

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

Table with columns: SEC, S, U, PRODUCT TRADE NAME OR CATALOG NAME, NATIONAL DRUG CODE, LABELER, PRODUCT.

Table with columns: FDA APPLICATION NO., REPORT DATE (MO, DA, YR), TYPES OF BUSINESS, PRODUCT TYPE, PRODUCT DISCONTINUED, BASIS OF CONCENTRATION (WHOLE NUMBERS, DECIMAL, UNIT).

Table with columns: DOSAGE FORM, ROUTES OF ADMINISTRATION, PACKAGE SIZE, PACKAGE TYPE, INITIAL/MOST RECENT/DISCONTINUED MARKETING DATE.

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).

Table with columns: 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 INGREDIENT NO., AMOUNT (WHOLE NUMBER, DECIMAL), UNIT.

Table with columns: 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.

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
CDER/Drug Registration and Listing (HFD-337)
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.

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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