

CLASSIFICATION OF COUGH SYRUPS

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Attached herewith is the general classification of cough formulation indicating their respective active ingredients category, prescription requirements and the agency exercising jurisdiction in relation with their regulatory requirement. All concerned are enjoined to observe and monitor compliance of the regulatory requirements with these pieces of information in view.

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Director

GENERAL CLASSIFICATION OF COUGH FORMULATION

Active Ingredient

Category

Prescription

Agency with Requirements Jurisdiction

HYDROCODONE OR DIHYDRO-CODEINONE

Prohibited Drugs

Yellow Prescription (DDB Form 1-72)

DDB[*]

EPHEDRINE & PSEUDO-EPHEDRINE

Regulated Drugs

Yellow Prescription (DDB Form 1-72)

DDB

CODEINE Exempt (BR No. 1, s. 1973)

Preparation

Ordinary Prescription with S-2 license

DDB

EPHEDRINE & PSEUDO-EPHEDRINE IN COMBINATION WITH OTHER INGREDIENTS

Exempt Preparation

Ordinary Prescription with S-2 license

DDB

DEXTROME-TORPHAN (Single Component)

Prescription Drug

Ordinary Prescription

BFAD[*][*]

PHENYLPRO-PANOLAMINE

OTC

NONE

BFAD

MUCOLYTIC AND EXPECTORANT

OTC

NONE

BFAD

ANTI-HISTAMINIC

OTC

NONE

BFAD

[*] DDB in charge of compliance regulatory requirements covering registration, record-keeping, production, distribution, retail, import and export of dangerous drugs.

[*[*]] BFAD in charge of registration, licensing, etc. as to efficacy, purity and quality of both dangerous drugs and non-dangerous drugs.

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