	07/28/2001	7	5.38	47.5	213	16.4	43.2 L	2.2	
95514	07	CRT	07/29/2001	6	5.24	46.7	230	16.2	47.9 L	1.5	
96528	08	NBJ	07/17/2001	6.6	5.41	45.8	257	15.4	65.6	1.9	
96528	08	NBJ	07/21/2001	5.7	5.68	50	248	16.3	65.4	3.1	
96528	08	NBJ	07/28/2001	5.6	5.6	47.7	241	16.3	66.8	2.1	
96528	08	NBJ	07/29/2001	7.8	5.23	45.4	270	15.4	65.1	1.6	

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Chart Number	Subject Number	Subject Initials	Draw Date	WBC	RBC	HCT	PLT	HGB	NEUT	EOS	LY
97501	09	ADR	07/12/2001	4.4 L	4.51	39.5 L	123 L	13.7	64.6	1.9	
97501	09	ADR	07/21/2001	4.0 L	4.48	41	132	13.6	49.5 L	5.9 H	
97501	09	ADR	07/28/2001	4.4 L	4.21 L	38.3 L	126	13.0 L	46.9 L	3.9	
97501	09	ADR	07/29/2001	4.4 L	4.46	40.1	160	13.7	58.5	1.8	
104678	10	AKH	07/11/2001	6	4.17	39.8	195	13.7	68.4	1.9	
104678	10	AKH	07/21/2001	5.3	4	39	242	13.4	49.9 L	1.7	
104678	10	AKH	07/31/2001	6.6	4.21	40.5	247	13.3	71.9 H	0.5	
104677	11	CWB	07/11/2001	6	4.99	43.5	246	15.2	49.3 L	2	
104677	11	CWB	07/21/2001	7.8	5.29	48.1	242	15.7	45.9 L	2.6	
104677	11	CWB	07/28/2001	7.9	5.33	47.5	272	16	47.8 L	2.7	
104677	11	CWB	07/29/2001	7.6	4.79	41.6	257	14.4	51.2	2.2	
96298	12	CMP	07/17/2001	7.2	5.74	49.3	293	17.2	61.7	2.2	
96298	12	CMP	07/21/2001	7	5.55	49.7	271	17.4	54.8	1.9	
96298	12	CMP	07/28/2001	7.6	5.37	46.8	277	16.6	44.5 L	2.7	
96298	12	CMP	07/29/2001	8.3	5.28	46.9	311	16.1	60.9	1.5	
102585	13	KWJ	07/17/2001	5	4.64	45	280	15	48.1 L	1.7	
102585	13	KWJ	07/21/2001	5.5	4.59	45.5	225	15.1	41.3 L	2.7	
102585	13	KWJ	07/28/2001	5.6	4.41	43.5	239	14.9	37.1 L	2.6	
102585	13	KWJ	07/29/2001	4.8	4.5	44.1	258	14.7	36.1 L	2.9	
104687	14	JEJ	07/12/2001	6.1	4.7	40.9	227	13.6	67.1	1.2	
104687	14	JEJ	07/21/2001	6.8	4.86	42.1	205	14.4	53.4	1.4	
104687	14	JEJ	07/28/2001	6.1	4.58	38.8	199	13.5	53.6	1	
104687	14	JEJ	07/29/2001	7.6	4.46	38.2	227	13.3	67.3	0.5	
104727	15	WLE	07/18/2001	5.6	5.43	45.6	256	15.5	57.5	3.3	
104727	15	WLE	07/21/2001	5.8	5.94	51.6 H	271	16.3	52.1	3.3	
104727	15	WLE	07/28/2001	5.6	5.51	46.3	284	15.6	50.1	3.5	
104727	15	WLE	07/29/2001	9.1	5.27	44.7	281	15	59.2	2.9	
104682	16	HMH	07/11/2001	7	4.86	41.1	296	13.9	69.2	1.2	
104682	16	HMH	07/21/2001	5.7	4.64	40.4	282	13.5	62.9	2.8	
104682	16	HMH	07/28/2001	5.6	4.78	41.8	278	14	52.9	2.7	
104682	16	HMH	07/29/2001	6.7	4.5	38.3	284	13.2	64.5	2.1	

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Chart Number	Subject Number	Subject Initials	Draw Date	-----AUTOMATED-----										
				WBC	RBC	HCT	PLT	HGB	NEUT	EOS	LYMPHS	BASOS	MONOS	
98427	17	CDD	07/11/2001	5.7	5.11	44.3	233	15.2	46.5 L	6.3 H	37.1	0.7	9.4	
98427	17	CDD	07/21/2001	5.7	4.9	43.5	224	14.5	47.2 L	8.8 H	34.6	1.2 H	8.2	
98427	17	CDD	07/28/2001	6.4	5.21	45.4	240	15.4	45.5 L	7.6 H	35.9	1.1 H	9.9	
98427	17	CDD	07/29/2001	9.1	5.31	46.6	282	15.6	43.5 L	5.2 H	41.2	1.1 H	9	
97021	18	JME	07/12/2001	4.8	5.2	47.2	284	16.1	50.6	7.3 H	32.4	1	8.7	
97021	18	JME	07/21/2001	7.5	5.27	49.1	259	16.2	65.2	3.1	24	0.3	7.4	
97021	18	JME	07/28/2001	6.3	5.03	45.1	313	15.9	43.5 L	3.7	41.2	0.9	10.7 H	
97021	18	JME	07/29/2001	6.9	4.77	43	345	15.1	63.6	0.6	29.3	0.5	6	
104690	19	CLH	07/12/2001	7.2	4.67	37.7	306	12.6	67.1	0.9	25.4	0.7	5.9	
104690	19	CLH	07/21/2001	7.7	4.77	39.7	313	13.4	62.6	1.2	33.6	0.1	2.5	
104690	19	CLH	07/28/2001	7.1	4.44	36.4	280	12.5	51.8	1.8	37.7	0.7	8	
104690	19	CLH	07/29/2001	8.6	4.45	35.8	319	12.3	66.7	1	25.6	0.9	5.8	
104693	20	CRG	07/12/2001	5.8	5.04	47.6	252	16.1	57	0.5	34.1	0.7	7.7	
104693	20	CRG	07/21/2001	7.6	5.1	49.3	275	16.5	50.6	1.2	38.6	1.2 H	8.4	
104693	20	CRG	07/28/2001	8.5	4.79	46.3	266	15.7	49.0 L	0.9	38.4	0.8	10.9 H	
104693	20	CRG	07/29/2001	6.3	5.03	47.6	284	16.6	52.6	0.8	30.1	0.2	16.3 H	
104693	20	CRG	07/31/2001	5.1	5.09	47.7	252	16.2	42.9 L	0.5	38.5	0.9	17.2 H	
104693	20	CRG	08/06/2001	5.7	4.82	45.7	269	15.5	48.1 L	1.4	35.9	0.6	14.0 H	
100930	21	KRM	07/18/2001	5.8	5.03	42.7	228	14.5	55.1	2.5	32	0.6	9.8	
100930	21	KRM	07/21/2001	5.9	4.98	43.8	220	14.8	52.4	3.3	37.2	0.4	6.7	
100930	21	KRM	07/28/2001	5.8	4.87	42.1	233	14.5	48.3 L	2.4	38.4	0.7	10.2 H	
100930	21	KRM	07/29/2001	7.2	5	43.4	254	14.6	56.1	2.1	32.3	0.7	8.8	
104746	22	TMF	07/19/2001	6.7	5.61	47.1	259	16.5	68.3	2.8	19.2	0.6	9.1	
104746	22	TMF	07/21/2001	6	5.48	47	267	15.8	60.5	3.3	26.4	0.6	9.2	
104746	22	TMF	07/28/2001	7.7	5.22	44	228	15.1	81.5 H	0.9	8.9 L	0.1	8.6	
104746	22	TMF	07/29/2001	6.6	5.35	45.5	262	15.5	64.7	2	20.3	0.8	12.2 H	
102915	23	GPA	07/12/2001	5.9	4.89	43.1	230	14.6	62.9	3.9	24.6	1.3 H	7.3	
102915	23	GPA	07/21/2001	5.6	5.07	45.1	211	15.1	55.6	4.3 H	31.1	0.8	8.2	
102915	23	GPA	07/28/2001	5.3	4.96	43.1	241	14.8	55.6	3.1	29.7	1.4 H	10.2 H	
102915	23	GPA	07/29/2001	7	4.74	41.1	244	14.3	61.9	2	26.9	0.8	8.4	
102153	24	BDH	07/11/2001	6.8	5.65	49	252	16.8	53.4	1.3	36.8	0.4	8.1	

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				WBC	RBC	HCT	PLT	HGB	NEUT	EOS	LYMPHS	BASOS	MONOS
102153	24	BDH	07/21/2001	6.6	5.26	47.5	239	15.7	46.8 L	1.5	42.2	0.5	9
102153	24	BDH	07/28/2001	6.4	5.5	48.5	247	16.4	45.9 L	1.6	44	0.3	8.2
102153	24	BDH	07/29/2001	7	5.29	46.7	248	15.8	51.4	1.1	38.7	0.5	8.3
97683	25	RMK	07/12/2001	7.2	5.28	45.2	266	15.3	51	6.2 H	34.1	0.7	8
97683	25	RMK	07/21/2001	6.4	5.38	46.5	230	15.6	52.8	6.3 H	32.1	0.6	8.2
97683	25	RMK	07/28/2001	6.7	5.44	46.3	253	15.8	51	5.8 H	31.2	1.4 H	10.6 H
97683	25	RMK	07/29/2001	9.8	5.44	46.4	282	15.7	55.2	4.9 H	32.1	0.3	7.5
100918	26	JLP	07/13/2001	5.3	4.96	42.1	273	15.1	60.1	4.4 H	26.8	0.2	8.5
100918	26	JLP	07/21/2001	5.4	5.62	49.8	308	16.7	52	4	37.3	0.7	6
100918	26	JLP	07/28/2001	5.9	5.32	45.9	273	16.2	66.1	3.8	19.9	0.5	9.7
100918	26	JLP	07/29/2001	5.8	4.91	42.4	283	15.1	53.4	3.3	33.7	0.2	9.4
104673	27	AIF	07/11/2001	6.3	4.66	40.3	224	13.7	64.3	2.1	26	0.7	6.9
104673	27	AIF	07/21/2001	7.5	4.64	41	233	13.9	58	2.9	33.1	1	5
104673	27	AIF	07/28/2001	7.9	4.51	39.1	228	13.3	60.1	2.2	30.5	0.6	6.6
104673	27	AIF	07/29/2001	8.4	4.39	37.9	252	13	66.4	1.2	26	0.6	5.8
99920	28	SMR	07/13/2001	4.9	4.95	41.7	195	14.4	62.9	2.3	25	0.5	9.3
99920	28	SMR	07/21/2001	4.8	4.84	41.9	188	14.3	54.8	3.2	31.9	0.9	9.2
99920	28	SMR	07/28/2001	4.8	5.09	43	200	14.7	45.3 L	3.7	39	0.8	11.2 H
99920	28	SMR	07/29/2001	6	4.79	40.9	217	14.1	66.8	2.4	23.1	0	7.7
104608	29	AJA	07/16/2001	5.6	5.34	45	279	15.4	59.1	2.1	29.2	0.5	9.1
104608	29	AJA	07/21/2001	5	5.34	45.7	268	15.6	50.4	2.2	40.3	0.6	6.5
104608	29	AJA	07/28/2001	4.7	5.23	44	283	15.2	48.0 L	1.8	42.1	0.5	7.6
104608	29	AJA	07/29/2001	7.3	4.78	40.9	302	14.1	65.9	0.3	26.9	0.7	6.2
101775	30	NCG	07/17/2001	6	5.42	50	247	16.9	63.4	1.3	25.9	2.0 H	7.4
101775	30	NCG	07/21/2001	7	5.37	50.4 H	204	16.8	62.8	2.2	27.1	1.1 H	6.8
101775	30	NCG	07/28/2001	5.8	5.53	51.2 H	214	16.9	49.8 L	2.7	37	1.9 H	8.6
101775	30	NCG	07/29/2001	8.6	5.14	47	238	16.3	60.7	1.2	31.3	0.7	6.1
101800	31	PAZ	07/13/2001	6.1	5.59	49.6	166	17.2	61.4	1.6	25.5	0.3	11.2 H
101800	31	PAZ	07/21/2001	7.2	5.44	50.1 H	178	16.9	56.7	2.3	33.3	0.6	7.1
101800	31	PAZ	07/28/2001	7.3	5.35	48.4	178	16.7	58.2	1.8	31.3	0.3	8.4
101800	31	PAZ	07/29/2001	7.2	5.43	49.1	204	16.9	64.5	1.4	26.7	0.7	6.7

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Chart Number	Subject Number	Subject Initials	Draw Date	WBC	RBC	HCT	PLT	HGB	NEUT	EOS	LYMPHS	BASOS	MONOS
99638	32	MJH	07/19/2001	6.1	5.12	46.9	195	16.6	58.2	2.6	31.3	0.8	7.1
99638	32	MJH	07/21/2001	7.1	4.96	46.6	210	16.3	54.3	2.9	36.5	0.9	5.4
99638	32	MJH	07/28/2001	6.9	5.06	47.7	222	16.4	51.1	3	38	1.2 H	6.7
99638	32	MJH	07/29/2001	7.5	4.85	45.1	231	15.7	61.4	1.5	30.6	0.8	5.7
104724	33	DMT	07/18/2001	4.6	5.06	42.5	367	14.1	46.0 L	2.7	40.4	1.3 H	9.6
104724	33	DMT	07/21/2001	5.6	5.01	42.8	356	14	48.2 L	3.2	42	0.2	6.4
104724	33	DMT	07/28/2001	5.3	4.57	38.1	304	12.7	47.5 L	3.3	36.9	0.9	11.4 H
104724	33	DMT	07/29/2001	6.9	4.48	37.7	330	12.5	45.7 L	2.5	39.9	0.8	11.1 H
95922	34	ACT	07/18/2001	6.2	4.55	39.3	355	13.3	67.2	1.1	22.8	0.4	8.5
95922	34	ACT	07/21/2001	6.4	4.61	40.6	340	13.4	69.3	1.5	23.5	0.8	4.9
95922	34	ACT	07/28/2001	7.2	4.74	40.9	375	13.8	69.8	1.7	20	0.3	8.2
95922	34	ACT	07/29/2001	9.4	4.38	38.3	363	12.7	71.2 H	1	19.7	0.2	7.9
104718	35	AMK	07/17/2001	6	4.69	41.3	443	13.8	61	0.8	27.1	0.8	10.3 H
104718	35	AMK	07/21/2001	7.8	4.87	43.4	461	14.3	58.7	1.3	33.1	0.1	6.8
104718	35	AMK	07/28/2001	8.6	4.68	41.6	440	14.2	58.7	1.1	28.8	0.9	10.5 H
104718	35	AMK	07/29/2001	10.5	4.67	41.1	458	14	65.3	0.6	26	0.1	8
104707	36	DLJ	07/16/2001	4.0 L	4.78	44	187	15	55	1.3	34	0.9	8.8
104707	36	DLJ	07/21/2001	3.5 L	4.85	45.3	173	15.3	50.3	3.5	32.8	0.3	13.1 H
104707	36	DLJ	07/28/2001	4.6	4.81	44.2	201	15	52.9	2.2	31.7	1.3 H	11.9 H
104707	36	DLJ	07/29/2001	5.8	4.63	42.3	233	14.7	54.9	1.9	33.4	1.2 H	8.6
100844	37	MAL	07/16/2001	5	4.89	44.1	281	15	57.5	3.3	27.8	1	10.4 H
100844	37	MAL	07/21/2001	4.8	4.7	42.6	257	14.6	49.5 L	6.9 H	33.4	0.6	9.6
100844	37	MAL	07/28/2001	5	4.8	43.5	300	14.8	54.1	7.1 H	28.4	0.9	9.5
100844	37	MAL	07/29/2001	7.9	4.77	42.5	318	14.7	65.9	3.2	21.3	0.1	9.5
102279	38	THP	07/17/2001	5.2	3.87	34.3	302	12	63.7	2.8	23.6	1.4 H	8.5
102279	38	THP	07/21/2001	7.8	3.99	37	297	12.2	70.5 H	2.4	20.2	0.6	6.3
102279	38	THP	07/28/2001	6.2	4.01	35.7	306	12.2	56	2.7	31.9	1.4 H	8
102279	38	THP	07/29/2001	12.3 H	3.59 L	31.6 L	298	11.0 L	88.3 H	0.9	8.1 L	0.7	2
102279	38	THP	08/02/2001	7.2	3.81	32.9 L	332	11.4 L	73.4 H	1.6	16.5 L	1.3 H	7.2
104299	39	JDF	07/17/2001	6.5	4.77	43.3	259	14.9	57.5	3.8	27.2	0.9	10.6 H
104299	39	JDF	07/21/2001	5.7	4.89	45.3	272	15.3	53.2	4.6 H	32.3	1.2 H	8.7

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Chart Number	Subject Number	Subject Initials	Draw Date	WBC	RBC	HCT	PLT	HGB	NEUT	EOS	LYMPHS	BASOS	MONOS
104299	39	JDF	07/28/2001	6.1	4.8	43.2	222	15.2	56.9	3	25.2	0.8	14.1 H
104299	39	JDF	07/29/2001	6.4	5.05	45.3	264	15.7	59.6	2.6	28.3	0.5	9
102629	40	TEM	07/16/2001	5.6	5.02	43.8	294	15.2	53.3	2	35.9	0.5	8.3
102629	40	TEM	07/21/2001	6.2	5.58	50.6 H	300	16.1	58.3	3.9	30	0.8	7
102629	40	TEM	07/28/2001	6.1	5.16	45.8	307	15.5	55.9	4.4 H	30.8	0.9	8
102629	40	TEM	07/29/2001	7.8	4.88	43	293	14.7	59	3.6	30.2	0.7	6.5
91906	41	JNH	07/13/2001	5.5	4.88	43.4	259	14.5	38.7 L	3.8	46.2 H	0.5	10.8 H
91906	41	JNH	07/21/2001	5.8	4.87	43.5	243	14.7	35.3 L	4	51.4 H	0.6	8.7
91906	41	JNH	07/28/2001	5.5	4.86	43	260	15	33.8 L	3.4	51.8 H	0.2	10.8 H
91906	41	JNH	07/29/2001	9	4.68	41.2	245	14.4	48.8 L	1.8	38.9	0.7	9.8
99843	42	N-F	07/18/2001	5.8	5.18	42.4	225	14.1	63	2.2	24.2	0.4	10.2 H
99843	42	N-F	07/21/2001	5.4	5.13	42.3	214	14.1	55.8	2.6	30.9	1	9.7
99843	42	N-F	07/28/2001	4.9	5.06	41.7	215	14	50.3	2.9	36.3	0.6	9.9
99843	42	N-F	07/29/2001	6.1	5.03	41.3	229	14.2	65	0.8	26.6	0.4	7.2
104700	43	KAO	07/13/2001	5.2	4.55	41	251	13.9	63.7	1.8	27.3	1.2 H	6
104700	43	KAO	07/21/2001	7.3	4.59	41.7	229	14.2	52.6	2.9	38.6	0.3	5.6
104700	43	KAO	07/28/2001	10.8	4.45	39.7	247	13.8	67.4	2.4	23.2	0.5	6.5
104700	43	KAO	07/29/2001	8	4.24	38.6	276	13.1	63.1	2.2	30	0.2	4.5
104681	44	BAH	07/11/2001	8.9	4.72	40	306	13.5	60.3	1	32.3	0.4	6
104681	44	BAH	07/21/2001	5	4.77	41	263	13.8	50.2	2.4	41.5	0.4	5.5
104681	44	BAH	07/28/2001	5.6	4.48	38.5	294	13.1	50.2	1	41.8	0.9	6.1
104681	44	BAH	07/29/2001	7.2	4.58	39.1	323	13.4	52.1	0.8	41.3	0.5	5.3

CBC Results

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Chart Number	Subject Number	Subject Initials	Draw Date	BANDS	SEGS	LYMPH	MONOS	EOS	BASOS	METAS
104248	01	ANJ	07/09/2001	-	-	-	-	-	-	-
104248	01	ANJ	07/21/2001	-	-	-	-	-	-	-
104248	01	ANJ	07/28/2001	-	-	-	-	-	-	-
100515	02	RAW	07/19/2001	-	-	-	-	-	-	-
100515	02	RAW	07/21/2001	-	-	-	-	-	-	-
100515	02	RAW	07/28/2001	-	-	-	-	-	-	-
100515	02	RAW	07/29/2001	-	-	-	-	-	-	-
104659	03	TLS	07/09/2001	-	-	-	-	-	-	-
104659	03	TLS	07/21/2001	-	-	-	-	-	-	-
104659	03	TLS	07/28/2001	-	-	-	-	-	-	-
104659	03	TLS	07/29/2001	-	-	-	-	-	-	-
104492	04	KRE	07/10/2001	-	-	-	-	-	-	-
104492	04	KRE	07/21/2001	-	-	-	-	-	-	-
104492	04	KRE	07/28/2001	-	-	-	-	-	-	-
104492	04	KRE	07/29/2001	-	-	-	-	-	-	-
98555	05	SAP	07/10/2001	-	-	-	-	-	-	-
98555	05	SAP	07/21/2001	-	-	-	-	-	-	-
98555	05	SAP	07/28/2001	-	-	-	-	-	-	-
98555	05	SAP	07/29/2001	-	-	-	-	-	-	-
104752	06	BAZ	07/19/2001	-	-	-	-	-	-	-
104752	06	BAZ	07/21/2001	-	-	-	-	-	-	-
104752	06	BAZ	07/28/2001	-	-	-	-	-	-	-
104752	06	BAZ	07/29/2001	-	-	-	-	-	-	-
95514	07	CRT	07/19/2001	-	-	-	-	-	-	-
95514	07	CRT	07/21/2001	-	-	-	-	-	-	-
95514	07	CRT	07/28/2001	-	-	-	-	-	-	-
95514	07	CRT	07/29/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/17/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/21/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/28/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/29/2001	-	-	-	-	-	-	-

CBC Results

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Chart Number	Subject Number	Subject Initials	Draw Date	BANDS	SEGS	LYMPH	MONOS	EOS	BASOS	METAS
97501	09	ADR	07/12/2001	1	68	27	3	1	0	-
97501	09	ADR	07/21/2001	-	-	-	-	-	-	-
97501	09	ADR	07/28/2001	-	-	-	-	-	-	-
97501	09	ADR	07/29/2001	-	-	-	-	-	-	-
104678	10	AKH	07/11/2001	-	-	-	-	-	-	-
104678	10	AKH	07/21/2001	-	-	-	-	-	-	-
104678	10	AKH	07/31/2001	-	-	-	-	-	-	-
104677	11	CWB	07/11/2001	-	-	-	-	-	-	-
104677	11	CWB	07/21/2001	-	-	-	-	-	-	-
104677	11	CWB	07/28/2001	-	-	-	-	-	-	-
104677	11	CWB	07/29/2001	-	-	-	-	-	-	-
96298	12	CMP	07/17/2001	-	-	-	-	-	-	-
96298	12	CMP	07/21/2001	-	-	-	-	-	-	-
96298	12	CMP	07/28/2001	-	-	-	-	-	-	-
96298	12	CMP	07/29/2001	-	-	-	-	-	-	-
102585	13	KWJ	07/17/2001	-	-	-	-	-	-	-
102585	13	KWJ	07/21/2001	-	-	-	-	-	-	-
102585	13	KWJ	07/28/2001	-	-	-	-	-	-	-
102585	13	KWJ	07/29/2001	-	-	-	-	-	-	-
104687	14	JEJ	07/12/2001	-	-	-	-	-	-	-
104687	14	JEJ	07/21/2001	-	-	-	-	-	-	-
104687	14	JEJ	07/28/2001	-	-	-	-	-	-	-
104687	14	JEJ	07/29/2001	-	-	-	-	-	-	-
104727	15	WLE	07/18/2001	-	-	-	-	-	-	-
104727	15	WLE	07/21/2001	-	-	-	-	-	-	-
104727	15	WLE	07/28/2001	-	-	-	-	-	-	-
104727	15	WLE	07/29/2001	-	-	-	-	-	-	-
104682	16	HMH	07/11/2001	-	-	-	-	-	-	-
104682	16	HMH	07/21/2001	-	-	-	-	-	-	-
104682	16	HMH	07/28/2001	-	-	-	-	-	-	-
104682	16	HMH	07/29/2001	-	-	-	-	-	-	-

CBC Results

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Chart Number	Subject Number	Subject Initials	Draw Date	BANDS	SEGS	LYMPH	MONOS	EOS	BASOS	METAS
98427	17	CDD	07/11/2001	-	-	-	-	-	-	-
98427	17	CDD	07/21/2001	-	-	-	-	-	-	-
98427	17	CDD	07/28/2001	-	-	-	-	-	-	-
98427	17	CDD	07/29/2001	-	-	-	-	-	-	-
97021	18	JME	07/12/2001	-	-	-	-	-	-	-
97021	18	JME	07/21/2001	-	-	-	-	-	-	-
97021	18	JME	07/28/2001	-	-	-	-	-	-	-
97021	18	JME	07/29/2001	-	-	-	-	-	-	-
104690	19	CLH	07/12/2001	-	-	-	-	-	-	-
104690	19	CLH	07/21/2001	-	-	-	-	-	-	-
104690	19	CLH	07/28/2001	-	-	-	-	-	-	-
104690	19	CLH	07/29/2001	-	-	-	-	-	-	-
104693	20	CRG	07/12/2001	-	-	-	-	-	-	-
104693	20	CRG	07/21/2001	-	-	-	-	-	-	-
104693	20	CRG	07/28/2001	-	-	-	-	-	-	-
104693	20	CRG	07/29/2001	-	-	-	-	-	-	-
104693	20	CRG	07/31/2001	-	-	-	-	-	-	-
104693	20	CRG	08/06/2001	-	-	-	-	-	-	-
100930	21	KRM	07/18/2001	-	-	-	-	-	-	-
100930	21	KRM	07/21/2001	-	-	-	-	-	-	-
100930	21	KRM	07/28/2001	-	-	-	-	-	-	-
100930	21	KRM	07/29/2001	-	-	-	-	-	-	-
104746	22	TMF	07/19/2001	-	-	-	-	-	-	-
104746	22	TMF	07/21/2001	-	-	-	-	-	-	-
104746	22	TMF	07/28/2001	-	-	-	-	-	-	-
104746	22	TMF	07/29/2001	-	-	-	-	-	-	-
102915	23	GPA	07/12/2001	-	-	-	-	-	-	-
102915	23	GPA	07/21/2001	-	-	-	-	-	-	-
102915	23	GPA	07/28/2001	-	-	-	-	-	-	-
102915	23	GPA	07/29/2001	-	-	-	-	-	-	-
102153	24	BDH	07/11/2001	-	-	-	-	-	-	-

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Chart Number	Subject Number	Subject Initials	Draw Date	-----MANUAL-----						
				BANDS	SEGS	LYMPH	MONOS	EOS	BASOS	METAS
102153	24	BDH	07/21/2001	-	-	-	-	-	-	-
102153	24	BDH	07/28/2001	-	-	-	-	-	-	-
102153	24	BDH	07/29/2001	-	-	-	-	-	-	-
97683	25	RMK	07/12/2001	-	-	-	-	-	-	-
97683	25	RMK	07/21/2001	-	-	-	-	-	-	-
97683	25	RMK	07/28/2001	-	-	-	-	-	-	-
97683	25	RMK	07/29/2001	-	-	-	-	-	-	-
100918	26	JLP	07/13/2001	-	-	-	-	-	-	-
100918	26	JLP	07/21/2001	-	-	-	-	-	-	-
100918	26	JLP	07/28/2001	-	-	-	-	-	-	-
100918	26	JLP	07/29/2001	-	-	-	-	-	-	-
104673	27	AIF	07/11/2001	-	-	-	-	-	-	-
104673	27	AIF	07/21/2001	-	-	-	-	-	-	-
104673	27	AIF	07/28/2001	-	-	-	-	-	-	-
104673	27	AIF	07/29/2001	-	-	-	-	-	-	-
99920	28	SMR	07/13/2001	-	-	-	-	-	-	-
99920	28	SMR	07/21/2001	-	-	-	-	-	-	-
99920	28	SMR	07/28/2001	-	-	-	-	-	-	-
99920	28	SMR	07/29/2001	-	-	-	-	-	-	-
104608	29	AJA	07/16/2001	-	-	-	-	-	-	-
104608	29	AJA	07/21/2001	-	-	-	-	-	-	-
104608	29	AJA	07/28/2001	-	-	-	-	-	-	-
104608	29	AJA	07/29/2001	-	-	-	-	-	-	-
101775	30	NCG	07/17/2001	-	-	-	-	-	-	-
101775	30	NCG	07/21/2001	-	-	-	-	-	-	-
101775	30	NCG	07/28/2001	-	-	-	-	-	-	-
101775	30	NCG	07/29/2001	-	-	-	-	-	-	-
101800	31	PAZ	07/13/2001	-	-	-	-	-	-	-
101800	31	PAZ	07/21/2001	-	-	-	-	-	-	-
101800	31	PAZ	07/28/2001	-	-	-	-	-	-	-
101800	31	PAZ	07/29/2001	-	-	-	-	-	-	-

CBC Results

Chart Number	Subject Number	Subject Initials	Draw Date	-----MANUAL-----						
				BANDS	SEGS	LYMPH	MONOS	EOS	BASOS	METAS
99638	32	MJH	07/19/2001	-	-	-	-	-	-	-
99638	32	MJH	07/21/2001	-	-	-	-	-	-	-
99638	32	MJH	07/28/2001	-	-	-	-	-	-	-
99638	32	MJH	07/29/2001	-	-	-	-	-	-	-
104724	33	DMT	07/18/2001	-	-	-	-	-	-	-
104724	33	DMT	07/21/2001	-	-	-	-	-	-	-
104724	33	DMT	07/28/2001	-	-	-	-	-	-	-
104724	33	DMT	07/29/2001	-	-	-	-	-	-	-
95922	34	ACT	07/18/2001	-	-	-	-	-	-	-
95922	34	ACT	07/21/2001	-	-	-	-	-	-	-
95922	34	ACT	07/28/2001	-	-	-	-	-	-	-
95922	34	ACT	07/29/2001	-	-	-	-	-	-	-
104718	35	AMK	07/17/2001	-	-	-	-	-	-	-
104718	35	AMK	07/21/2001	-	-	-	-	-	-	-
104718	35	AMK	07/28/2001	-	-	-	-	-	-	-
104718	35	AMK	07/29/2001	-	-	-	-	-	-	-
104707	36	DLJ	07/16/2001	-	-	-	-	-	-	-
104707	36	DLJ	07/21/2001	-	-	-	-	-	-	-
104707	36	DLJ	07/28/2001	-	-	-	-	-	-	-
104707	36	DLJ	07/29/2001	-	-	-	-	-	-	-
100844	37	MAL	07/16/2001	-	-	-	-	-	-	-
100844	37	MAL	07/21/2001	-	-	-	-	-	-	-
100844	37	MAL	07/28/2001	-	-	-	-	-	-	-
100844	37	MAL	07/29/2001	-	-	-	-	-	-	-
102279	38	THP	07/17/2001	-	-	-	-	-	-	-
102279	38	THP	07/21/2001	-	-	-	-	-	-	-
102279	38	THP	07/28/2001	-	-	-	-	-	-	-
102279	38	THP	07/29/2001	4	81 H	11 L	3	1	0	-
102279	38	THP	08/02/2001	-	-	-	-	-	-	-
104299	39	JDF	07/17/2001	-	-	-	-	-	-	-
104299	39	JDF	07/21/2001	-	-	-	-	-	-	-

CBC Results

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Chart Number	Subject Number	Subject Initials	Draw Date	BANDS	SEGS	LYMPH	MONOS	EOS	BASOS	METAS
104299	39	JDF	07/28/2001	-	-	-	-	-	-	-
104299	39	JDF	07/29/2001	-	-	-	-	-	-	-
102629	40	TEM	07/16/2001	-	-	-	-	-	-	-
102629	40	TEM	07/21/2001	-	-	-	-	-	-	-
102629	40	TEM	07/28/2001	-	-	-	-	-	-	-
102629	40	TEM	07/29/2001	-	-	-	-	-	-	-
91906	41	JNH	07/13/2001	-	-	-	-	-	-	-
91906	41	JNH	07/21/2001	-	-	-	-	-	-	-
91906	41	JNH	07/28/2001	-	-	-	-	-	-	-
91906	41	JNH	07/29/2001	-	-	-	-	-	-	-
99843	42	N-F	07/18/2001	-	-	-	-	-	-	-
99843	42	N-F	07/21/2001	-	-	-	-	-	-	-
99843	42	N-F	07/28/2001	-	-	-	-	-	-	-
99843	42	N-F	07/29/2001	-	-	-	-	-	-	-
104700	43	KAO	07/13/2001	-	-	-	-	-	-	-
104700	43	KAO	07/21/2001	-	-	-	-	-	-	-
104700	43	KAO	07/28/2001	-	-	-	-	-	-	-
104700	43	KAO	07/29/2001	2	57	33	6	2	0	-
104681	44	BAH	07/11/2001	-	-	-	-	-	-	-
104681	44	BAH	07/21/2001	-	-	-	-	-	-	-
104681	44	BAH	07/28/2001	-	-	-	-	-	-	-
104681	44	BAH	07/29/2001	-	-	-	-	-	-	-

CHEM Results

Chart Number	Subject Number	Subject Initials	Draw Date	CREA	BUN	GLUC	TOTAL PROTEIN	ALB	AST	ALT	TOTAL ALK	TOTAL BILI
104248	01	ANJ	07/09/2001	0.8	10	90	7.7	4.2	23	12	96	0.4
104248	01	ANJ	07/21/2001	0.8	9	85	7.2	3.8	21	11	91	0.6
104248	01	ANJ	07/28/2001	0.8	7	78	7	3.7	21	11	84	0.6
100515	02	RAW	07/19/2001	1	15	92	6.9	4.4	25	26	59	1.3 H
100515	02	RAW	07/21/2001	1.1	16	103	7.2	4.6	26	29	61	1.4 H
100515	02	RAW	07/28/2001	1	12	91	6.7	4.3	25	25	54	1
100515	02	RAW	07/29/2001	0.8	15	85	7	4.7	26	26	54	1
104659	03	TLS	07/09/2001	0.7	12	93	7.5	4.9	17	13	64	0.8
104659	03	TLS	07/21/2001	0.6	11	88	6.9	4.4	18	12	56	0.8
104659	03	TLS	07/28/2001	0.7	12	93	6.5	4.2	17	11	49	1
104659	03	TLS	07/29/2001	0.6	12	88	7.1	4.7	19	14	52	0.7
104492	04	KRE	07/10/2001	1	10	92	7.2	4.3	37	40	89	1
104492	04	KRE	07/21/2001	1	10	87	7	4.2	22	24	77	0.8
104492	04	KRE	07/28/2001	1.1	10	81	7	4.1	22	26	74	0.7
104492	04	KRE	07/29/2001	1	10	75	7.4	4.7	23	26	74	1
98555	05	SAP	07/10/2001	0.8	12	61 L	7.2	4.1	25	23	87	0.8
98555	05	SAP	07/21/2001	0.8	14	100	6.8	3.9	19	18	74	0.9
98555	05	SAP	07/28/2001	0.8	13	95	6.6	4	18	17	68	0.9
98555	05	SAP	07/29/2001	0.8	10	130 H	7.3	4.6	22	19	76	0.7
98555	05	SAP	08/01/2001	-	-	102	-	-	-	-	-	-
104752	06	BAZ	07/19/2001	1.2	18	91	6.8	4.4	20	17	65	1.3 H
104752	06	BAZ	07/21/2001	1.2	22	103	6.7	4.3	20	18	60	1.7 H
104752	06	BAZ	07/28/2001	1.2	17	94	6.5	4.2	20	18	59	1.3 H
104752	06	BAZ	07/29/2001	1.1	20	83	6.9	4.7	23	18	60	1.4 H
95514	07	CRT	07/19/2001	0.8	8	96	6.3 L	3.8	22	18	71	2.1 H
95514	07	CRT	07/21/2001	0.9	14	102	6.5	3.9	20	18	76	1.6 H
95514	07	CRT	07/28/2001	0.8	13	89	6.8	4.2	17	15	80	1.5 H
95514	07	CRT	07/29/2001	1	14	79	6.9	4.6	19	15	81	1.3 H
96528	08	NBJ	07/17/2001	1.2	11	91	7.8	4.5	21	15	62	1
96528	08	NBJ	07/21/2001	1.2	18	93	7.5	4.2	19	18	61	0.8
96528	08	NBJ	07/28/2001	1.2	17	84	7.7	4.5	21	18	63	1.1

CHEM Results

Chart Number	Subject Number	Subject Initials	Draw Date	TOTAL								
				CREA	BUN	GLUC	PROTEIN	ALB	AST	ALT	ALK	BILI
96528	08	NBJ	07/29/2001	1.2	18	81	7.7	4.7	20	16	60	0.8
96528	08	NBJ	07/31/2001	-	-	-	-	-	-	-	-	-
97501	09	ADR	07/12/2001	1.1	17	89	7.3	4.2	27	22	57	1.3 H
97501	09	ADR	07/19/2001	1	14	95	7.4	4.3	28	23	56	1.4 H
97501	09	ADR	07/21/2001	1	15	99	7	4	29	27	52	1.3 H
97501	09	ADR	07/28/2001	0.9	17	84	6.7	3.8	25	20	49	1.1
97501	09	ADR	07/29/2001	1	12	82	7.7	4.7	31	23	51	1.2
104678	10	AKH	07/11/2001	1	6	91	6.4	4.1	25	29	51	0.9
104678	10	AKH	07/21/2001	0.7	10	91	6.1 L	3.9	15	12	54	1
104678	10	AKH	07/31/2001	0.8	11	85	6.6	4.5	20	14	53	1.1
104677	11	CWB	07/11/2001	0.9	10	94	7.8	4.6	30	51 H	56	1.3 H
104677	11	CWB	07/17/2001	-	-	-	-	-	-	43 H	-	-
104677	11	CWB	07/21/2001	0.9	16	95	7.4	4.3	21	35	50	1.1
104677	11	CWB	07/28/2001	1	20	91	8.1	4.8	30	33	52	0.9
104677	11	CWB	07/28/2001	-	-	-	-	-	-	-	-	-
104677	11	CWB	07/29/2001	1	15	84	7.7	4.7	21	29	51	0.8
96298	12	CMP	07/17/2001	1.2	15	94	7.6	4.6	27	22	72	1.5 H
96298	12	CMP	07/21/2001	1.1	15	87	7.2	4.4	23	20	68	1.2
96298	12	CMP	07/28/2001	1.2	15	86	7	4.4	21	18	64	1
96298	12	CMP	07/29/2001	1	17	82	7.4	4.8	25	18	63	1.2
102585	13	KWJ	07/17/2001	1	8	97	7.6	4.3	35	8	75	0.7
102585	13	KWJ	07/21/2001	1	17	96	7.3	4	36	7	72	0.7
102585	13	KWJ	07/28/2001	1	11	95	7.3	4	37	8	79	0.9
102585	13	KWJ	07/29/2001	1.1	11	88	7.6	4.4	34	7	81	0.7
104687	14	JEJ	07/12/2001	1	13	93	7.4	4.7	36	15	75	0.7
104687	14	JEJ	07/21/2001	0.8	9	85	6.9	4.3	25	13	70	0.8
104687	14	JEJ	07/28/2001	0.9	13	82	6.5	4.1	27	19	67	0.7
104687	14	JEJ	07/29/2001	0.7	9	77	7.4	4.9	27	18	77	0.7
104727	15	WLE	07/18/2001	0.9	11	99	7.3	4.4	23	15	74	1.5 H
104727	15	WLE	07/21/2001	0.9	16	105	7.6	4.5	21	15	80	1.2
104727	15	WLE	07/28/2001	1.2	19	91	7.3	4.3	26	16	75	1.7 H

CHEM Results

Chart Number	Subject Number	Subject Initials	Draw Date	CREA	BUN	GLUC	TOTAL PROTEIN	ALB	AST	ALT	ALK	TOTAL BILI
104727	15	WLE	07/29/2001	1	18	86	7.5	4.7	23	16	80	1.1
104682	16	HMH	07/11/2001	0.8	13	100	8.2	4.5	35	28	70	0.8
104682	16	HMH	07/19/2001	0.8	9	101	7.8	4.3	24	12	63	0.6
104682	16	HMH	07/21/2001	0.8	13	104	7.5	4.2	22	11	56	0.7
104682	16	HMH	07/28/2001	0.7	12	93	7.6	4.1	22	13	64	0.6
104682	16	HMH	07/29/2001	0.8	11	80	7.9	4.6	25	14	62	0.5
98427	17	CDD	07/11/2001	1.2	26 H	102	6.6	4	21	18	76	1
98427	17	CDD	07/20/2001	-	26 H	-	-	-	-	-	-	-
98427	17	CDD	07/21/2001	1.1	23 H	113 H	6.7	4.1	20	15	76	0.8
98427	17	CDD	07/28/2001	1.1	21	104	6.9	4.2	17	19	79	0.8
98427	17	CDD	07/29/2001	1.1	22	95	7.2	4.7	19	20	84	0.7
97021	18	JME	07/12/2001	1.1	12	98	7.1	4	20	21	58	0.8
97021	18	JME	07/21/2001	1.1	13	98	7.3	4	25	44 H	64	1
97021	18	JME	07/28/2001	1.1	14	86	7.3	4.1	22	22	59	0.9
97021	18	JME	07/29/2001	1.1	14	98	7.8	4.6	22	21	60	0.6
104690	19	CLH	07/12/2001	0.8	7	92	6.9	4.2	20	19	60	0.8
104690	19	CLH	07/21/2001	0.8	13	101	7.2	4.5	18	15	69	0.7
104690	19	CLH	07/28/2001	0.7	13	92	6.5	4.1	15	13	63	0.5
104690	19	CLH	07/29/2001	0.8	10	90	7	4.5	17	15	65	0.6
104693	20	CRG	07/12/2001	1.1	8	77	7.8	4.7	18	14	73	0.8
104693	20	CRG	07/21/2001	1	15	99	7.2	4.5	17	16	66	0.9
104693	20	CRG	07/28/2001	1	13	94	7.2	4.4	14	11	65	0.9
104693	20	CRG	07/29/2001	0.9	11	88	7.7	5	17	12	67	0.6
100930	21	KRM	07/18/2001	0.8	9	91	7.3	4.4	23	19	48	0.8
100930	21	KRM	07/21/2001	0.9	12	104	7.2	4.4	23	22	47	0.8
100930	21	KRM	07/28/2001	0.9	9	94	7.2	4.4	23	20	48	0.9
100930	21	KRM	07/29/2001	0.9	15	82	7.6	4.8	23	22	54	0.8
104746	22	TMF	07/19/2001	1.2	17	103	8.3	4.9	31	46 H	83	0.8
104746	22	TMF	07/21/2001	1.1	18	104	7.6	4.6	25	41 H	80	0.6
104746	22	TMF	07/28/2001	1.2	13	95	7	4.3	31	42 H	74	0.7
104746	22	TMF	07/29/2001	1.1	14	83	7.6	4.6	33	59 H	75	0.9

CHEM Results

Chart Number	Subject Number	Subject Initials	Draw Date	TOTAL							TOTAL		
				CREA	BUN	GLUC	PROTEIN	ALB	AST	ALT	ALK	BILI	
104746	22	TMF	08/04/2001	-	-	-	-	-	-	-	54 H	-	-
104746	22	TMF	08/21/2001	-	-	-	-	-	-	-	32	-	-
102915	23	GPA	07/12/2001	1.2	16	95	7.4	4.6	26	23	83	0.9	
102915	23	GPA	07/21/2001	1	13	97	7.3	4.5	31	36	71	1	
102915	23	GPA	07/28/2001	1.2	15	87	7.1	4.6	21	27	72	0.8	
102915	23	GPA	07/29/2001	1.1	13	75	7.6	5.1 H	26	24	74	1	
102153	24	BDH	07/11/2001	1	15	95	7.7	4.8	23	21	78	0.9	
102153	24	BDH	07/20/2001	1	24 H	93	7.3	4.5	21	18	70	1	
102153	24	BDH	07/21/2001	1	18	96	6.9	4.3	19	16	65	0.6	
102153	24	BDH	07/28/2001	1	15	89	7.3	4.6	19	16	71	0.6	
102153	24	BDH	07/29/2001	0.9	20	76	7.7	5.1 H	19	15	71	0.6	
97683	25	RMK	07/12/2001	0.9	13	99	6.8	4.2	23	17	86	0.8	
97683	25	RMK	07/21/2001	0.9	18	99	6.5	3.9	24	16	91	0.8	
97683	25	RMK	07/28/2001	0.9	14	86	6.7	4.1	24	17	89	1	
97683	25	RMK	07/29/2001	1	19	75	7	4.5	22	16	88	0.7	
100918	26	JLP	07/13/2001	0.3 L	17	111 H	7	4.3	22	20	49	1.1	
100918	26	JLP	07/21/2001	0.9	13	101	7.4	4.5	26	26	49	1.7 H	
100918	26	JLP	07/28/2001	0.8	17	95	6.9	4.1	23	23	49	1.5 H	
100918	26	JLP	07/29/2001	0.9	15	85	7.1	4.4	30	24	59	1.1	
104673	27	AIF	07/11/2001	0.7	14	103	7	4.2	21	13	48	0.8	
104673	27	AIF	07/19/2001	0.8	13	101	7	4.4	19	12	50	0.6	
104673	27	AIF	07/21/2001	0.8	11	99	6.8	4.3	17	12	47	0.7	
104673	27	AIF	07/28/2001	0.8	13	93	6.6	4.1	17	12	45	0.6	
104673	27	AIF	07/29/2001	0.8	12	77	7.1	4.5	21	12	45	0.7	
99920	28	SMR	07/13/2001	1	12	92	6.8	4.2	14	10	77	1.1	
99920	28	SMR	07/21/2001	1	12	96	6.4	4	12	10	72	0.9	
99920	28	SMR	07/28/2001	1.1	14	87	6.7	4.1	14	11	74	0.9	
99920	28	SMR	07/29/2001	1	13	103	6.9	4.6	17	9	85	0.6	
104608	29	AJA	07/16/2001	1.1	12	103	7.2	4.7	23	22	73	1.2	
104608	29	AJA	07/21/2001	1.1	13	106	7.4	4.8	17	20	72	1.2	
104608	29	AJA	07/28/2001	1.1	11	95	7.3	4.8	20	25	71	1.1	

CHEM Results

Chart Number	Subject Number	Subject Initials	Draw Date	CREA	BUN	GLUC	TOTAL PROTEIN	ALB	AST	ALT	ALK	TOTAL BILI
104608	29	AJA	07/29/2001	1.2	13	88	7.3	5	22	24	68	0.7
101775	30	NCG	07/17/2001	1.3	19	98	7.3	4.7	26	24	93	1.9 H
101775	30	NCG	07/21/2001	1.3	16	103	6.8	4.3	24	23	85	0.9
101775	30	NCG	07/28/2001	1.1	13	96	6.9	4.5	24	26	84	1.1
101775	30	NCG	07/29/2001	1.3	19	71	7.4	4.9	26	26	81	0.9
101800	31	PAZ	07/13/2001	1.1	13	98	7	4.1	16	14	94	1.3 H
101800	31	PAZ	07/21/2001	1.1	19	102	6.8	4.2	15	13	82	0.9
101800	31	PAZ	07/28/2001	1.2	17	95	6.7	4.1	21	17	84	1.1
101800	31	PAZ	07/29/2001	0.9	13	77	6.9	4.4	14	16	84	0.9
99638	32	MJH	07/19/2001	0.9	15	91	7	4.5	30	43 H	48	0.8
99638	32	MJH	07/21/2001	0.9	15	96	6.8	4.3	32	42 H	45	0.9
99638	32	MJH	07/28/2001	0.9	13	89	6.8	4.5	30	45 H	50	0.9
99638	32	MJH	07/29/2001	0.8	12	90	7.1	4.9	26	38	50	0.9
104724	33	DMT	07/18/2001	0.8	11	92	7.6	4.5	22	15	64	0.6
104724	33	DMT	07/21/2001	0.8	11	98	6.7	4	22	14	60	0.4
104724	33	DMT	07/28/2001	0.7	11	87	6.3 L	3.8	19	13	50	0.6
104724	33	DMT	07/29/2001	0.9	13	81	6.7	4.2	19	13	52	0.4
95922	34	ACT	07/18/2001	0.7	7	101	6.9	4	12	12	64	0.9
95922	34	ACT	07/21/2001	0.6	12	116 H	6.7	3.8	13	11	63	0.7
95922	34	ACT	07/28/2001	0.7	12	109	6.9	3.9	15	16	66	0.8
95922	34	ACT	07/29/2001	0.5 L	10	88	7.2	4.2	15	17	61	0.9
104718	35	AMK	07/17/2001	0.9	13	96	7.1	4	18	17	68	0.7
104718	35	AMK	07/21/2001	0.8	12	93	7.3	4.3	17	15	62	0.7
104718	35	AMK	07/28/2001	1	14	96	7.2	4.2	27	20	63	0.6
104718	35	AMK	07/29/2001	0.9	9	75	7.9	4.7	33	24	70	0.4
104718	35	AMK	08/01/2001	-	-	-	-	-	-	-	-	-
104707	36	DLJ	07/16/2001	1.1	8	88	7.5	4.2	29	28	65	0.7
104707	36	DLJ	07/21/2001	1.1	11	103	7.5	4.1	23	25	64	0.6
104707	36	DLJ	07/28/2001	1.1	13	93	7.6	4.2	24	31	71	0.5
104707	36	DLJ	07/29/2001	1	13	75	7.6	4.4	20	26	66	0.6
100844	37	MAL	07/16/2001	1.3	14	85	7.2	4.3	16	11	51	1.2

CHEM Results

Chart Number	Subject Number	Subject Initials	Draw Date	TOTAL							TOTAL	
				CREA	BUN	GLUC	PROTEIN	ALB	AST	ALT	ALK	BILI
100844	37	MAL	07/21/2001	1.2	17	95	6.9	4.2	15	12	52	0.7
100844	37	MAL	07/28/2001	0.9	14	93	7.2	4.2	17	15	52	0.7
100844	37	MAL	07/29/2001	1	19	81	7.3	4.5	21	16	52	0.4
102279	38	THP	07/17/2001	0.8	12	81	7.5	4.2	25	13	53	0.6
102279	38	THP	07/21/2001	0.9	10	94	7.4	4.1	25	12	52	0.8
102279	38	THP	07/28/2001	0.9	13	81	7.5	4.2	25	12	55	0.8
102279	38	THP	07/29/2001	0.8	11	83	7.6	4.6	26	12	55	0.7
104299	39	JDF	07/17/2001	1.1	17	96	7.1	4.1	23	21	67	1
104299	39	JDF	07/21/2001	1.2	14	99	7.2	4.3	22	20	70	1.2
104299	39	JDF	07/28/2001	1.2	14	95	7.1	4.2	25	23	71	0.8
104299	39	JDF	07/29/2001	1.1	14	86	8	4.9	26	27	76	1
102629	40	TEM	07/16/2001	0.9	23 H	91	7.4	4.3	27	18	62	0.7
102629	40	TEM	07/19/2001	0.9	20	89	6.9	4.2	22	17	61	0.6
102629	40	TEM	07/21/2001	1	20	107	7.2	4.2	23	16	62	0.5
102629	40	TEM	07/28/2001	0.9	20	95	7	4.2	24	18	64	0.7
102629	40	TEM	07/29/2001	0.9	22	79	7.2	4.6	22	16	62	0.6
91906	41	JNH	07/13/2001	0.9	11	89	7	4.1	20	14	65	0.6
91906	41	JNH	07/21/2001	1	20	94	7.1	4.2	20	13	60	0.9
91906	41	JNH	07/28/2001	1.1	17	89	6.9	4.2	22	20	65	0.9
91906	41	JNH	07/29/2001	1.1	20	80	7.5	4.8	21	19	64	0.9
99843	42	N-F	07/18/2001	1.1	18	95	7.1	4.3	35	31	66	1.1
99843	42	N-F	07/21/2001	1.1	18	100	7	4.3	22	27	68	1.1
99843	42	N-F	07/28/2001	1.2	14	92	6.6	4	74 H	58 H	67	1
99843	42	N-F	07/29/2001	1.1	13	103	7.2	4.6	44 H	50 H	67	0.8
99843	42	N-F	07/31/2001	-	-	-	-	-	-	37	-	-
104700	43	KAO	07/13/2001	0.6	10	82	7	4.4	18	11	46	0.8
104700	43	KAO	07/21/2001	0.6	10	92	6.8	4.3	19	11	45	0.6
104700	43	KAO	07/28/2001	0.7	9	88	6.9	4.2	20	11	45	0.8
104700	43	KAO	07/29/2001	0.6	10	88	7.1	4.6	26	11	45	0.7
104681	44	BAH	07/11/2001	0.8	10	99	7.4	4.3	19	13	69	1.1
104681	44	BAH	07/21/2001	0.8	11	104	7.3	4.2	19	19	66	1.3 H

CHEM Results

Chart Number	Subject Number	Subject Initials	Draw Date	CREA	BUN	GLUC	TOTAL PROTEIN	ALB	AST	ALT	ALK	TOTAL BILI
104681	44	BAH	07/28/2001	0.8	10	101	7.3	4.2	16	11	68	0.8
104681	44	BAH	07/29/2001	0.6	12	89	7.7	4.6	18	12	68	0.8

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	CHOL	LDH	TRIG	CO2	CL	CA	GGT	URIC	PHOS	K	NA
104248	01	ANJ	07/09/2001	-	119	-	26	108	9.6	10	2.7	-	4.1	138
104248	01	ANJ	07/21/2001	-	115	-	24.2	111 H	9.1	9	2.7	-	4.2	138
104248	01	ANJ	07/28/2001	-	109	-	25.5	110	9	10	2.9	-	3.9	139
100515	02	RAW	07/19/2001	-	144	-	27.3	102	10.1	18	5.1	-	4.5	137
100515	02	RAW	07/21/2001	-	143	-	29	105	10.2	15	5.7	-	4.8	138
100515	02	RAW	07/28/2001	-	135	-	29.7	107	9.8	17	5	-	4.9	137
100515	02	RAW	07/29/2001	-	155	-	28.3	103	10	18	4.6	-	5.3	140
104659	03	TLS	07/09/2001	-	112	-	28.4	103	10.8 H	10	3.4	-	3.6	141
104659	03	TLS	07/21/2001	-	103	-	28.5	107	9.6	10	3.4	-	4.5	138
104659	03	TLS	07/28/2001	-	107	-	29.3	108	9.5	8	4.2	-	5	139
104659	03	TLS	07/29/2001	-	128	-	29.3	105	9.9	10	3.1	-	4.8	142
104492	04	KRE	07/10/2001	-	172	-	23.2	106	10.3 H	35	6.5	-	4.4	141
104492	04	KRE	07/21/2001	-	139	-	29.3	109	9.6	25	5.4	-	4.4	141
104492	04	KRE	07/28/2001	-	132	-	29.3	110	9.5	24	5.8	-	4.5	140
104492	04	KRE	07/29/2001	-	173	-	26.8	104	9.8	23	5.3	-	5.2	141
98555	05	SAP	07/10/2001	-	158	-	25.4	111 H	9.7	19	6.4	-	4.5	141
98555	05	SAP	07/21/2001	-	129	-	27	110	9.4	18	6.5	-	4.3	140
98555	05	SAP	07/28/2001	-	124	-	25.4	111 H	9	15	6	-	4	139
98555	05	SAP	07/29/2001	-	149	-	25.6	104	9.6	19	5.6	-	4.8	141
104752	06	BAZ	07/19/2001	-	134	-	29.4	103	9.4	11	5.5	-	4.4	138
104752	06	BAZ	07/21/2001	-	117	-	30.3	107	9.6	10	6.2	-	4.5	139
104752	06	BAZ	07/28/2001	-	120	-	29.2	110	9.1	12	6.9	-	4.3	141
104752	06	BAZ	07/29/2001	-	151	-	26.8	105	9.5	12	7.7 H	-	4.7	141
95514	07	CRT	07/19/2001	-	118	-	29.9	103	9.6	16	5.7	-	4.6	139
95514	07	CRT	07/21/2001	-	138	-	30.1	108	9.6	18	6.5	-	4.5	140
95514	07	CRT	07/28/2001	-	137	-	31	106	9.6	20	6.6	-	4.3	139
95514	07	CRT	07/29/2001	-	151	-	28.2	103	9.5	23	5	-	5.2	141
96528	08	NBJ	07/17/2001	-	136	-	26.3	108	9.7	12	5.5	-	4.2	142
96528	08	NBJ	07/21/2001	-	119	-	28.4	110	9.7	12	6.1	-	5	140
96528	08	NBJ	07/28/2001	-	123	-	27.7	108	9.6	14	6	-	5.1	140
96528	08	NBJ	07/29/2001	-	152	-	26	105	10.2	14	5.4	-	6.0 H	142
96528	08	NBJ	07/31/2001	-	-	-	-	-	-	-	-	-	5.7 H	-

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	CHOL	LDH	TRIG	CO2	CL	CA	GGT	URIC	PHOS	K	NA
97501	09	ADR	07/19/2001	-	158	-	23.5	111 H	10.4 H	26	6	-	3.8	142
97501	09	ADR	07/21/2001	-	152	-	27.5	111 H	9.6	28	5.8	-	4.2	139
97501	09	ADR	07/28/2001	-	142	-	26.8	110	9.2	23	6.4	-	4.2	138
97501	09	ADR	07/29/2001	-	183 H	-	24.7	106	10	29	6	-	5	141
104678	10	AKH	07/11/2001	-	130	-	27.6	107	9	17	2.7	-	4.6	137
104678	10	AKH	07/21/2001	-	121	-	28.6	109	9	20	2.7	-	3.8	139
104678	10	AKH	07/31/2001	-	132	-	24.8	110	9.3	18	3.1	-	4.1	139
104677	11	CWB	07/11/2001	-	133	-	28.3	106	9.9	28	6.5	-	4.6	139
104677	11	CWB	07/21/2001	-	128	-	28.3	106	9.8	26	6.1	-	4.7	138
104677	11	CWB	07/28/2001	-	132	-	30.1	108	10.6 H	29	7.5 H	-	6.6 P	142
104677	11	CWB	07/28/2001	-	-	-	-	-	-	-	-	-	5.8 H	-
104677	11	CWB	07/29/2001	-	145	-	28.5	101	10	26	6.3	-	5.8 H	140
96298	12	CMP	07/17/2001	-	141	-	27.2	104	10.4 H	16	5.4	-	4.3	140
96298	12	CMP	07/21/2001	-	136	-	26.4	105	9.5	16	5.5	-	4.4	138
96298	12	CMP	07/28/2001	-	132	-	29.8	105	9.5	16	4.8	-	4.3	137
96298	12	CMP	07/29/2001	-	169	-	26.2	105	10.1	15	4.9	-	5	140
102585	13	KWJ	07/17/2001	-	119	-	29	106	9.4	21	5.7	-	3.9	139
102585	13	KWJ	07/21/2001	-	126	-	28.1	107	9.7	17	5.8	-	3.9	139
102585	13	KWJ	07/28/2001	-	133	-	28.9	107	9.6	19	5.3	-	4.1	139
102585	13	KWJ	07/29/2001	-	137	-	27.4	103	9.5	22	4.9	-	5	139
104687	14	JEJ	07/12/2001	-	144	-	29.1	104	11.0 H	11	3.6	-	5.1	146 H
104687	14	JEJ	07/21/2001	-	146	-	28	105	10	10	3.1	-	4.3	138
104687	14	JEJ	07/28/2001	-	133	-	30.1	106	9.5	13	3.9	-	4.1	139
104687	14	JEJ	07/29/2001	-	174	-	26.7	101	10	14	3	-	4.8	140
104727	15	WLE	07/18/2001	-	139	-	29.4	106	9.6	15	5.3	-	4.3	137
104727	15	WLE	07/21/2001	-	158	-	28.2	107	9.8	15	5	-	4.9	138
104727	15	WLE	07/28/2001	-	153	-	28.9	108	9.6	15	5.5	-	4.6	138
104727	15	WLE	07/29/2001	-	182 H	-	27.3	105	10	16	4.1	-	5.8 H	140
104682	16	HMH	07/19/2001	-	142	-	25.1	107	9.9	13	4.2	-	5.1	139
104682	16	HMH	07/21/2001	-	160	-	26.9	110	9.7	11	4.9	-	5.1	139
104682	16	HMH	07/28/2001	-	115	-	26.8	107	9.5	14	4.7	-	4.7	137
104682	16	HMH	07/29/2001	-	151	-	25.4	102	9.5	14	4.2	-	5.2	139

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	CHOL	LDH	TRIG	CO2	CL	CA	GGT	URIC	PHOS	K	NA
98427	17	CDD	07/11/2001	-	127	-	28	109	9.6	10	6.2	-	4.7	138
98427	17	CDD	07/21/2001	-	128	-	26	111 H	9.5	11	5.5	-	4.8	139
98427	17	CDD	07/28/2001	-	119	-	26.7	110	9.2	10	5.4	-	4.3	137
98427	17	CDD	07/29/2001	-	144	-	25.5	106	9.9	11	5	-	5.2	141
97021	18	JME	07/12/2001	-	114	-	31.1	105	9.9	20	4.9	-	5.4 H	141
97021	18	JME	07/21/2001	-	127	-	30	105	9.4	21	6.7	-	4.6	138
97021	18	JME	07/28/2001	-	126	-	30.4	105	9.1	21	6.4	-	3.9	137
97021	18	JME	07/29/2001	-	153	-	29.5	104	9.8	22	6.4	-	5.5 H	142
104690	19	CLH	07/12/2001	-	119	-	25.8	110	9.1	18	4.2	-	4.1	139
104690	19	CLH	07/21/2001	-	126	-	26.6	108	9.5	17	4.8	-	4.2	139
104690	19	CLH	07/28/2001	-	115	-	28.3	107	8.9	15	4.1	-	4.1	139
104690	19	CLH	07/29/2001	-	146	-	26.2	107	9.4	15	4	-	4.9	143
104693	20	CRG	07/12/2001	-	122	-	25.2	107	10.4 H	14	5	-	4.4	139
104693	20	CRG	07/21/2001	-	103	-	27.4	110	9.5	15	6.7	-	3.9	140
104693	20	CRG	07/28/2001	-	90 L	-	26.9	108	9.2	15	4.7	-	4	138
104693	20	CRG	07/29/2001	-	102	-	26.3	104	9.7	15	4.8	-	4.9	141
100930	21	KRM	07/18/2001	-	111	-	27.3	105	10	13	5.1	-	4.3	140
100930	21	KRM	07/21/2001	-	98	-	28.5	108	9.5	15	5.4	-	3.9	140
100930	21	KRM	07/28/2001	-	94	-	27.9	106	9.3	15	6	-	3.5	138
100930	21	KRM	07/29/2001	-	122	-	27.2	104	9.5	13	5.6	-	4.9	140
104746	22	TMF	07/19/2001	-	148	-	29.3	106	10.3 H	24	7.7 H	-	4.1	143
104746	22	TMF	07/21/2001	-	159	-	27.8	109	9.9	23	7.8 H	-	4.6	143
104746	22	TMF	07/28/2001	-	161	-	27.3	106	9.2	24	8.3 H	-	4	138
104746	22	TMF	07/29/2001	-	182 H	-	27.7	105	9.8	25	8.7 H	-	5.1	142
102915	23	GPA	07/12/2001	-	169	-	25.1	106	10.3 H	45	6.2	-	4.3	139
102915	23	GPA	07/21/2001	-	134	-	26.5	106	10.1	43	6.9	-	4.2	138
102915	23	GPA	07/28/2001	-	118	-	27.2	109	9.7	36	7.1	-	4.2	139
102915	23	GPA	07/29/2001	-	166	-	23.6	104	10.1	37	7.4 H	-	4.7	140
102153	24	BDH	07/20/2001	-	144	-	28.6	105	10.1	15	7	-	4.3	141
102153	24	BDH	07/21/2001	-	108	-	28.4	109	9.4	16	6.2	-	4.5	140
102153	24	BDH	07/28/2001	-	120	-	30	109	9.7	17	6.6	-	5	141
102153	24	BDH	07/29/2001	-	139	-	26.6	106	10.1	18	5.6	-	5.2	142

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	CHOL	LDH	TRIG	CO2	CL	CA	GGT	URIC	PHOS	K	NA
97683	25	RMK	07/12/2001	-	136	-	30.5	106	9.6	23	4.7	-	4.7	141
97683	25	RMK	07/21/2001	-	134	-	27.1	111 H	9.2	22	4.5	-	4	140
97683	25	RMK	07/28/2001	-	133	-	28.6	108	9.1	21	4.5	-	3.9	138
97683	25	RMK	07/29/2001	-	167	-	28.5	105	9.8	22	4.7	-	5	142
100918	26	JLP	07/13/2001	-	134	-	28	110	9.7	10	7.3 H	-	4.2	143
100918	26	JLP	07/21/2001	-	163	-	29.1	109	9.5	8	7.7 H	-	4.5	142
100918	26	JLP	07/28/2001	-	140	-	29.3	107	8.8	11	8.2 H	-	4.5	138
100918	26	JLP	07/29/2001	-	169	-	29.3	105	9.3	13	7.5 H	-	5.3	141
104673	27	AIF	07/19/2001	-	102	-	25.9	106	9.9	13	3.1	-	3.9	139
104673	27	AIF	07/21/2001	-	101	-	27.8	108	9.5	10	3.2	-	3.8	139
104673	27	AIF	07/28/2001	-	95	-	26.9	109	9.3	12	3.2	-	4.3	138
104673	27	AIF	07/29/2001	-	113	-	28.4	107	9.8	13	3	-	5.5 H	142
99920	28	SMR	07/13/2001	-	95	-	30.1	106	9.4	21	5.4	-	4.2	139
99920	28	SMR	07/21/2001	-	88 L	-	29.5	108	9.1	17	5.6	-	4.2	139
99920	28	SMR	07/28/2001	-	94	-	30.5	108	9	19	5.8	-	4.1	140
99920	28	SMR	07/29/2001	-	122	-	29	104	9.6	20	4.8	-	5.2	142
104608	29	AJA	07/16/2001	-	141	-	28.5	108	10	21	6.3	-	4.6	141
104608	29	AJA	07/21/2001	-	116	-	29.6	105	10	20	5.9	-	4.4	139
104608	29	AJA	07/28/2001	-	126	-	29.7	104	10.1	25	6.3	-	4.8	138
104608	29	AJA	07/29/2001	-	170	-	26.7	104	9.6	24	5.8	-	4.4	140
101775	30	NCG	07/17/2001	-	126	-	32	102	9.9	17	8.2 H	-	4.2	139
101775	30	NCG	07/21/2001	-	112	-	30.4	106	9.8	16	7	-	4.5	141
101775	30	NCG	07/28/2001	-	98	-	30.3	106	9.5	15	6.7	-	4.1	140
101775	30	NCG	07/29/2001	-	123	-	30	106	10.4 H	16	6.4	-	5.2	145
101800	31	PAZ	07/13/2001	-	112	-	29.5	104	10.1	16	7.1	-	3.8	141
101800	31	PAZ	07/21/2001	-	110	-	29.6	106	9.2	17	6.6	-	4.3	138
101800	31	PAZ	07/28/2001	-	117	-	30.3	110	9.4	18	6.8	-	5.7 H	143
101800	31	PAZ	07/29/2001	-	150	-	28.7	106	9.5	16	5.5	-	5.5 H	143
99638	32	MJH	07/19/2001	-	117	-	28.9	105	10.2	30	5.7	-	4.5	141
99638	32	MJH	07/21/2001	-	101	-	28.2	108	9.5	27	5.4	-	3.8	140
99638	32	MJH	07/28/2001	-	97	-	29.4	108	9.5	28	6.1	-	4.1	140
99638	32	MJH	07/29/2001	-	124	-	28.6	105	9.8	24	5.7	-	5	143

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	CHOL	LDH	TRIG	CO2	CL	CA	GGT	URIC	PHOS	K	NA
104724	33	DMT	07/18/2001	-	137	-	29.1	105	9.6	15	3.8	-	4.4	138
104724	33	DMT	07/21/2001	-	122	-	26.6	110	9.1	13	3.3	-	4.5	139
104724	33	DMT	07/28/2001	-	119	-	26.7	109	8.6	11	3.3	-	4.1	138
104724	33	DMT	07/29/2001	-	144	-	25.8	105	9.2	11	2.9	-	5.1	139
95922	34	ACT	07/18/2001	-	82 L	-	30	105	9.6	15	4.1	-	4.6	138
95922	34	ACT	07/21/2001	-	86 L	-	26.9	109	9.3	13	4.4	-	4.6	139
95922	34	ACT	07/28/2001	-	85 L	-	25.9	109	9.1	18	4.7	-	4.6	137
95922	34	ACT	07/29/2001	-	120	-	24.3	104	9.1	19	4	-	4.9	137
104718	35	AMK	07/17/2001	-	130	-	28.1	106	11.1 H	20	5.2	-	5.5 H	142
104718	35	AMK	07/21/2001	-	145	-	25.2	109	10.2	15	5.2	-	4.7	139
104718	35	AMK	07/28/2001	-	127	-	26.8	112 H	9.9	17	5.2	-	5.6 H	140
104718	35	AMK	07/29/2001	-	157	-	24.7	107	10.2	20	4.1	-	6.7 P	143
104718	35	AMK	08/01/2001	-	-	-	-	-	-	-	-	-	5.1	-
104707	36	DLJ	07/16/2001	-	124	-	28.3	107	9.7	40	6.4	-	4.6	139
104707	36	DLJ	07/21/2001	-	116	-	26.2	108	9.5	38	6.3	-	4.6	138
104707	36	DLJ	07/28/2001	-	136	-	28.9	104	9.3	48	7.2	-	4.3	137
104707	36	DLJ	07/29/2001	-	145	-	26.7	103	9.8	44	5.6	-	4.8	140
100844	37	MAL	07/16/2001	-	104	-	29.1	106	9.8	16	8.5 H	-	4.2	139
100844	37	MAL	07/21/2001	-	117	-	27.1	108	9.5	17	7.4 H	-	4.6	139
100844	37	MAL	07/28/2001	-	105	-	29.3	107	9.7	17	6.8	-	4.5	138
100844	37	MAL	07/29/2001	-	145	-	26	104	9.9	19	6.6	-	4.8	138
102279	38	THP	07/17/2001	-	169	-	29.2	107	10	13	3.9	-	4.7	142
102279	38	THP	07/21/2001	-	171	-	29.8	107	9.6	10	4	-	4.7	140
102279	38	THP	07/28/2001	-	137	-	30.3	107	9.4	12	4.8	-	4.5	140
102279	38	THP	07/29/2001	-	177	-	27.7	101	9.8	12	3.8	-	4.8	140
104299	39	JDF	07/17/2001	-	172	-	27.6	105	9.9	18	5.9	-	4.3	139
104299	39	JDF	07/21/2001	-	150	-	30.1	105	9.7	17	5.8	-	4.6	139
104299	39	JDF	07/28/2001	-	156	-	28.9	106	9.2	16	6.5	-	4.3	137
104299	39	JDF	07/29/2001	-	188 H	-	27.4	100	10.1	19	5.8	-	5.5 H	139
102629	40	TEM	07/19/2001	-	137	-	27.9	108	9.7	22	4.7	-	4.7	140
102629	40	TEM	07/21/2001	-	144	-	28.2	108	9.4	22	5.2	-	4.6	138
102629	40	TEM	07/28/2001	-	136	-	27.5	110	9.3	20	5.2	-	5.1	139

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	CHOL	LDH	TRIG	CO2	CL	CA	GGT	URIC	PHOS	K	NA
102629	40	TEM	07/29/2001	-	165	-	27.3	104	9.6	24	4.5	-	5.8 H	139
91906	41	JNH	07/13/2001	-	118	-	30.7	103	9	28	5.9	-	3.8	139
91906	41	JNH	07/21/2001	-	133	-	29.2	106	9.2	26	6.5	-	4.2	138
91906	41	JNH	07/28/2001	-	124	-	31.5	105	9	33	6.4	-	4.2	139
91906	41	JNH	07/29/2001	-	177	-	29.8	104	9.9	31	6.5	-	5.5 H	142
99843	42	N-F	07/18/2001	-	153	-	30.6	106	9.6	14	6.2	-	4.3	138
99843	42	N-F	07/21/2001	-	131	-	29	109	9.5	15	5.9	-	4.2	140
99843	42	N-F	07/28/2001	-	150	-	29	107	9.3	14	5.3	-	4.4	138
99843	42	N-F	07/29/2001	-	154	-	28	105	9.9	16	5	-	5.3	142
104700	43	KAO	07/13/2001	-	120	-	28.6	110	9.6	11	2.3 L	-	4.7	142
104700	43	KAO	07/21/2001	-	143	-	27.1	109	9.4	7	2.4 L	-	5.1	137
104700	43	KAO	07/28/2001	-	125	-	27.6	109	9.4	10	2.5 L	-	5.3	138
104700	43	KAO	07/29/2001	-	148	-	25	109	9.8	10	2.3 L	-	5.4 H	148 H
104681	44	BAH	07/11/2001	-	158	-	25	109	9.9	11	4.7	-	4.6	139
104681	44	BAH	07/21/2001	-	155	-	27.9	110	9.7	10	5.6	-	4.2	140
104681	44	BAH	07/28/2001	-	138	-	28.9	109	9.5	10	4.9	-	4.2	139
104681	44	BAH	07/29/2001	-	166	-	26.4	105	10	12	4.7	-	5	141

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	FREE						
				TSH	THYROXINE	T7	T-4	T3	CK	IRON
104248	01	ANJ	07/09/2001	-	-	-	-	-	-	-
104248	01	ANJ	07/21/2001	-	-	-	-	-	-	-
104248	01	ANJ	07/28/2001	-	-	-	-	-	-	-
100515	02	RAW	07/19/2001	-	-	-	-	-	-	-
100515	02	RAW	07/21/2001	-	-	-	-	-	-	-
100515	02	RAW	07/28/2001	-	-	-	-	-	-	-
100515	02	RAW	07/29/2001	-	-	-	-	-	-	-
104659	03	TLS	07/09/2001	-	-	-	-	-	-	-
104659	03	TLS	07/21/2001	-	-	-	-	-	-	-
104659	03	TLS	07/28/2001	-	-	-	-	-	-	-
104659	03	TLS	07/29/2001	-	-	-	-	-	-	-
104492	04	KRE	07/10/2001	-	-	-	-	-	-	-
104492	04	KRE	07/21/2001	-	-	-	-	-	-	-
104492	04	KRE	07/28/2001	-	-	-	-	-	-	-
104492	04	KRE	07/29/2001	-	-	-	-	-	-	-
98555	05	SAP	07/10/2001	-	-	-	-	-	-	-
98555	05	SAP	07/21/2001	-	-	-	-	-	-	-
98555	05	SAP	07/28/2001	-	-	-	-	-	-	-
98555	05	SAP	07/29/2001	-	-	-	-	-	-	-
104752	06	BAZ	07/19/2001	-	-	-	-	-	-	-
104752	06	BAZ	07/21/2001	-	-	-	-	-	-	-
104752	06	BAZ	07/28/2001	-	-	-	-	-	-	-
104752	06	BAZ	07/29/2001	-	-	-	-	-	-	-
95514	07	CRT	07/19/2001	-	-	-	-	-	-	-
95514	07	CRT	07/21/2001	-	-	-	-	-	-	-
95514	07	CRT	07/28/2001	-	-	-	-	-	-	-
95514	07	CRT	07/29/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/17/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/21/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/28/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/29/2001	-	-	-	-	-	-	-
96528	08	NBJ	07/31/2001	-	-	-	-	-	-	-

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	FREE						
				TSH	THYROXINE	T7	T-4	T3	CK	IRON
97501	09	ADR	07/19/2001	-	-	-	-	-	-	-
97501	09	ADR	07/21/2001	-	-	-	-	-	-	-
97501	09	ADR	07/28/2001	-	-	-	-	-	-	-
97501	09	ADR	07/29/2001	-	-	-	-	-	-	-
104678	10	AKH	07/11/2001	-	-	-	-	-	-	-
104678	10	AKH	07/21/2001	-	-	-	-	-	-	-
104678	10	AKH	07/31/2001	-	-	-	-	-	-	-
104677	11	CWB	07/11/2001	-	-	-	-	-	-	-
104677	11	CWB	07/21/2001	-	-	-	-	-	-	-
104677	11	CWB	07/28/2001	-	-	-	-	-	-	-
104677	11	CWB	07/28/2001	-	-	-	-	-	-	-
104677	11	CWB	07/29/2001	-	-	-	-	-	-	-
96298	12	CMP	07/17/2001	-	-	-	-	-	-	-
96298	12	CMP	07/21/2001	-	-	-	-	-	-	-
96298	12	CMP	07/28/2001	-	-	-	-	-	-	-
96298	12	CMP	07/29/2001	-	-	-	-	-	-	-
102585	13	KWJ	07/17/2001	-	-	-	-	-	-	-
102585	13	KWJ	07/21/2001	-	-	-	-	-	-	-
102585	13	KWJ	07/28/2001	-	-	-	-	-	-	-
102585	13	KWJ	07/29/2001	-	-	-	-	-	-	-
104687	14	JEJ	07/12/2001	-	-	-	-	-	-	-
104687	14	JEJ	07/21/2001	-	-	-	-	-	-	-
104687	14	JEJ	07/28/2001	-	-	-	-	-	-	-
104687	14	JEJ	07/29/2001	-	-	-	-	-	-	-
104727	15	WLE	07/18/2001	-	-	-	-	-	-	-
104727	15	WLE	07/21/2001	-	-	-	-	-	-	-
104727	15	WLE	07/28/2001	-	-	-	-	-	-	-
104727	15	WLE	07/29/2001	-	-	-	-	-	-	-
104682	16	HMH	07/19/2001	-	-	-	-	-	-	-
104682	16	HMH	07/21/2001	-	-	-	-	-	-	-
104682	16	HMH	07/28/2001	-	-	-	-	-	-	-
104682	16	HMH	07/29/2001	-	-	-	-	-	-	-

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	FREE						
				TSH	THYROXINE	T7	T-4	T3	CK	IRON
98427	17	CDD	07/11/2001	-	-	-	-	-	-	-
98427	17	CDD	07/21/2001	-	-	-	-	-	-	-
98427	17	CDD	07/28/2001	-	-	-	-	-	-	-
98427	17	CDD	07/29/2001	-	-	-	-	-	-	-
97021	18	JME	07/12/2001	-	-	-	-	-	-	-
97021	18	JME	07/21/2001	-	-	-	-	-	-	-
97021	18	JME	07/28/2001	-	-	-	-	-	-	-
97021	18	JME	07/29/2001	-	-	-	-	-	-	-
104690	19	CLH	07/12/2001	-	-	-	-	-	-	-
104690	19	CLH	07/21/2001	-	-	-	-	-	-	-
104690	19	CLH	07/28/2001	-	-	-	-	-	-	-
104690	19	CLH	07/29/2001	-	-	-	-	-	-	-
104693	20	CRG	07/12/2001	-	-	-	-	-	-	-
104693	20	CRG	07/21/2001	-	-	-	-	-	-	-
104693	20	CRG	07/28/2001	-	-	-	-	-	-	-
104693	20	CRG	07/29/2001	-	-	-	-	-	-	-
100930	21	KRM	07/18/2001	-	-	-	-	-	-	-
100930	21	KRM	07/21/2001	-	-	-	-	-	-	-
100930	21	KRM	07/28/2001	-	-	-	-	-	-	-
100930	21	KRM	07/29/2001	-	-	-	-	-	-	-
104746	22	TMF	07/19/2001	-	-	-	-	-	-	-
104746	22	TMF	07/21/2001	-	-	-	-	-	-	-
104746	22	TMF	07/28/2001	-	-	-	-	-	-	-
104746	22	TMF	07/29/2001	-	-	-	-	-	-	-
102915	23	GPA	07/12/2001	-	-	-	-	-	-	-
102915	23	GPA	07/21/2001	-	-	-	-	-	-	-
102915	23	GPA	07/28/2001	-	-	-	-	-	-	-
102915	23	GPA	07/29/2001	-	-	-	-	-	-	-
102153	24	BDH	07/20/2001	-	-	-	-	-	-	-
102153	24	BDH	07/21/2001	-	-	-	-	-	-	-
102153	24	BDH	07/28/2001	-	-	-	-	-	-	-
102153	24	BDH	07/29/2001	-	-	-	-	-	-	-

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Chart Number	Subject Number	Subject Initials	Draw Date	FREE						
				TSH	THYROXINE	T7	T-4	T3	CK	IRON
97683	25	RMK	07/12/2001	-	-	-	-	-	-	-
97683	25	RMK	07/21/2001	-	-	-	-	-	-	-
97683	25	RMK	07/28/2001	-	-	-	-	-	-	-
97683	25	RMK	07/29/2001	-	-	-	-	-	-	-
100918	26	JLP	07/13/2001	-	-	-	-	-	-	-
100918	26	JLP	07/21/2001	-	-	-	-	-	-	-
100918	26	JLP	07/28/2001	-	-	-	-	-	-	-
100918	26	JLP	07/29/2001	-	-	-	-	-	-	-
104673	27	AIF	07/19/2001	-	-	-	-	-	-	-
104673	27	AIF	07/21/2001	-	-	-	-	-	-	-
104673	27	AIF	07/28/2001	-	-	-	-	-	-	-
104673	27	AIF	07/29/2001	-	-	-	-	-	-	-
99920	28	SMR	07/13/2001	-	-	-	-	-	-	-
99920	28	SMR	07/21/2001	-	-	-	-	-	-	-
99920	28	SMR	07/28/2001	-	-	-	-	-	-	-
99920	28	SMR	07/29/2001	-	-	-	-	-	-	-
104608	29	AJA	07/16/2001	-	-	-	-	-	-	-
104608	29	AJA	07/21/2001	-	-	-	-	-	-	-
104608	29	AJA	07/28/2001	-	-	-	-	-	-	-
104608	29	AJA	07/29/2001	-	-	-	-	-	-	-
101775	30	NCG	07/17/2001	-	-	-	-	-	-	-
101775	30	NCG	07/21/2001	-	-	-	-	-	-	-
101775	30	NCG	07/28/2001	-	-	-	-	-	-	-
101775	30	NCG	07/29/2001	-	-	-	-	-	-	-
101800	31	PAZ	07/13/2001	-	-	-	-	-	-	-
101800	31	PAZ	07/21/2001	-	-	-	-	-	-	-
101800	31	PAZ	07/28/2001	-	-	-	-	-	-	-
101800	31	PAZ	07/29/2001	-	-	-	-	-	-	-
99638	32	MJH	07/19/2001	-	-	-	-	-	-	-
99638	32	MJH	07/21/2001	-	-	-	-	-	-	-
99638	32	MJH	07/28/2001	-	-	-	-	-	-	-
99638	32	MJH	07/29/2001	-	-	-	-	-	-	-

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	FREE						
				TSH	THYROXINE	T7	T-4	T3	CK	IRON
104724	33	DMT	07/18/2001	-	-	-	-	-	-	-
104724	33	DMT	07/21/2001	-	-	-	-	-	-	-
104724	33	DMT	07/28/2001	-	-	-	-	-	-	-
104724	33	DMT	07/29/2001	-	-	-	-	-	-	-
95922	34	ACT	07/18/2001	-	-	-	-	-	-	-
95922	34	ACT	07/21/2001	-	-	-	-	-	-	-
95922	34	ACT	07/28/2001	-	-	-	-	-	-	-
95922	34	ACT	07/29/2001	-	-	-	-	-	-	-
104718	35	AMK	07/17/2001	-	-	-	-	-	-	-
104718	35	AMK	07/21/2001	-	-	-	-	-	-	-
104718	35	AMK	07/28/2001	-	-	-	-	-	-	-
104718	35	AMK	07/29/2001	-	-	-	-	-	-	-
104718	35	AMK	08/01/2001	-	-	-	-	-	-	-
104707	36	DLJ	07/16/2001	-	-	-	-	-	-	-
104707	36	DLJ	07/21/2001	-	-	-	-	-	-	-
104707	36	DLJ	07/28/2001	-	-	-	-	-	-	-
104707	36	DLJ	07/29/2001	-	-	-	-	-	-	-
100844	37	MAL	07/16/2001	-	-	-	-	-	-	-
100844	37	MAL	07/21/2001	-	-	-	-	-	-	-
100844	37	MAL	07/28/2001	-	-	-	-	-	-	-
100844	37	MAL	07/29/2001	-	-	-	-	-	-	-
102279	38	THP	07/17/2001	-	-	-	-	-	-	-
102279	38	THP	07/21/2001	-	-	-	-	-	-	-
102279	38	THP	07/28/2001	-	-	-	-	-	-	-
102279	38	THP	07/29/2001	-	-	-	-	-	-	-
104299	39	JDF	07/17/2001	-	-	-	-	-	-	-
104299	39	JDF	07/21/2001	-	-	-	-	-	-	-
104299	39	JDF	07/28/2001	-	-	-	-	-	-	-
104299	39	JDF	07/29/2001	-	-	-	-	-	-	-
102629	40	TEM	07/19/2001	-	-	-	-	-	-	-
102629	40	TEM	07/21/2001	-	-	-	-	-	-	-
102629	40	TEM	07/28/2001	-	-	-	-	-	-	-

Special Chem Results

Chart Number	Subject Number	Subject Initials	Draw Date	FREE						
				TSH	THYROXINE	T7	T-4	T3	CK	IRON
102629	40	TEM	07/29/2001	-	-	-	-	-	-	-
91906	41	JNH	07/13/2001	-	-	-	-	-	-	-
91906	41	JNH	07/21/2001	-	-	-	-	-	-	-
91906	41	JNH	07/28/2001	-	-	-	-	-	-	-
91906	41	JNH	07/29/2001	-	-	-	-	-	-	-
99843	42	N-F	07/18/2001	-	-	-	-	-	-	-
99843	42	N-F	07/21/2001	-	-	-	-	-	-	-
99843	42	N-F	07/28/2001	-	-	-	-	-	-	-
99843	42	N-F	07/29/2001	-	-	-	-	-	-	-
104700	43	KAO	07/13/2001	-	-	-	-	-	-	-
104700	43	KAO	07/21/2001	-	-	-	-	-	-	-
104700	43	KAO	07/28/2001	-	-	-	-	-	-	-
104700	43	KAO	07/29/2001	-	-	-	-	-	-	-
104681	44	BAH	07/11/2001	-	-	-	-	-	-	-
104681	44	BAH	07/21/2001	-	-	-	-	-	-	-
104681	44	BAH	07/28/2001	-	-	-	-	-	-	-
104681	44	BAH	07/29/2001	-	-	-	-	-	-	-

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Chart Number	Subject Number	Subject Initials	Draw Date	PH	SP. GRAV	PROTEIN	GLUCOSE	KETONE	BILI	BLOOD	LEUK	UWBC
104248	01	ANJ	07/09/2001	5.5	1.01	NEG	NEG	NEG	NEG	NEG	Small H	3-4
104248	01	ANJ	07/21/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104248	01	ANJ	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
100515	02	RAW	07/19/2001	6	1.004 L	NEG	NEG	NEG	NEG	NEG	NEG	0
100515	02	RAW	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
100515	02	RAW	07/28/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
100515	02	RAW	07/29/2001	7.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104659	03	TLS	07/09/2001	5.5	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0
104659	03	TLS	07/21/2001	6.5	1.015	NEG	NEG	NEG	NEG	NEG	Trace H	0-1
104659	03	TLS	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104659	03	TLS	07/29/2001	5.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104492	04	KRE	07/10/2001	6	1.02	NEG	NEG	NEG	NEG	Small H	NEG	0
104492	04	KRE	07/17/2001	6	1.025	NEG	NEG	Trace H	NEG	Small H	Trace H	0-1
104492	04	KRE	07/21/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104492	04	KRE	07/28/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104492	04	KRE	07/29/2001	7	1.002 L	NEG	NEG	NEG	NEG	NEG	NEG	0
98555	05	SAP	07/10/2001	6.5	1.01	NEG	NEG	NEG	NEG	NEG	NEG	0
98555	05	SAP	07/21/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
98555	05	SAP	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
98555	05	SAP	07/29/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104752	06	BAZ	07/19/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104752	06	BAZ	07/21/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104752	06	BAZ	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104752	06	BAZ	07/29/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
95514	07	CRT	07/19/2001	6.5	1.001 L	NEG	NEG	NEG	NEG	NEG	NEG	0
95514	07	CRT	07/21/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
95514	07	CRT	07/28/2001	6.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
95514	07	CRT	07/29/2001	6	1.025	NEG	NEG	Trace H	NEG	NEG	NEG	0
96528	08	NBJ	07/17/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
96528	08	NBJ	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
96528	08	NBJ	07/28/2001	6	1.025	NEG	NEG	Trace H	NEG	NEG	NEG	0-1
96528	08	NBJ	07/29/2001	6	1.025	NEG	NEG	15 H	NEG	NEG	NEG	0

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Chart Number	Subject Number	Subject Initials	Draw Date	PH	SP. GRAV	PROTEIN	GLUCOSE	KETONE	BILI	BLOOD	LEUK	UWBC
97501	09	ADR	07/12/2001	5.5	1.029	NEG	NEG	Trace H	NEG	NEG	NEG	-
97501	09	ADR	07/19/2001	5.5	1.028	NEG	NEG	NEG	NEG	NEG	NEG	0
97501	09	ADR	07/21/2001	6	1.028	NEG	NEG	NEG	NEG	NEG	NEG	0
97501	09	ADR	07/28/2001	6.5	1.028	NEG	NEG	NEG	NEG	NEG	NEG	0-2
97501	09	ADR	07/29/2001	6	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0
104678	10	AKH	07/11/2001	6	1.01	NEG	NEG	NEG	NEG	NEG	NEG	0
104678	10	AKH	07/21/2001	6.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104677	11	CWB	07/11/2001	8	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104677	11	CWB	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104677	11	CWB	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104677	11	CWB	07/29/2001	6.5	1.025	NEG	NEG	Trace H	NEG	NEG	NEG	0
96298	12	CMP	07/17/2001	6	1.025	NEG	NEG	Trace H	NEG	NEG	NEG	0
96298	12	CMP	07/21/2001	6	1.025	NEG	NEG	Trace H	NEG	NEG	NEG	0
96298	12	CMP	07/28/2001	7	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
96298	12	CMP	07/29/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
102585	13	KWJ	07/17/2001	6.5	1.025	NEG	NEG	Trace H	NEG	NEG	NEG	0
102585	13	KWJ	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
102585	13	KWJ	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
102585	13	KWJ	07/29/2001	6.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104687	14	JEJ	07/12/2001	5.5	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0
104687	14	JEJ	07/21/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	Trace H	0
104687	14	JEJ	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-2
104687	14	JEJ	07/29/2001	6.5	1.01	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104727	15	WLE	07/18/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104727	15	WLE	07/21/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104727	15	WLE	07/28/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104727	15	WLE	07/29/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104682	16	HMH	07/11/2001	7.5	1.004 L	NEG	NEG	NEG	NEG	Small H	Large H	70-75 H
104682	16	HMH	07/14/2001	6.5	1.006	NEG	NEG	NEG	NEG	Small H	Large H	45-50 H
104682	16	HMH	07/17/2001	6	1.004 L	NEG	NEG	NEG	NEG	Trace H	Moderate H	20-25 H
104682	16	HMH	07/19/2001	6.5	1.015	NEG	NEG	NEG	NEG	Trace H	Large H	25 - 30 H
104682	16	HMH	07/20/2001	5.5	1.027	NEG	NEG	Trace H	NEG	NEG	Small H	1 - 4

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Chart Number	Subject Number	Subject Initials	Draw Date	PH	SP. GRAV	PROTEIN	GLUCOSE	KETONE	BILI	BLOOD	LEUK	UWBC
104682	16	HMH	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	Moderate H	7-12 H
104682	16	HMH	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	Moderate H	Trace H	0-2
104682	16	HMH	07/29/2001	6	1.025	NEG	NEG	NEG	NEG	Large H	Moderate H	3-6 H
98427	17	CDD	07/11/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
98427	17	CDD	07/21/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
98427	17	CDD	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
98427	17	CDD	07/29/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
97021	18	JME	07/12/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
97021	18	JME	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
97021	18	JME	07/28/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
97021	18	JME	07/29/2001	6	1.025	NEG	NEG	NEG	NEG	Large H	NEG	0
97021	18	JME	07/31/2001	7.5	1.02	NEG	NEG	NEG	NEG	NEG	Trace H	0-1
104690	19	CLH	07/12/2001	8	1.004 L	NEG	NEG	NEG	NEG	Large H	NEG	0
104690	19	CLH	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104690	19	CLH	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-2
104690	19	CLH	07/29/2001	8	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104693	20	CRG	07/12/2001	6	1.001 L	NEG	NEG	NEG	NEG	NEG	NEG	0
104693	20	CRG	07/21/2001	5	1.031 H	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104693	20	CRG	07/28/2001	6.5	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0
104693	20	CRG	07/29/2001	5.5	1.029	NEG	NEG	NEG	NEG	NEG	NEG	0
104693	20	CRG	07/31/2001	5.5	1.03	NEG	NEG	NEG	NEG	NEG	Trace H	0-2
100930	21	KRM	07/18/2001	6.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
100930	21	KRM	07/21/2001	6.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
100930	21	KRM	07/28/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
100930	21	KRM	07/29/2001	7	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104746	22	TMF	07/19/2001	5.5	1.029	NEG	NEG	Trace H	NEG	NEG	NEG	0 - 1
104746	22	TMF	07/21/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104746	22	TMF	07/28/2001	6.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104746	22	TMF	07/29/2001	5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
102915	23	GPA	07/12/2001	7	1.005	NEG	NEG	NEG	NEG	NEG	NEG	0
102915	23	GPA	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
102915	23	GPA	07/28/2001	5.5	1.03	NEG	NEG	NEG	NEG	NEG	NEG	0

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Chart Number	Subject Number	Subject Initials	Draw Date	PH	SP. GRAV	PROTEIN	GLUCOSE	KETONE	BILI	BLOOD	LEUK	UWBC
102915	23	GPA	07/29/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
102153	24	BDH	07/11/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	-
102153	24	BDH	07/20/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
102153	24	BDH	07/21/2001	7.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
102153	24	BDH	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
102153	24	BDH	07/29/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
97683	25	RMK	07/12/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
97683	25	RMK	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
97683	25	RMK	07/28/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
97683	25	RMK	07/29/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
100918	26	JLP	07/13/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	Trace H	0-1
100918	26	JLP	07/21/2001	6	1.028	NEG	NEG	NEG	NEG	NEG	NEG	0
100918	26	JLP	07/28/2001	6	1.025	NEG	NEG	Trace H	NEG	NEG	NEG	0-1
100918	26	JLP	07/29/2001	7	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
100918	26	JLP	07/31/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104673	27	AIF	07/11/2001	8	1.02	NEG	NEG	Trace H	NEG	Moderate H	NEG	0-1
104673	27	AIF	07/19/2001	5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104673	27	AIF	07/21/2001	7	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104673	27	AIF	07/28/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0-2
104673	27	AIF	07/29/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
99920	28	SMR	07/13/2001	5.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
99920	28	SMR	07/21/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
99920	28	SMR	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
99920	28	SMR	07/29/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104608	29	AJA	07/16/2001	6	1.034 H	NEG	NEG	NEG	NEG	NEG	NEG	0
104608	29	AJA	07/19/2001	8	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104608	29	AJA	07/21/2001	6	1.026	NEG	NEG	NEG	NEG	NEG	NEG	0
104608	29	AJA	07/28/2001	6	1.031 H	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104608	29	AJA	07/29/2001	6	1.025	NEG	NEG	Trace H	NEG	NEG	NEG	0
101775	30	NCG	07/17/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
101775	30	NCG	07/21/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
101775	30	NCG	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0

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Chart Number	Subject Number	Subject Initials	Draw Date	PH	SP. GRAV	PROTEIN	GLUCOSE	KETONE	BILI	BLOOD	LEUK	UWBC
101775	30	NCG	07/29/2001	5.5	1.026	NEG	NEG	NEG	NEG	NEG	NEG	0-2
101800	31	PAZ	07/13/2001	6	1.025	NEG	NEG	NEG	NEG	Small H	NEG	0
101800	31	PAZ	07/21/2001	5.5	1.03	NEG	NEG	NEG	NEG	NEG	NEG	0
101800	31	PAZ	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
101800	31	PAZ	07/29/2001	7.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
99638	32	MJH	07/19/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
99638	32	MJH	07/21/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
99638	32	MJH	07/28/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
99638	32	MJH	07/29/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104724	33	DMT	07/18/2001	6.5	<=1.005 H	NEG	NEG	NEG	NEG	NEG	NEG	0
104724	33	DMT	07/21/2001	6	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0
104724	33	DMT	07/28/2001	6.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104724	33	DMT	07/29/2001	6	1.004 L	NEG	NEG	NEG	NEG	NEG	Trace H	0-2
95922	34	ACT	07/18/2001	6.5	1.015	NEG	NEG	NEG	NEG	Small H	Trace H	0-1
95922	34	ACT	07/21/2001	6	1.02	NEG	NEG	NEG	NEG	Small H	NEG	0
95922	34	ACT	07/28/2001	6	1.015	NEG	NEG	NEG	NEG	Trace H	NEG	0-1
95922	34	ACT	07/29/2001	6.5	1.006	NEG	NEG	NEG	NEG	Trace H	NEG	0
104718	35	AMK	07/17/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104718	35	AMK	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-2
104718	35	AMK	07/28/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-2
104718	35	AMK	07/29/2001	5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	1-3
104707	36	DLJ	07/16/2001	8	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0
104707	36	DLJ	07/21/2001	5.5	1.023	NEG	NEG	NEG	NEG	NEG	NEG	0
104707	36	DLJ	07/28/2001	5.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104707	36	DLJ	07/29/2001	6	1.002 L	NEG	NEG	NEG	NEG	NEG	NEG	0
100844	37	MAL	07/16/2001	6.5	1.01	NEG	NEG	NEG	NEG	NEG	NEG	0
100844	37	MAL	07/21/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
100844	37	MAL	07/28/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
100844	37	MAL	07/29/2001	7	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0
102279	38	THP	07/17/2001	8	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
102279	38	THP	07/20/2001	8	1.003 L	NEG	NEG	NEG	NEG	NEG	NEG	0
102279	38	THP	07/21/2001	6.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0

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Chart Number	Subject Number	Subject Initials	Draw Date	PH	SP. GRAV	PROTEIN	GLUCOSE	KETONE	BILI	BLOOD	LEUK	UWBC
102279	38	THP	07/28/2001	7	1.02	NEG	NEG	NEG	NEG	NEG	NEG	1-3
102279	38	THP	07/29/2001	7.5	1.01	NEG	NEG	NEG	NEG	NEG	NEG	0
104299	39	JDF	07/17/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104299	39	JDF	07/21/2001	5.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104299	39	JDF	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104299	39	JDF	07/29/2001	7	1.003 L	NEG	NEG	NEG	NEG	NEG	NEG	0
102629	40	TEM	07/16/2001	7	1.025	NEG	NEG	NEG	NEG	NEG	NEG	-
102629	40	TEM	07/19/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
102629	40	TEM	07/21/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
102629	40	TEM	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0-1
102629	40	TEM	07/29/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	1-3
91906	41	JNH	07/13/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
91906	41	JNH	07/19/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-1
91906	41	JNH	07/21/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
91906	41	JNH	07/28/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-2
91906	41	JNH	07/29/2001	6.5	1.005	NEG	NEG	NEG	NEG	NEG	NEG	0
99843	42	N-F	07/18/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
99843	42	N-F	07/21/2001	6.5	1.025	NEG	NEG	NEG	NEG	NEG	Trace H	0-1
99843	42	N-F	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0-1
99843	42	N-F	07/29/2001	5.5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0
104700	43	KAO	07/13/2001	6	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-3
104700	43	KAO	07/19/2001	8	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104700	43	KAO	07/21/2001	8	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104700	43	KAO	07/28/2001	6	1.015	NEG	NEG	NEG	NEG	NEG	NEG	0-1
104700	43	KAO	07/29/2001	7.5	1.02	NEG	NEG	NEG	NEG	NEG	NEG	0
104681	44	BAH	07/11/2001	5.5	1.025	NEG	NEG	NEG	NEG	Trace H	NEG	0
104681	44	BAH	07/21/2001	6	1.029	NEG	NEG	Trace H	NEG	NEG	NEG	0-1
104681	44	BAH	07/28/2001	6	1.02	NEG	NEG	NEG	NEG	NEG	NEG	1-3
104681	44	BAH	07/29/2001	5	1.025	NEG	NEG	NEG	NEG	NEG	NEG	0-2

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Chart Number	Subject Number	Subject Initials	Draw Date	URBC	CRYSTALS	NITRATES	CASTS	BACTERIA	UROBILI
104248	01	ANJ	07/09/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104248	01	ANJ	07/21/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
104248	01	ANJ	07/28/2001	0-2	None Obs.	NEG	None Obs.	Few	1
100515	02	RAW	07/19/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
100515	02	RAW	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
100515	02	RAW	07/28/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
100515	02	RAW	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2
104659	03	TLS	07/09/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104659	03	TLS	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104659	03	TLS	07/28/2001	0-2	None Obs.	NEG	None Obs.	Few	0.2
104659	03	TLS	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104492	04	KRE	07/10/2001	0 - 1	None Obs.	NEG	None Obs.	Few	0.2
104492	04	KRE	07/17/2001	1-5 H	None Obs.	NEG	None Obs.	Few	0.2
104492	04	KRE	07/21/2001	0-1	Present H	NEG	None Obs.	Few	0.2
104492	04	KRE	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104492	04	KRE	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
98555	05	SAP	07/10/2001	0	None Obs.	NEG	None Obs.	Few	0.2
98555	05	SAP	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
98555	05	SAP	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
98555	05	SAP	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104752	06	BAZ	07/19/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104752	06	BAZ	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104752	06	BAZ	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104752	06	BAZ	07/29/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
95514	07	CRT	07/19/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
95514	07	CRT	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
95514	07	CRT	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
95514	07	CRT	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2
96528	08	NBJ	07/17/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
96528	08	NBJ	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
96528	08	NBJ	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
96528	08	NBJ	07/29/2001	0-2	None Obs.	NEG	None Obs.	Few	0.2

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Chart Number	Subject Number	Subject Initials	Draw Date	URBC	CRYSTALS	NITRATES	CASTS	BACTERIA	UROBILI
97501	09	ADR	07/12/2001	-	-	NEG	-	-	0.2
97501	09	ADR	07/19/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
97501	09	ADR	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
97501	09	ADR	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
97501	09	ADR	07/29/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104678	10	AKH	07/11/2001	0	None Obs.	NEG	None Obs.	Mod. H	0.2
104678	10	AKH	07/21/2001	0-1	Present H	NEG	None Obs.	Mod. H	0.2
104677	11	CWB	07/11/2001	0	None Obs.	NEG	None Obs.	Few	1
104677	11	CWB	07/21/2001	0	Present H	NEG	None Obs.	None Obs.	0.2
104677	11	CWB	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104677	11	CWB	07/29/2001	0	None Obs.	NEG	None Obs.	Few	1
96298	12	CMP	07/17/2001	0	None Obs.	NEG	None Obs.	Few	0.2
96298	12	CMP	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
96298	12	CMP	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
96298	12	CMP	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2
102585	13	KWJ	07/17/2001	0	Present H	NEG	None Obs.	Few	1
102585	13	KWJ	07/21/2001	0	None Obs.	NEG	None Obs.	Few	1
102585	13	KWJ	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	1
102585	13	KWJ	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104687	14	JEJ	07/12/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104687	14	JEJ	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
104687	14	JEJ	07/28/2001	0-2	None Obs.	NEG	None Obs.	Few	0.2
104687	14	JEJ	07/29/2001	0	None Obs.	NEG	None Obs.	Mod. H	0.2
104727	15	WLE	07/18/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104727	15	WLE	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
104727	15	WLE	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104727	15	WLE	07/29/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104682	16	HMH	07/11/2001	0-1	None Obs.	NEG	None Obs.	Mod. H	0.2
104682	16	HMH	07/14/2001	0-2	None Obs.	NEG	None Obs.	Few	0.2
104682	16	HMH	07/17/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
104682	16	HMH	07/19/2001	0 - 1	None Obs.	NEG	None Obs.	Few	0.2
104682	16	HMH	07/20/2001	0	Present H	NEG	None Obs.	Few	0.2

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Chart Number	Subject Number	Subject Initials	Draw Date	URBC	CRYSTALS	NITRATES	CASTS	BACTERIA	UROBILI
104682	16	HMH	07/21/2001	0	Present H	NEG	None Obs.	Mod. H	0.2
104682	16	HMH	07/28/2001	6-8 H	None Obs.	NEG	None Obs.	Few	0.2
104682	16	HMH	07/29/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
98427	17	CDD	07/11/2001	0	None Obs.	NEG	None Obs.	Few	0.2
98427	17	CDD	07/21/2001	0	Present H	NEG	None Obs.	Few	1
98427	17	CDD	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
98427	17	CDD	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2
97021	18	JME	07/12/2001	0	None Obs.	NEG	None Obs.	Few	0.2
97021	18	JME	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
97021	18	JME	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
97021	18	JME	07/29/2001	4-7 H	None Obs.	NEG	None Obs.	None Obs.	0.2
97021	18	JME	07/31/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104690	19	CLH	07/12/2001	22 - 28 H	None Obs.	NEG	None Obs.	Few	0.2
104690	19	CLH	07/21/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
104690	19	CLH	07/28/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
104690	19	CLH	07/29/2001	0-1	None Obs.	NEG	None Obs.	Mod. H	0.2
104693	20	CRG	07/12/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104693	20	CRG	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
104693	20	CRG	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104693	20	CRG	07/29/2001	0-2	Present H	NEG	None Obs.	Mod. H	0.2
104693	20	CRG	07/31/2001	0-1	None Obs.	NEG	None Obs.	None Obs.	0.2
100930	21	KRM	07/18/2001	0	None Obs.	NEG	None Obs.	Few	0.2
100930	21	KRM	07/21/2001	0	Present H	NEG	None Obs.	None Obs.	0.2
100930	21	KRM	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
100930	21	KRM	07/29/2001	0	Present H	NEG	None Obs.	None Obs.	0.2
104746	22	TMF	07/19/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104746	22	TMF	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
104746	22	TMF	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104746	22	TMF	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2
102915	23	GPA	07/12/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
102915	23	GPA	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
102915	23	GPA	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2

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Chart Number	Subject Number	Subject Initials	Draw Date	URBC	CRYSTALS	NITRATES	CASTS	BACTERIA	UROBILI
102915	23	GPA	07/29/2001	0	Present H	NEG	None Obs.	None Obs.	0.2
102153	24	BDH	07/11/2001	-	-	NEG	-	-	0.2
102153	24	BDH	07/20/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
102153	24	BDH	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
102153	24	BDH	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
102153	24	BDH	07/29/2001	0-1	None Obs.	NEG	None Obs.	None Obs.	0.2
97683	25	RMK	07/12/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
97683	25	RMK	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
97683	25	RMK	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
97683	25	RMK	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
100918	26	JLP	07/13/2001	0-1	None Obs.	NEG	None Obs.	None Obs.	1
100918	26	JLP	07/21/2001	0	Present H	NEG	None Obs.	Few	1
100918	26	JLP	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	2.0 H
100918	26	JLP	07/29/2001	0	None Obs.	NEG	None Obs.	Few	2.0 H
100918	26	JLP	07/31/2001	0-1	None Obs.	NEG	None Obs.	Few	4.0 H
104673	27	AIF	07/11/2001	0-1	None Obs.	NEG	None Obs.	Few	1
104673	27	AIF	07/19/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104673	27	AIF	07/21/2001	0	None Obs.	NEG	None Obs.	Mod. H	0.2
104673	27	AIF	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104673	27	AIF	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
99920	28	SMR	07/13/2001	0	None Obs.	NEG	None Obs.	Few	0.2
99920	28	SMR	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
99920	28	SMR	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
99920	28	SMR	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104608	29	AJA	07/16/2001	0 - 1	Present H	NEG	None Obs.	Mod. H	0.2
104608	29	AJA	07/19/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104608	29	AJA	07/21/2001	0	Present H	NEG	None Obs.	Few	1
104608	29	AJA	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104608	29	AJA	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2
101775	30	NCG	07/17/2001	0	None Obs.	NEG	None Obs.	Few	1
101775	30	NCG	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
101775	30	NCG	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2

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Chart Number	Subject Number	Subject Initials	Draw Date	URBC	CRYSTALS	NITRATES	CASTS	BACTERIA	UROBILI
101775	30	NCG	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2
101800	31	PAZ	07/13/2001	0-3 H	None Obs.	NEG	None Obs.	Few	0.2
101800	31	PAZ	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
101800	31	PAZ	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
101800	31	PAZ	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2
99638	32	MJH	07/19/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
99638	32	MJH	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
99638	32	MJH	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
99638	32	MJH	07/29/2001	0-1	None Obs.	NEG	None Obs.	None Obs.	0.2
104724	33	DMT	07/18/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104724	33	DMT	07/21/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104724	33	DMT	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104724	33	DMT	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
95922	34	ACT	07/18/2001	1-3 H	None Obs.	NEG	None Obs.	None Obs.	0.2
95922	34	ACT	07/21/2001	0-3 H	None Obs.	NEG	None Obs.	Few	0.2
95922	34	ACT	07/28/2001	1-3 H	None Obs.	NEG	None Obs.	Few	0.2
95922	34	ACT	07/29/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104718	35	AMK	07/17/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104718	35	AMK	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104718	35	AMK	07/28/2001	0-1	None Obs.	NEG	None Obs.	Few	1
104718	35	AMK	07/29/2001	0	Present H	NEG	None Obs.	Mod. H	0.2
104707	36	DLJ	07/16/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104707	36	DLJ	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
104707	36	DLJ	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104707	36	DLJ	07/29/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
100844	37	MAL	07/16/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
100844	37	MAL	07/21/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
100844	37	MAL	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
100844	37	MAL	07/29/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
102279	38	THP	07/17/2001	0	Present H	NEG	None Obs.	None Obs.	0.2
102279	38	THP	07/20/2001	0	None Obs.	NEG	None Obs.	Few	0.2
102279	38	THP	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2

Urinalysis

Chart Number	Subject Number	Subject Initials	Draw Date	URBC	CRYSTALS	NITRATES	CASTS	BACTERIA	UROBILI
102279	38	THP	07/28/2001	0-2	None Obs.	NEG	None Obs	Few	0.2
102279	38	THP	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104299	39	JDF	07/17/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
104299	39	JDF	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104299	39	JDF	07/28/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
104299	39	JDF	07/29/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
102629	40	TEM	07/16/2001	-	-	NEG	-	-	0.2
102629	40	TEM	07/19/2001	0	None Obs.	NEG	None Obs.	Few	0.2
102629	40	TEM	07/21/2001	0	None Obs.	NEG	None Obs.	Few	0.2
102629	40	TEM	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
102629	40	TEM	07/29/2001	0	None Obs.	NEG	None Obs.	Few	0.2
91906	41	JNH	07/13/2001	0	Present H	NEG	None Obs.	None Obs.	0.2
91906	41	JNH	07/19/2001	0	None Obs.	NEG	None Obs.	Few	0.2
91906	41	JNH	07/21/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
91906	41	JNH	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
91906	41	JNH	07/29/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
99843	42	N-F	07/18/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
99843	42	N-F	07/21/2001	0	None Obs.	NEG	None Obs.	Few	1
99843	42	N-F	07/28/2001	0	None Obs.	NEG	None Obs.	None Obs.	0.2
99843	42	N-F	07/29/2001	0-1	None Obs.	NEG	None Obs.	None Obs.	0.2
104700	43	KAO	07/13/2001	0-2	Present H	NEG	None Obs.	Few	0.2
104700	43	KAO	07/19/2001	0	Present H	NEG	None Obs	Few	0.2
104700	43	KAO	07/21/2001	0	Present H	NEG	None Obs.	Few	0.2
104700	43	KAO	07/28/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
104700	43	KAO	07/29/2001	0-1	Present H	NEG	None Obs.	Few	0.2
104681	44	BAH	07/11/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
104681	44	BAH	07/21/2001	0-1	None Obs.	NEG	None Obs.	Few	0.2
104681	44	BAH	07/28/2001	0	None Obs.	NEG	None Obs.	Few	0.2
104681	44	BAH	07/29/2001	0	Present H	NEG	None Obs.	Few	0.2

URINE DRUG SCREEN

Chart Number	Subject Number	Subject Initials	Draw Date	AMP	BARB	COCA	OPIA	BENZ	PCP	THC	ETHO
104248	01	ANJ	07/09/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104248	01	ANJ	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104248	01	ANJ	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100515	02	RAW	07/19/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100515	02	RAW	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100515	02	RAW	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104659	03	TLS	07/09/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104659	03	TLS	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104659	03	TLS	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104492	04	KRE	07/10/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104492	04	KRE	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104492	04	KRE	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
98555	05	SAP	07/10/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
98555	05	SAP	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
98555	05	SAP	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104752	06	BAZ	07/19/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104752	06	BAZ	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104752	06	BAZ	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
95514	07	CRT	07/19/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
95514	07	CRT	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
95514	07	CRT	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
96528	08	NBJ	07/17/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
96528	08	NBJ	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
96528	08	NBJ	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97501	09	ADR	07/12/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97501	09	ADR	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97501	09	ADR	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104678	10	AKH	07/11/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104678	10	AKH	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104678	10	AKH	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	POS H	NEG
104677	11	CWB	07/11/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104677	11	CWB	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

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Chart Number	Subject Number	Subject Initials	Draw Date	AMP	BARB	COCA	OPIA	BENZ	PCP	THC	ETHO
104677	11	CWB	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
96298	12	CMP	07/17/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
96298	12	CMP	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
96298	12	CMP	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102585	13	KWJ	07/17/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102585	13	KWJ	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102585	13	KWJ	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104687	14	JEJ	07/12/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104687	14	JEJ	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104687	14	JEJ	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104727	15	WLE	07/18/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104727	15	WLE	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104727	15	WLE	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104682	16	HMH	07/11/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104682	16	HMH	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104682	16	HMH	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
98427	17	CDD	07/11/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
98427	17	CDD	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
98427	17	CDD	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97021	18	JME	07/12/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97021	18	JME	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97021	18	JME	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104690	19	CLH	07/12/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104690	19	CLH	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104690	19	CLH	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104693	20	CRG	07/12/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104693	20	CRG	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104693	20	CRG	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100930	21	KRM	07/18/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100930	21	KRM	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100930	21	KRM	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104746	22	TMF	07/19/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

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Chart Number	Subject Number	Subject Initials	Draw Date	AMP	BARB	COCA	OPIA	BENZ	PCP	THC	ETHO
104746	22	TMF	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104746	22	TMF	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102915	23	GPA	07/12/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102915	23	GPA	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102915	23	GPA	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102153	24	BDH	07/11/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102153	24	BDH	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102153	24	BDH	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97683	25	RMK	07/12/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97683	25	RMK	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
97683	25	RMK	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100918	26	JLP	07/13/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100918	26	JLP	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100918	26	JLP	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104673	27	AIF	07/11/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104673	27	AIF	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104673	27	AIF	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99920	28	SMR	07/13/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99920	28	SMR	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99920	28	SMR	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104608	29	AJA	07/16/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104608	29	AJA	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104608	29	AJA	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
101775	30	NCG	07/17/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
101775	30	NCG	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
101775	30	NCG	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
101800	31	PAZ	07/13/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
101800	31	PAZ	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
101800	31	PAZ	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99638	32	MJH	07/19/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99638	32	MJH	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99638	32	MJH	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

URINE DRUG SCREEN

Chart Number	Subject Number	Subject Initials	Draw Date	AMP	BARB	COCA	OPIA	BENZ	PCP	THC	ETHO
104724	33	DMT	07/18/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104724	33	DMT	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104724	33	DMT	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
95922	34	ACT	07/18/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
95922	34	ACT	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
95922	34	ACT	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104718	35	AMK	07/17/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104718	35	AMK	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104718	35	AMK	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104707	36	DLJ	07/16/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104707	36	DLJ	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104707	36	DLJ	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100844	37	MAL	07/16/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100844	37	MAL	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
100844	37	MAL	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102279	38	THP	07/17/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102279	38	THP	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102279	38	THP	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104299	39	JDF	07/17/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104299	39	JDF	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104299	39	JDF	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
102629	40	TEM	07/16/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
91906	41	JNH	07/13/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
91906	41	JNH	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
91906	41	JNH	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99843	42	N-F	07/18/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99843	42	N-F	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
99843	42	N-F	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104700	43	KAO	07/13/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104700	43	KAO	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104700	43	KAO	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104681	44	BAH	07/11/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

URINE DRUG SCREEN

Chart Number	Subject Number	Subject Initials	Draw Date	AMP	BARB	COCA	OPIA	BENZ	PCP	THC	ETHO
104681	44	BAH	07/20/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
104681	44	BAH	07/27/2001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

HIV and HEP Results

Chart Number	Subject Number	Subject Initials	Draw Date	HIV	HEP	HEP C
104248	01	ANJ	07/09/2001	NEG	NEG	
100515	02	RAW	07/19/2001	NEG	NEG	NEG
104659	03	TLS	07/09/2001	NEG	NEG	
104492	04	KRE	07/10/2001	NEG	NEG	NEG
98555	05	SAP	07/10/2001	NEG	NEG	NEG
104752	06	BAZ	07/19/2001	NEG	NEG	NEG
95514	07	CRT	07/19/2001	NEG	NEG	NEG
96528	08	NBJ	07/17/2001	NEG	NEG	NEG
97501	09	ADR	07/12/2001	NEG	NEG	NEG
104678	10	AKH	07/11/2001	NEG	NEG	NEG
104677	11	CWB	07/11/2001	NEG	NEG	NEG
96298	12	CMP	07/11/2001	NEG	NEG	NEG
102585	13	KWJ	07/17/2001	NEG	NEG	NEG
104687	14	JEJ	07/11/2001	NEG	NEG	NEG
104727	15	WLE	07/18/2001	NEG	NEG	NEG
104682	16	HMH	07/16/2001	NEG	NEG	NEG
98427	17	CDD	07/11/2001	NEG	NEG	NEG
97021	18	JME	07/12/2001	NEG	NEG	NEG
104690	19	CLH	07/12/2001	NEG	NEG	NEG
104693	20	CRG	07/12/2001	NEG	NEG	NEG
100930	21	KRM	07/18/2001	NEG	NEG	NEG
104746	22	TMF	07/19/2001	NEG	NEG	NEG
102915	23	GPA	07/12/2001	NEG	NEG	NEG
102153	24	BDH	07/11/2001	NEG	NEG	NEG
97683	25	RMK	07/12/2001	NEG	NEG	NEG
100918	26	JLP	07/13/2001	NEG	NEG	NEG
104673	27	AIF	07/11/2001	NEG	NEG	
99920	28	SMR	07/13/2001	NEG	NEG	NEG
104608	29	AJA	07/16/2001	NEG	NEG	NEG
101775	30	NCG	07/16/2001	NEG	NEG	NEG
101800	31	PAZ	07/13/2001	NEG	NEG	NEG
99638	32	MJH	07/19/2001	NEG	NEG	NEG

HIV and HEP Results

Chart Number	Subject Number	Subject Initials	Draw Date	HIV	HEP	HEP C
104724	33	DMT	07/18/2001	NEG	NEG	NEG
95922	34	ACT	07/18/2001	NEG	NEG	NEG
104718	35	AMK	07/17/2001	NEG	NEG	NEG
104707	36	DLJ	07/16/2001	NEG	NEG	NEG
100844	37	MAL	07/16/2001	NEG	NEG	NEG
102279	38	THP	07/17/2001	NEG	NEG	NEG
104299	39	JDF	07/17/2001	NEG	NEG	NEG
102629	40	TEM	07/16/2001	NEG	NEG	NEG
91906	41	JNH	07/13/2001	NEG	NEG	NEG
99843	42	N-F	07/18/2001	NEG	NEG	NEG
104700	43	KAO	07/13/2001	NEG	NEG	NEG
104681	44	BAH	07/11/2001	NEG	NEG	NEG

Pregnancy Screen Results

Chart Number	Subject Number	Subject Initials	Draw Date	HCG	BHCG	HCGU
104248	01	ANJ	07/09/2001	-	<0.5	-
104248	01	ANJ	07/20/2001	-	<0.5	-
104248	01	ANJ	07/27/2001	-	<0.5	-
104659	03	TLS	07/09/2001	-	<0.5	-
104659	03	TLS	07/20/2001	-	<0.5	-
104659	03	TLS	07/27/2001	-	<0.5	-
104659	03	TLS	07/29/2001	-	<0.5	-
104678	10	AKH	07/11/2001	-	<0.5	-
104678	10	AKH	07/20/2001	-	<0.5	-
104678	10	AKH	07/27/2001	-	<0.5	-
104678	10	AKH	07/31/2001	-	<0.5	-
104687	14	JEJ	07/12/2001	-	<0.5	-
104687	14	JEJ	07/20/2001	-	<0.5	-
104687	14	JEJ	07/27/2001	-	<0.5	-
104687	14	JEJ	07/29/2001	-	<0.5	-
104682	16	HMH	07/11/2001	-	<0.5	-
104724	33	DMT	07/29/2001	-	<0.5	-
95922	34	ACT	07/18/2001	-	<0.5	-
95922	34	ACT	07/20/2001	-	<0.5	-
95922	34	ACT	07/27/2001	-	<0.5	-
95922	34	ACT	07/29/2001	-	<0.5	-
104718	35	AMK	07/17/2001	-	<0.5	-
104718	35	AMK	07/20/2001	-	<0.5	-
104718	35	AMK	07/27/2001	-	<0.5	-
104718	35	AMK	07/29/2001	-	<0.5	-
102279	38	THP	07/17/2001	-	<0.5	-
102279	38	THP	07/20/2001	-	<0.5	-
102279	38	THP	07/27/2001	-	<0.5	-
102279	38	THP	07/29/2001	-	<0.5	-
104700	43	KAO	07/13/2001	-	<0.5	-
104700	43	KAO	07/20/2001	-	<0.5	-
104700	43	KAO	07/27/2001	-	<0.5	-

Pregnancy Screen Results

Chart Number	Subject Number	Subject Initials	Draw Date	HCG	BHCG	HCGU
104682	16	HMH	07/14/2001	-	<0.5	-
104682	16	HMH	07/20/2001	-	<0.5	-
104682	16	HMH	07/27/2001	-	<0.5	-
104682	16	HMH	07/29/2001	-	<0.5	-
104690	19	CLH	07/12/2001	-	<0.5	-
104690	19	CLH	07/20/2001	-	<0.5	-
104690	19	CLH	07/27/2001	-	<0.5	-
104690	19	CLH	07/29/2001	-	<0.5	-
104673	27	AIF	07/11/2001	-	<0.5	-
104673	27	AIF	07/14/2001	-	<0.5	-
104673	27	AIF	07/20/2001	-	<0.5	-
104673	27	AIF	07/27/2001	-	<0.5	-
104673	27	AIF	07/29/2001	-	<0.5	-
104724	33	DMT	07/18/2001	-	<0.5	-
104724	33	DMT	07/20/2001	-	<0.5	-
104724	33	DMT	07/27/2001	-	<0.5	-
104700	43	KAO	07/29/2001	-	<0.5	-
104681	44	BAH	07/11/2001	-	<0.5	-
104681	44	BAH	07/20/2001	-	<0.5	-
104681	44	BAH	07/27/2001	-	<0.5	-
104681	44	BAH	07/29/2001	-	<0.5	-

Case Report Forms

SECTION 17.3

CASE REPORT FORMS

SECTION 17.3.1

**Case Report Forms (for deaths, other serious adverse events, and
withdraws due to adverse events)**

There were no deaths, other serious adverse events, and no subjects withdrew from the study due to adverse events.



SECTION 17.3.2
Other Case Report Forms

There were no other relevant individual case report forms.

Individual
Data Listing

SECTION 17.4
INDIVIDUAL SUBJECT DATA LISTINGS

No individual subject data listings were reported.