

LACHMAN CONSULTANT SERVICES, INC.
Westbury, NY 11590

ATTACHMENT C

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2000.

21ST EDITION



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGEMENT AND SERVICES

2001

PRESCRIPTION DRUG PRODUCT LIST

3-3

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

<u>ACETAMINOPHEN AND CODEINE PHOSPHATE</u>	
AA	DURAMED 300MG;15MG
AA	300MG;30MG
AA	300MG;60MG
AA	GENEVA PHARMS 300MG;30MG
AA	300MG;60MG
AA	MIKART 300MG;30MG
+	650MG;30MG
+	650MG;60MG
AA	MUTUAL PHARM 300MG;15MG
AA	300MG;30MG
AA	300MG;60MG
AA	PHARMERAL 300MG;30MG
AA	PUREPAC PHARM 300MG;30MG
AA	300MG;60MG
AA	TEVA 300MG;15MG
AA	300MG;30MG
AA	300MG;60MG
AA	VINTAGE PHARMS 300MG;15MG
AA	300MG;30MG
AA	300MG;60MG
AA	WATSON LABS 300MG;15MG
AA	300MG;30MG
AA	300MG;60MG
AA	ZENITH GOLDLINE 300MG;60MG

N40223 001	NOV 18, 1997
N40223 002	NOV 18, 1997
N40223 003	NOV 18, 1997
N81250 001	JUL 16, 1992
N81249 001	JUL 16, 1992
N89238 001	FEB 25, 1986
N89231 001	MAR 03, 1986
N89363 001	SEP 09, 1991
N89671 001	FEB 10, 1988
N89672 001	FEB 10, 1988
N89673 001	FEB 10, 1988
N87762 001	DEC 10, 1982
N86681 001	MAR 06, 1985
N86683 001	MAR 06, 1985
N88627 001	MAR 06, 1985
N88628 001	MAR 06, 1985
N88629 001	MAR 06, 1985
N89990 001	SEP 30, 1988
N89805 001	SEP 30, 1988
N89828 001	SEP 30, 1988
N89997 001	DEC 28, 1994
N89998 001	DEC 28, 1994
N89999 001	DEC 28, 1994
N87083 001	

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

<u>ACETAMINOPHEN AND CODEINE PHOSPHATE #2</u>		
AA	SUPERPHARM 300MG;15MG	N89183 001
		OCT 18, 1985
AA	<u>ACETAMINOPHEN W/ CODEINE NO. 3</u>	
	ROXANE 300MG;30MG	N84656 001
AA	<u>ACETAMINOPHEN W/ CODEINE PHOSPHATE #3</u>	
	ZENITH GOLDLINE 300MG;30MG	N85868 001
AA	CAPITAL WITH CODEINE	
+	CARNRICK 325MG;30MG	N83643 001
	TYLENOL W/ CODEINE NO. 1	
+	JOHNSON RW 300MG;7.5MG	N85055 001
AA	<u>TYLENOL W/ CODEINE NO. 2</u>	
	JOHNSON RW 300MG;15MG	N85055 002
AA	<u>TYLENOL W/ CODEINE NO. 3</u>	
	JOHNSON RW 300MG;30MG	N85055 003
AA	<u>TYLENOL W/ CODEINE NO. 4</u>	
	JOHNSON RW 300MG;60MG	N85055 004

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

<u>ACETAMINOPHEN AND HYDROCODONE BITARTRATE</u>		
AA	CENT PHARMS 500MG;5MG	N88898 001
		MAR 27, 1985
AA	<u>ALLAY</u>	
	ZENITH GOLDLINE 500MG;5MG	N89907 001
		JAN 13, 1989
AA	<u>HYDROCET</u>	
	MALLINCKRODT 500MG;5MG	N89006 001
		AUG 09, 1985
AA	<u>HYDROCODONE BITARTRATE AND ACETAMINOPHEN</u>	
	MALLINCKRODT 500MG;5MG	N88956 001
		JUL 19, 1985
AA	MIKART 500MG;5MG	N81067 001
		NOV 30, 1989
AA	500MG;5MG	N81068 001
		NOV 30, 1989
AA	500MG;5MG	N81069 001
		NOV 30, 1989
AA	500MG;5MG	N81070 001
		NOV 30, 1989
AA	500MG;5MG	N89008 001
		FEB 21, 1985
AA	<u>LORCET-HD</u>	
	+ MALLINCKRODT 500MG;5MG	N87336 001
		JUL 08, 1982