ZODRYL DEC 25 - codeine phosphate, guaifenesin and pseudoephedrine hydrochloride suspension
CodaDose, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ZODRYL DEC 25 - codeine phosphate, guaifenesin and pseudoephedrine hydrochloride suspension

OTC - ACTIVE INGREDIENT

Codeine phosphate 1 mg/1mL: cough suppressant; Guaifenesin 20 mg/1mL: expectorant; Pseudoephedrine hydrochloride 5 mg/1mL: decongestant

PURPOSE

Temporarily relieves: cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants; the intensity of coughing; the impulse to cough to help you go to sleep; temporarily relieves nasal congestion due to a cold; temporarily restores freer breathing through the nose; helps loosen phlegm (mucus) and thin bronchial passageways of bothersome mucus and makes coughs more productive

Warnings

OTC - DO NOT USE

in children who have chronic pulmonary disease, shortness of breath, or such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor; if taking a monoamine oxidase inhibitor (MAOI)

OTC - ASK DOCTOR

if your child has glaucoma, a breathing problem such as emphysema or chronic bronchitis, heart disease, high blood pressure, thyroid disease, diabetes.

OTC - ASK DOCTOR/PHARMACIST SECTION

if you or your child are taking sedatives or tranquilizers; if you or your child are taking prescription MAOI (certain drugs for depression, psychiatric, or emotional conditions), or for 2 weeks after stopping the MAOI drug.

OTC - WHEN USING THIS PRODUCT

do not exceed recommended dosage; may cause or aggravate constipation; if nervousness, dizziness, or sleepiness occur, discontinue use and consult a doctor

OTC - STOP USE AND ASK A DOCTOR IF

cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.

OTC - KEEP THESE AND ALL DRUGS OUT OF REACH OF CHILDREN

In case of overdose, seek professional assistance for contact a Poison Control Center immediately.

Directions:

- Take every 4-6 hours
- Use only with enclosed calibrated oral dispenser
- Do not take more than 4 doses in 24 hours or as directed by a doctor

Children 2 to under 6 years of age: ask a doctor

Other information store at controlled room temperature 20°-25°C (68°-77°F).

INACTIVE INGREDIENT

Bittermask, citric acid, FD& C blue #1, FD& C red #40, galloquinate, glycerin, grape flavor, magnesium aluminometasilicate, methylparaben, purified water, sodium citrate dihydrate, sucralose, xanthan gum

OTC – QUESTIONS SECTION

Call 1-866-574-8861 24 hours a day, 7 days a week.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

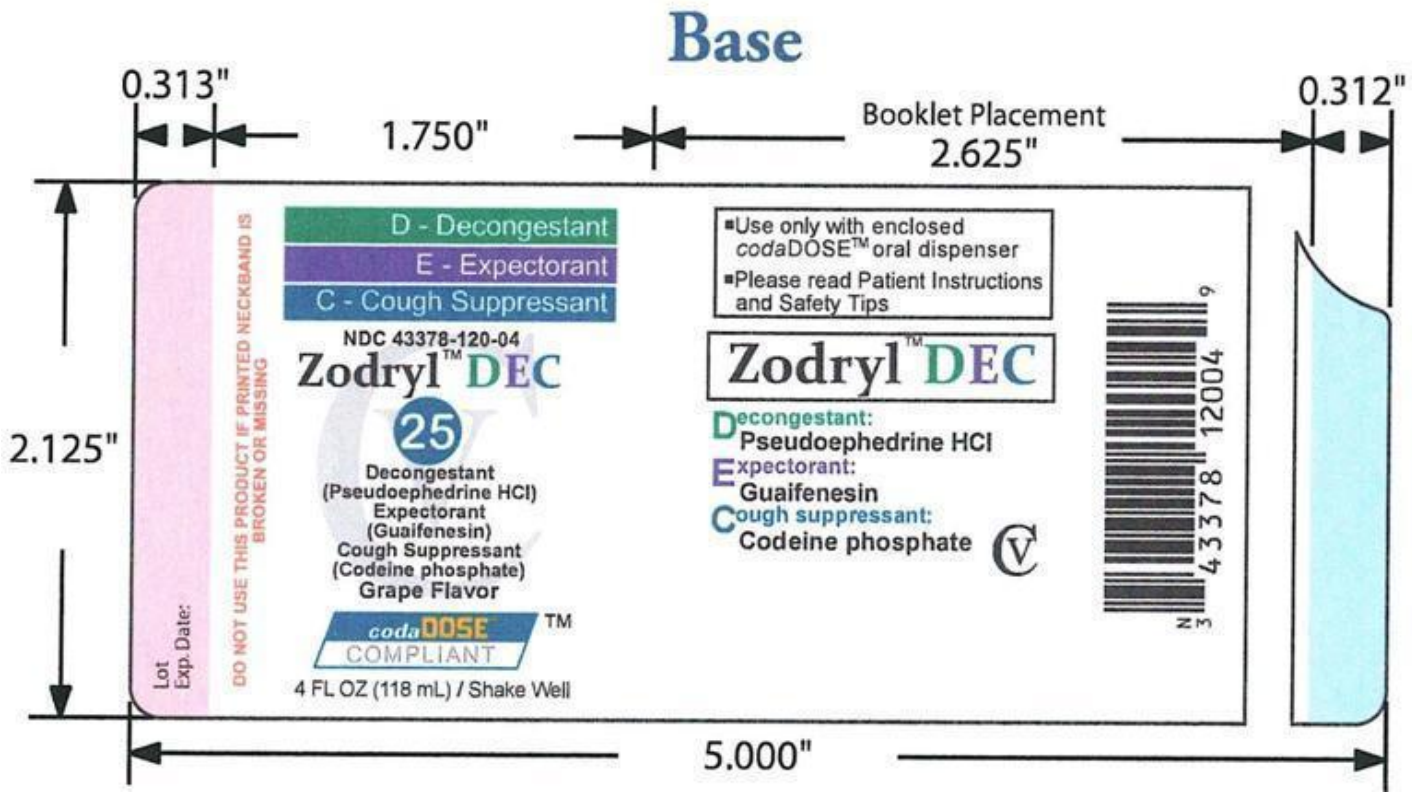

Figure 1. Primary Label- Front Page

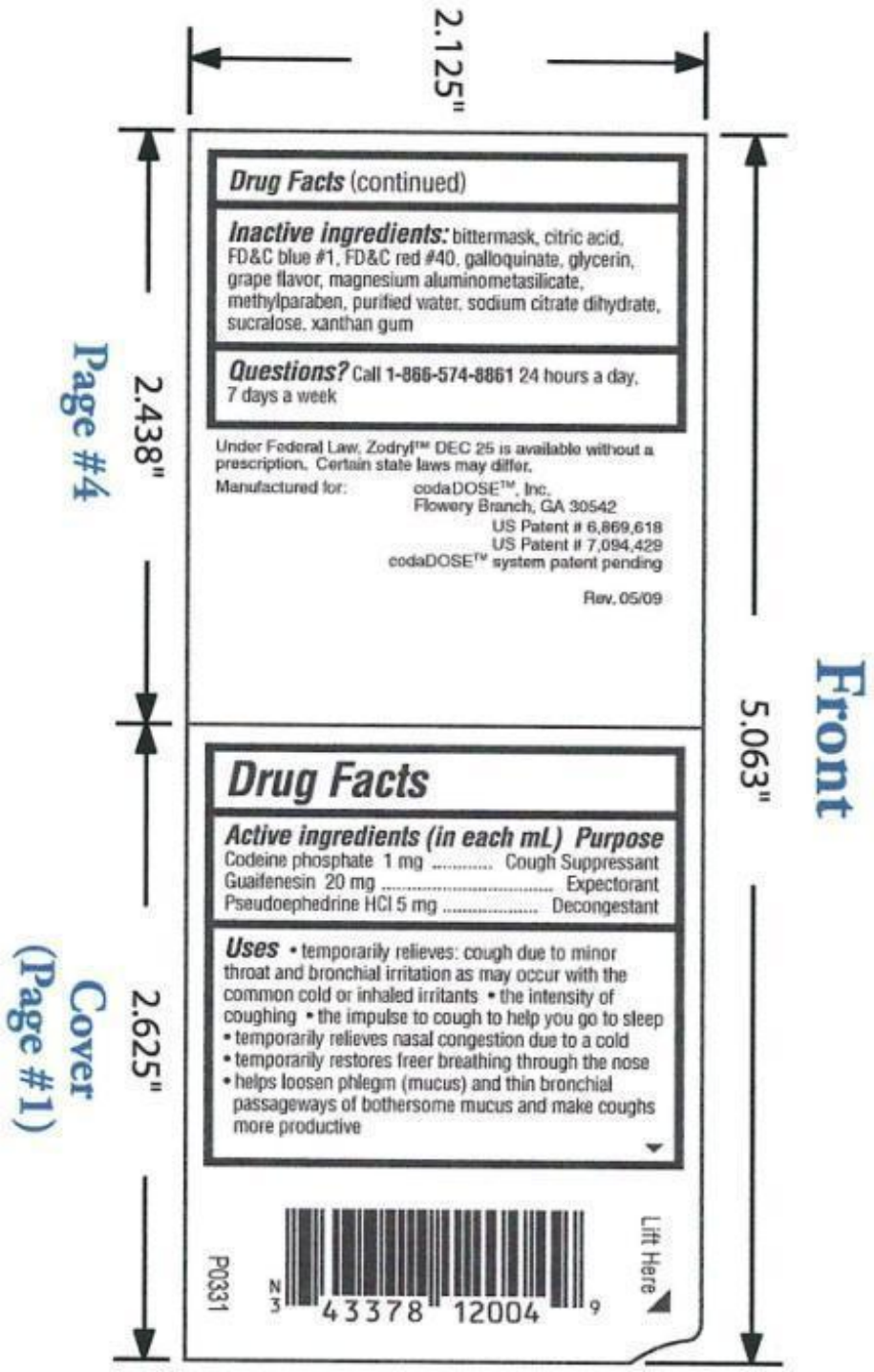

Figure 2. Primary Label – Second Page

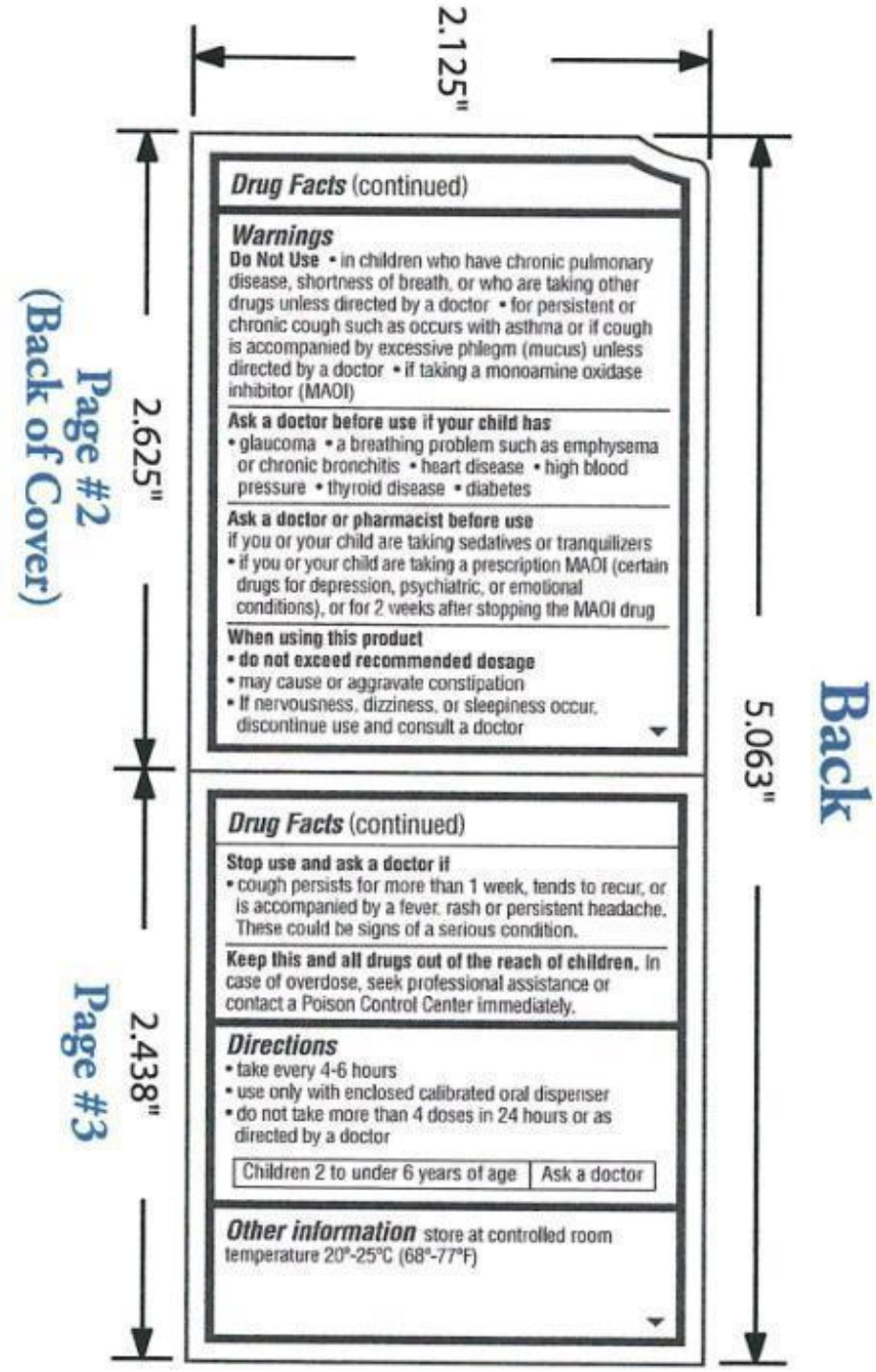

Figure 3. Primary Label – Last Page

ZODRYL DEC 25

codeine phosphate, guaifenesin and pseudoephedrine hydrochloride suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43378-120
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	15 mg in 3 mL
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE - UNII:Q830PW7520)	CODEINE PHOSPHATE	3 mg in 3 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	60 mg in 3 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TANNIC ACID (UNII: 28F9E0DJY6)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	purple	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43378-120-04	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/24/2009	

Labeler - CodaDose, Inc. (831355115)

Registrant - Gorbec Pharmaceutical Services Inc. (791919678)

Establishment

Name	Address	ID/FEI	Business Operations
Gorbec Pharmaceutical Services Inc.		791919678	manufacture