Form Approved: OMB No. 0910-0045. Expiration Date: February 28, 2011. See OMB Statement on Reverse.

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. (1–5) | RECORD ID (6–11, 12–15)

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

FDA APPLICATION NO. (94–99)	REPORT DATE: MO (100–101)	DA (102–103)	YR (104–105)	TYPE RPRT (106)	TYPES OF BUSINESS (107–111)	OTHER *(Specify)*	PRODUCT TYPE (112–116)	OTHER *(Specify)*	BNDD (117)	LEGAL STATUS (118)	SCHED (119)	PROF USE (120)	PRODUCT DISCONTINUED (121–125)	OTHER *(Specify)*	BASIS OF CONCENTRATION: WHOLE NUMBERS (126–133)	DECIMAL (134–137)	UNIT (138–140)

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

INITIAL MARKETING DATE: MO (159–160)	YEAR (161–164)	MOST RECENT MARKETING DATE: MO (165–166)	YEAR (167–170)	DISCONTINUED DATE: MO (171–172)	YEAR (173–176)

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 (16–17)	S (18)	U (19)	TYPE (20)	PT (21–22)	ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC. (44–100)	FDA USE ONLY: INGREDIENT NO. (23–28)	AMOUNT: WHOLE NUMBER (29–35)	DECIMAL (37–40)	UNIT (41–43)
0 5									
0 5									
0 5									
0 5									
0 5									
0 5									
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0 5									
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0 5									

SEC (16–17)	S (18)	U (19)	SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER (20–29)	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT (30–67)	STATE (68–69)	FOREIGN COUNTRY (70–79)	NDC LABELER CODE (80–85)	SHORT NAME (86–100)
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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