

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
19-962/S-013**

Correspondence

MESSAGE CONFIRMATION

04/21/00 16:08
ID=FDA CDER DCRDP

NO.	MODE	BOX	GROUP
657	TX		

DATE/TIME	TIME	DISTANT STATION ID	PAGES	RESULT	ERROR PAGES	S. CODE
04/21 16:06	01'47"	6106951828	004/004	OK		0000

DIVISION OF CARDIO-RENAL DRUG PRODUCTS FOOD AND DRUG ADMINISTRATION



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Transmitted to FAX Number: 610-695-1828

Attention: Dr. Steven Miller

Company Name: AstraZeneca LP

Phone: 610-695-1816

Subject: 4/11/00 Meeting Minutes

Date: 4/21/00

Pages including this sheet: 4

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Attention: Dr. Steven Miller

Company Name: AstraZeneca LP

Phone: 610-695-1816

Subject: 4/11/00 Meeting Minutes

Date: 4/21/00

Pages including this sheet: 4

From: Zelda McDonald
Phone: 301-594-5333
Fax: 301-594-5494

YOU ARE RESPONSIBLE FOR NOTIFYING US OF ANY SIGNIFICANT DIFFERENCES IN UNDERSTANDING YOU MAY HAVE REGARDING THE MEETING OUTCOMES (AS REFLECTED IN THE MINUTES).

PLEASE LET ME KNOW YOU RECEIVED THIS. THANKS!

cc:
Orig.
HFD-110
HFD-110/McDonald/Matthews

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Transmitted to FAX Number: 610-695-1828

Attention: Dr. Steven Miller

Company Name: AstraZeneca

Phone: 610-695-1816

Subject: 5/9/00 Meeting Minutes

Date: 5/12/00

Pages including this sheet: 3

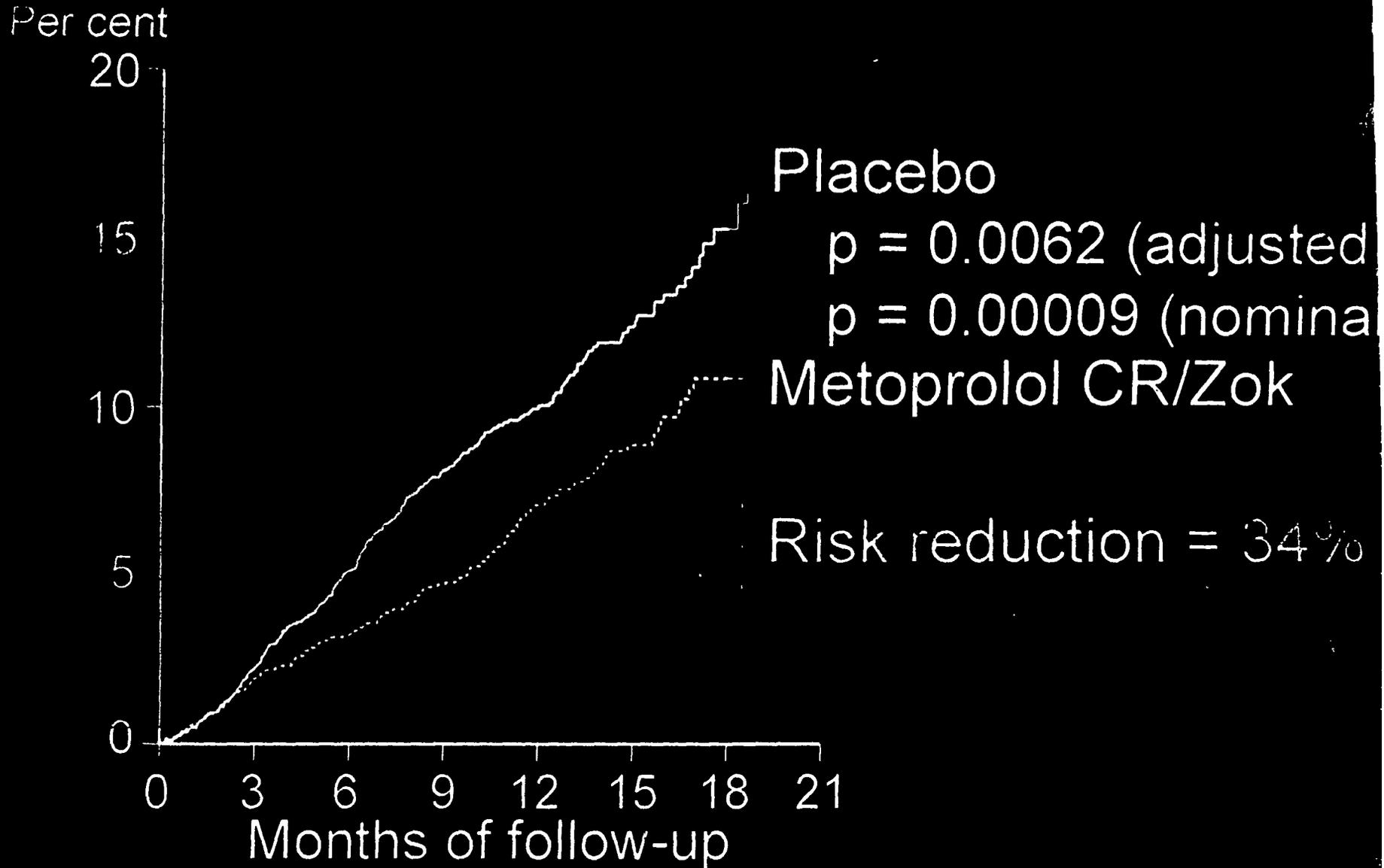
From: Zelda McDonald
Phone: 301-594-5333
Fax: 301-594-5494

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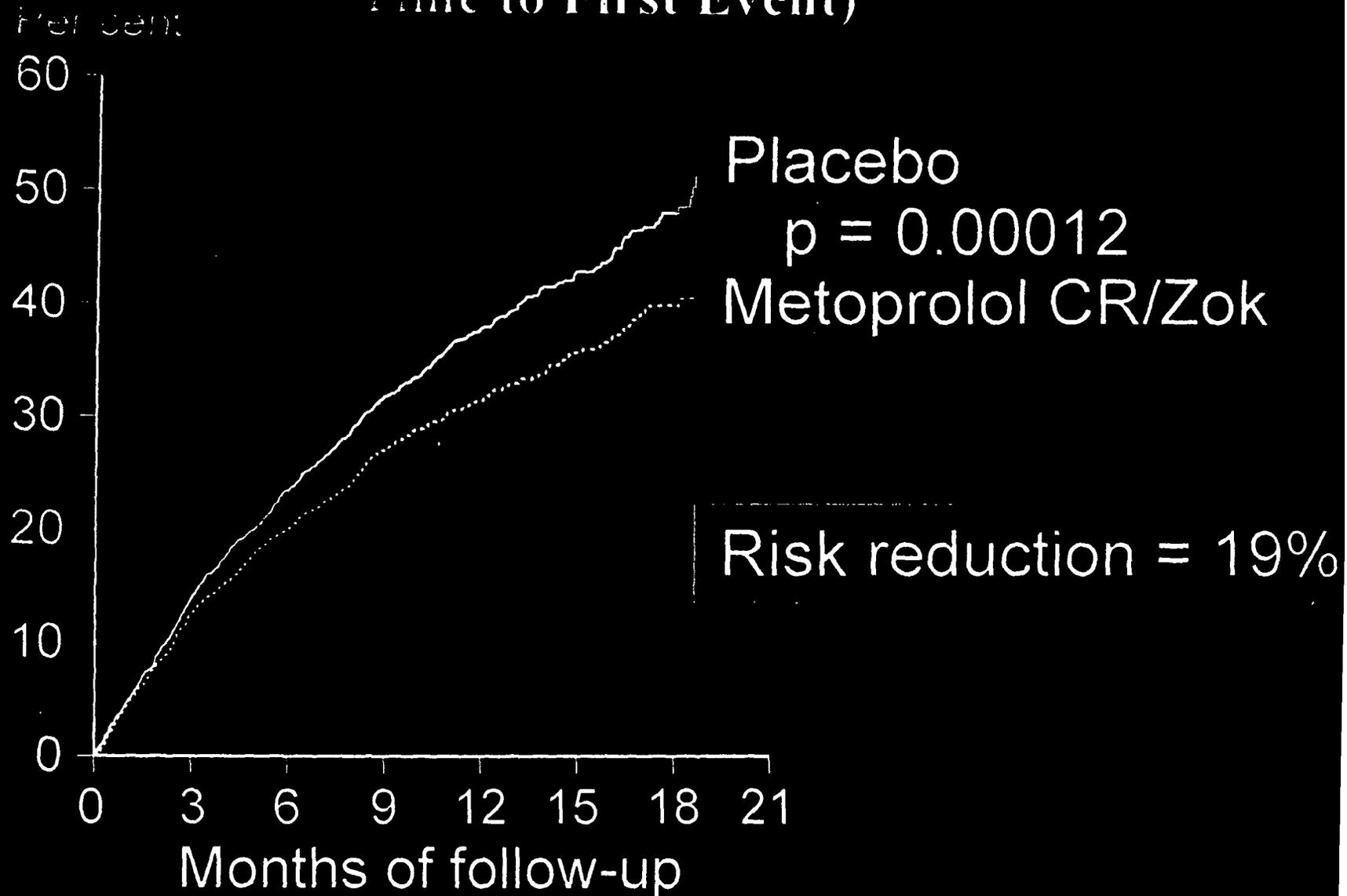
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Total Mortality



Time to First Event) All Cause Hospitalization



The MERIT-HF Study Group, JAMA 2000;283:1295-130

MESSAGE CONFIRMATION

05/12/00 11:03
ID=FDA CDER DCRDP

J.	MODE	BOX	GROUP
888	TX		

DATE/TIME	TIME	DISTANT STATION ID	PAGES	RESULT	ERROR PAGES	S. CODE
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Attention: Dr. Steven Miller
Company Name: AstraZeneca
Phone: 610-695-1816
Subject: 5/9/00 Meeting Minutes
Date: 5/12/00
Pages including this sheet: 3

Z. McDonald c1

MAY 31 2000

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Transmitted to FAX Number: 610-695-1828
Attention: Dr. Steven Miller
Company Name: AstraZeneca
Phone: 610-695-1816
Subject: 5/22/00 Meeting Minutes
Date: 5/31/00
Pages including this sheet: 3

From: Zelda McDonald
Phone: 301-594-5333
Fax: 301-594-5494

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MESSAGE CONFIRMATION

05/31/00 14:15
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NO.	MODE	BOX	GROUP
080	TX		

DATE/TIME	TIME	DISTANT STATION ID	PAGES	RESULT	ERROR PAGES	S.CODE
05/31 14:14	01'22"	6106951828	003/003	OK		0000

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Attention: Dr. Steven Miller
Company Name: AstraZeneca
Phone: 610-695-1816
Subject: 5/22/00 Meeting Minutes
Date: 5/31/00
Pages including this sheet: 3

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Transmitted to FAX Number: 610-695-1828

Attention: Ms. Cinday Lancaster

Company Name: AstraZeneca

Phone: 610-695-1348

Subject: Confirmation of 10/23/00 Meeting

Date: 9/26/00

Pages including this sheet: 2

From: Zelda McDonald
Phone: 301-594-5333
Fax: 301-594-5494

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Transmitted to FAX Number: 610-695-1828
Attention: Ms. Cindy Lancaster
Company Name: AstraZeneca
Phone: 610-695-1348
Subject: 10/23/00 Meeting Minutes
Date: 11/6/00
Pages including this sheet: 3

From: Zelda McDonald
Phone: 301-594-5333
Fax: 301-594-5494

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cc:
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HFD-110
HFD-110/McDonald/Matthews

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Transmitted to FAX Number:

610-695-18²⁸

Attention:

Ms. Cindy Lancaster

Company Name:

AstraZeneca

Phone:

610-695-1348

Subject:

Approval Letter

Date:

2/5/01

Pages including this sheet:

4

From:

Zelda McDonald

Phone:

301-594-5333

Fax:

301-594-5494

PLEASE LET ME KNOW YOU RECEIVED THIS. THANKS!

MESSAGE CONFIRMATION

02/05/01 15:09
ID=FDA CDER DCRDP

NO.	MODE	BOX	GROUP
924	TX		

DATE/TIME	TIME	DISTANT STATION ID	PAGES	RESULT	ERROR PAGES	S. CODE
02/05 15:07	01'25"	6106951828	004/004	OK		0000

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Transmitted to FAX Number:

610-695-18²⁸

Attention:

Ms. Cindy Lancaster

Company Name:

AstraZeneca

Phone:

610-695-1348

Subject:

Approval Letter

Date:

2/5/01

Pages including this sheet:

4

From:

Zelda McDonald

Redacted 9

pages of trade

secret and/or

confidential

commercial

information

AstraZeneca 
Steven J. Miller, Ph.D.,
Executive Director
Cardiovascular Regulatory Affairs

June 23, 2000

Raymond J. Lipicky, M.D., Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products
Attn: Document Control Room, HFD-110
1451 Rockville Pike
Rockville, MD 20852



Dear Dr. Lipicky:

NDA 19-962/S-013
TOPROL-XL® (metoprolol succinate) Extended Release Tablets
GENERAL CORRESPONDENCE
Request for Full Waiver of the Pediatric Use Information Requirement

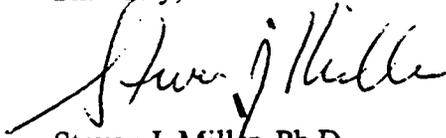
Reference is made to NDA 19-962 submitted on December 22, 1989 and Supplement S-013 submitted on September 10, 1999. AstraZeneca LP is hereby submitting information in support of the request for a full waiver from the requirement to conduct an assessment of the safety and effectiveness of TOPROL-XL tablets in pediatric patients with heart failure. This submission consists of one (1) volume and a detailed table of contents is provided to assist you with your review.

AstraZeneca understands that the information contained herein, unless otherwise made public by AstraZeneca is confidential. Government agencies are not authorized to make it public without written permission from AstraZeneca.

Raymond J. Lipicky, M.D., Director
NDA 19-962/S-013
June 23, 2000
Page 2 of 2

Questions concerning this submission should be directed to me at (610) 695-1328 or by facsimile at (610) 695-1828, or in my absence, to Patricia Patterson, Regulatory Project Manager at (610) 695-1539.

Sincerely,



Steven J. Miller, Ph.D.
Executive Director
Regulatory Affairs

Attachments

1 Archival Original and 1 Review Copy

1 Copy: Ms. Zelda McDonald, RHPM, HFD-110



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rocville MD 20857

NDA 19-962/S-013

SEP 17 1999

AstraZeneca LP
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Attention: Steven J. Miller, Ph.D.
Director, Regulatory Liaison

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Toprol-XL (metoprolol succinate) Extended Release Tablets

NDA Number: 19-962

Supplement Number: S-013

Date of Supplement: September 10, 1999

Date of Receipt: September 10, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on November 9, 1999 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Office of Drug Evaluation I
Attention: Document Control Room 5005
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

JS
Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products, HFD-110
Office of Drug Evaluation I
Center for Drug Evaluation and Research