

**DEPARTMENT OF HEALTH AND HUMANS SERVICES**  
 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

1 5 6 11 12 15

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

FDA APPLICATION NO.		REPORT DATE			TYPES OF BUSINESS			PRODUCT TYPE			PRODUCT DISCONTINUED			BASIS OF CONCENTRATION							
MO	DA	YR	TYPE RPT	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	SAMPL	PKG CODE	PACKAGE SIZE						PACKAGE TYPE					
1	2	3	OTH							16	17	18	19	20	21	22	23						
141	143	144	147	148	151	152	155	156	157-158	0	3												
INITIAL MARKETING DATE		MOST RECENT MARKETING DATE				DISCONTINUED DATE																	
MO	YEAR	MO	YEAR	MO	YEAR																		
159	161	164	165	167	170	171	173	176	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		
16	17	18	19	20	21	22	44																INGREDIENT NO.	WHOLE NUMBER	DECIMAL	
0	5																100	23	28	29	35	37	40	41	43	
0	5																									
0	5																									
0	5																									
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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	29	30											67	68	69	70	79	80	85	86			
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:

Department of Health and Human Services  
Food and Drug Administration  
Office of the Chief Information Officer (HFA-250)  
5600 Fishers Lane  
Rockville, Maryland 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.*

**RETURN THIS FORM TO:**

FOOD AND DRUG ADMINISTRATION  
CDER/DRUG REGISTRATION AND LISTING (HFD-337)  
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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