

DEPARTMENT OF HEALTH AND HUMANS SERVICES
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
DRUG PRODUCT LISTING
(In accordance with Public Law 92-387)

NAME AND ADDRESS OF FIRM

LABELING REVISION

CHANGE OF:

- RTE OF ADMIN INDICATION
 NAME / DOSE / STR / INGR
 OTHER (Specify)

**FOR
 FDA
 USE**

CONTROL NO.

RECORD ID

SEC	S	U	PRODUCT TRADE NAME OR CATALOG NAME																NATIONAL DRUG CODE						
16	17	18	19	20																	83	84	89	90	93
0	1																	LABELER		PRODUCT					

FDA APPLICATION NO.	REPORT DATE			TYPE RPT	TYPES OF BUSINESS			PRODUCT TYPE			BND	LGL	S	SCH	PRF	USE	PRODUCT DISCONTINUED			BASIS OF CONCENTRATION		
	MO	DA	YR		OTHER (Specify)	OTHER (Specify)	OTHER (Specify)	OTHER (Specify)	WHOLE NUMBERS	DECIMAL							UNIT					
94	99	100	102	105	106	107	111	112	116	117	118	119	120	121	125	126	133	134	137	138	140	

DOSAGE FORM	ROUTES OF ADMINISTRATION					PT	SEC	S	U	SPL	PKG CODE	PACKAGE SIZE					PACKAGE TYPE				
	1	2	3	OTH								16	17	18	19	20	21	22	23	47	48
141	143	144	147	148	151	152	155	156	157-158	16	17	18	19	20	21	22	23	47	48	72	
							0	3													
							0	3													
							0	3													
							0	3													
							0	3													

NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than \$1,000, or both (FDA&C Act, Section 303).

SEC	S	U	TYPE	PT	ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC.	FDA USE ONLY			AMOUNT		UNIT					
						INGREDIENT NO.	WHOLE NUMBER	DECIMAL								
16	17	18	19	20	21	22	44	107	23	28	29	36	37	40	41	43
0	5															
0	5															
0	5															
0	5															
0	5															
0	5															
0	5															
0	5															
0	5															

SEC	S	U	SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT	STATE	FOREIGN COUNTRY	NDC LABELER CODE	SHORT NAME							
16	17	18	19	20	26	27	66	67	68	69	78	79	84	85	99
0	7														
0	7														
0	7														

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
Information Management Team, HFD-095
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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Please fold form where indicated, place in a window envelope, and return to address indicated.

Food and Drug Administration
Information Management Team, HFD-095
5600 Fishers Lane
Rockville, MD 20857

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If using Federal Express, DHL or any special carrier to return this form, please use the following address:

(Please refer to the Drug Registration and Listing Booklet.)

When completing this form, please refer to the Drug Registration and Listing Instruction Booklet for assistance.
PLEASE PRINT IN ENGLISH USING BLACK INK.

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