**NOTIFICATION**

**New Delhi, the 2nd August, 2024**

S.O. 3354(E). Whereas, the Central Government is satisfied that the use of the drug Fixed Dose Combination (hereinafter to be referred as FDC) of Gamma Linolenic Acid + Methylcobalamin is likely to involve risk to human beings whereas safer alternatives to the said drug are available;

And whereas, the matter was examined by an Expert Committee appointed by the Central Government and the said Expert Committee considered this FDC as irrational;

And whereas, the Drugs Technical Advisory Board also examined the said FDC and recommended that “there is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patient is not justifiable. Therefore, only prohibition under section 26A is recommended”.

And whereas on the basis of the recommendations of the said Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to prohibit the manufacture for sale, sale and distribution for human use of the said drug in the country;

Now, therefore, in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of drug FDC of Gamma Linolenic Acid + Methylcobalamin with immediate effect [F. No.

X-11035/53/2014-DFQC (Part-IV)]

RAJIV WADHAWAN, Advisor (Cost)

**FORM28**

**[See Rule 76]**

Licence to manufacture for sale [or for Distribution of] drugs specified in Schedules C and c(1) [excluding those specified in Schedule X ].

Number of licence.and date of issue: DD/417 dated 03/03/2004.

1. **M/S. SOFTECH PHARMA PVT. LIMITED:** is hereby licensed to. manufacture at the premises situated at Survey No.708/6, Dabhel, Nani Daman the following drugs, being drugs specified in Schedules and Cosmetics Rules, 1945.

Names of drugs: As per list attached.

2. Names of approved competent technical staff : As per list attached.

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the condition applicable to licences for sale.

4. The licence wi1l be in force from 03/03/2004 to 02/03/2009.

5. The licence is subject to the conditions stated below and to being in force under the Drugs and Cosmetics Act,1940.

Date of issue:03/03/2004.

(S.S. Vaishya)

Drugs Licensing Authority/

Director, Medical & Health Services,

UT of Daman and Diu, Daman

**DAMAN**

**Conditions of Licence**

1. This license and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedules c and c(1) 9 [excluding those specified in Sch.x] not included above, he should apply to the licensing authority for the necessary endorsement as provided in Rule 75(3). This licence will be deemed to extend to the items so endorsed.

3. Any change in the competent technical staff be forthwith reported to the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

**Softech Pharma Pvt. Ltd**

Plot No 708/6Behind Somnath Temple, Somnath Road Dabhel,

Nani Daman-396215 Phone:0260554 6565/554 6566.Fax:0260)2242811.

E-mail id:softech\_pharma@rediffmail.com

December 12, 2005

**LIST OF PRODUCT TO BE MANUFACTURED UNDER MANUFACTURING LICENCE NO.DD/416 OTHER THAN SCHEDULE C & C1**

**Gamma Linolenic Acid with Methylcobalamin Capsules**

**GLA TM-M CAPSULES**

Each soft gelatin capsule contains:

Gamma Linolenic Acid 120 mg

From Borage Oil)

Methylcobalamin 500 mcg

Approved colour used in capsule shell: Red Oxide of Iron

**UNDERTAKING**

The above product is the only product to be manufactured by us at present. We undertake that any addition or any deletion in the formula of the product will not be carried out.

We hereby undertake to comply with all the Provisions of the acts in force and directions issued from time to time and not to manufacture any product under a name belonging to another manufacturer.

We undertake not to manufacture or sell or distribute any drug / cosmetic even if it included in the approved list of products if it or as and when it will be banned by licensing authority of drugs controller of (India) or Govt. of India.

The brand names, artworks and designs of the products submitted for approval in this application are not copied from others. It is further declared that these or similar Brand names, artworks or designs are not used by any other manufacturer to the best of our belief. If the brand names, artworks or designs of our products are found to be imitation of or resemble in a manner likely to deceive, another drugs manufactured by another company prior to ours, we undertake to stop to sell, or distribute of our products and we understand that we shall be liable for legal action is such eventuality.

Thanking You,

For SOFTECH PHARMA PRIVATE LIMITED

Nitin M. Thakkar

Managing Director

**Softech Pharma Pvt. Ltd.** Plot Nol 708/6, Behind Somnath Temple

Somnath Road, Dabhel, Nani Daman-396215, INDIA

Phone:(02080)2242705/2242806Fax:(0260) 2242011

Email: [info@softechpharma.com](mailto:info@softechpharma.com) Website: wwwsoftechpharma.com

LIST OF PRODUCT TO BE MANUFACTURED AT SOFTECH PHARMA PVT. LTD. SURVEY NO: 7886, KAMALI, NASHIK-MUMBAI, UNDER MANUFACTURE LICENSE NO. DH-417

DCGI Ref. No. 4798 Dt. 25/09/11

**Gamma Linolenic with Methylcobalamin Capsules** For Domestic

**Each soft gelatin capsule contains:**

Gamma Linolenic Acid 120 mg

(from Borage Oils)

Methylcobalamin IP 500 mcg

Excipients: q.s.

Colour: Red Oxide of Iron.

**GENERAL UNDERTAKING:**

(1) The above are the only Drugs approved for manufacture at present and be present. We undertake any addition thereto or any deletion therefrom will not be carried out with out any prior permission of the Licensing Authority.

(2) We undertake to comply with all the provisions of the law in force and the direction issue from the time by Licensing Authority we intend to manufacture the above product with Trade Name GLA TM – M Capsules Cpresently and not to manufacture any drug name belonging to another manufacturer.

(3) We undertake not to manufacture or sale or distribute any drug even if it approved list of products but by or any competent Authority if it is or as and when it will be banned by the Drug Controller (India) or Govt. of India.

(4) It is further declared that if the brand names, artworks or designs of our products are found to be imitation of or resemble in a manner likely to deceive, another drugs manufactured by another company prior to ours, we undertakes to stop to sell, or distribute of our products and we understand that we shall be liable for legal action in such eventuality.

(5) We herewith undertake that the thermos labile products, which will be manufactured by us, will be subjected to the stability for the period of at least one year with periodic testing at least for three batches of every product and the reports thereof will be submitted to the Licensing Authority.

(6) The vehicle, excipients, additives and pharmaceutical aids used in the formulation and under the conditions in which are formulations for administration and use are recommended are safe.

**For SOFTECH PHARMA PRIVATE LIMITED**

Authorised Signatory

NITIN M. THAKKER

MANAGING DIRECTOR

**Softech Pharma Pvt. Ltd.** Plot Nol 708/6, Behind Somnath Temple

Somnath Road, Dabhel, Nani Daman-396215, INDIA

Phone:(02080)2242705/2242806Fax:(0260) 2242011

Email: [info@softechpharma.com](mailto:info@softechpharma.com) Website: wwwsoftechpharma.com

LIST OF PRODUCT TO BE MANUFACTURED AT SOFTECH PHARMA PVT. LTD. SURVEY NO: 708/6, DABHEL, NANI DAMAN- 396215 UNDER MANUFACTURING LICENCE IN FORM 28- UNDER MANUFACTURING LICENCE, DRUGS SPECIFIED IN SCHEDULE C AND C(1) EXCLUDING THOSE SPECIFIED IN SCHEDULE X, VIDE LICENCE NO. DD/417 DATED 03/03/2004 PREPENTUALLY VALID UPTO 02/03/2029.

DCGI Ref. No. 47935 Dt. 25/09/13

**Gamma Linolenic with Methylcobalamin Capsules** For Domestic

Each soft gelatin capsule contains:

Gamma Linolenic Acid 120 mg

(from Borage Oils)

Methylcobalamin IP 500 mcg

Excipients: q.s.

Colour: Red Oxide of Iron.

**UNDERTAKING:**

(1) The above are the only Drugs approved for manufacture at present and be present. We undertake that any addition thereto or any deletion therefrom will not be carried out with out any prior permission of the Licensing Authority.

(2) We undertake to comply with all the provisions of the law in force and the direction issue from the time by Licensing Authority we intend to manufacture the above product with Trade Name GLA TM – M Capsules Cpresently and not to manufacture any drug name belonging to another manufacturer.

(3) We undertake not to manufacture or sale or distribute any drug even if it approved list of products but by or any competent Authority if it is or as and when it will be banned by the Drug Controller (India) or Govt. of India.

(4) It is further declared that if the brand names, artworks or designs of our products are found to be imitation of or resemble in a manner likely to deceive, another drugs manufactured by another company prior to ours, we undertakes to stop to sell, or distribute of our products and we understand that we shall be liable for legal action in such eventuality.

(5) We herewith undertake that the thermos labile products, which will be manufactured by us, will be subjected to the stability for the period of at least one year with periodic testing at least for three batches of every product and the reports thereof will be submitted to the Licensing Authority.

(6) The vehicle, excipients, additives and pharmaceutical aids used in the formulation and under the conditions in which are formulations for administration and use are recommended are safe.

**For SOFTECH PHARMA PRIVATE LIMITED**

Authorised Signatory

NITIN M. THAKKER

MANAGING DIRECTOR

**ADMINISTRATION OF DAMAN & DIU (UT)**

**DRUGS LICENSING AUTHORITY**

**DRUGS CONTROL DEPARTMENT**

**PRIMARY HEALTH CENTRE**

**MOTI DAMAN-396220**

No. DCD/D&D/LA/2018-2019/3586 Dated: 25 /03/2019

LICENCE VALIDITY CERTIFICATE

(SEE RULE 72 AND 84 C)

Ref No. SOFTECH/DMN/020/2018-19 DATED 28/02/2019.

1. A LICENCE No. DD/416 & DD/417 GRANTED ON 03/03/2004 TO M/S. SOFTECH PHARMA PRIVATE LIMITED; SITUATED AT PLOT No. 708/6, BEHIND SOMNATH TEMPLE, SOMNATH ROAD, DADHEL, NANI DAMAN-396210, INDIA, IN FORM 25 AND FORM 28 SHALL REMAIN PERPETUALLY VALID UPTO 02/03/2024 AS THE LICENCE HAS DEPOSITED A LICENCE RETENTION FEE VIDE CHALLAN No. 3787 DATED 28/02/2019 AND CHALLAN No. 3796 DATED 05/03/2019 AS PER THE DRUGS & COSMETICS RULES, 1945.
2. NAMES OF DRUGS: AS PER LIST ATTACHED.
3. NAMES OF APPROVED COMPETENT TECHNICAL STAFF: AS PER LIST ATTACHED.
4. FIRM SHALL COMPLY TO THE DRUGS & COSMETICS ACT, 1940 & RULES 1945 THEREUNDER.

DATED: 25 MAR 2019

(DR. V. K. DAS)

DIRECTOR,

MEDICAL & HEALTH SERVICES,

DRUGS LICENSING AUTHORITY

UT OF DAMAN & DIU

DAMAN.

**NOTE:**

1. IN FORM 25 FOR PARAGRAPH 3 THE FOLLOWING PARAGRAPH SHALL RESPECTIVELY BE SUBSTITUTED, THE LICENCE UNLESS SOONER SUSPEENDED OR CANCELLED SHALL REMAIN VALID PERPETUALLLY, HOWEVER THE COMPLIANCE WITHT THE CONDITIONS OF LICENCE AND DRUGS AND COSMETICS RULES, 1945 SHALL BE ASSESSED NOT LESS THAN ONCE IN THREE YEARS OR AS NEEDED AS PER RISK BASED APPROACH.”
2. IN FORM 28 FOR PARAGRAPH 4, THE FOLLOWING PARAGRAPH SHALL RESPECTIVELY BE SUBSTITUTED, “THE LICENCE UNLESS SOONER SUSPEENDED OR CANCELLED SHALL REMAIN VALID PERPETUALLLY, HOWEVER THE COMPLIANCE WITHT THE CONDITIONS OF LICENCE AND THE PROVISIONS OF THE DRUGS & COSMETICS ACT, 1940N (23 OF 1940), AND THE DRUGS AND COSMETICS RULES, 1945 SHALL BE ASSESSED NOT LESS THAN ONCE IN THREE YEARS OR AS NEEDED AS PER RISK BASED APPROACH.”

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI AND DAMAN & DIU ASSISTANT DRUGS CONTROLLER (I/C) &

LICENSING AUTHORITY

DRUGS CONTROL ADMINISTRATION

PRIMARY HEALTH CENTRE

MOTI DAMAN-396220

NO. DCD/D&D/LA/2024-2025/ 212 9 DATED: 16/04/2024

LICENCE VALIDITY CERTIFICATE

(SEE RULE 72 AND 84 C)

REF. NO. SPPL/DMN/22/23-24 DATED 18/03/2024.

1. A LICENCE NO. DD/416 & DD/417 GRANTED ON 03/03/2004 TO SOFTECH PHARMA PRIVATE LIMITED; SITUATED AT PLOT NO. 708/6, BEHIND SOMNATH TEMPLE, SOMNATH ROAD, DADHEL, NANI DAMAN-396 215, INDIA, IN FORM 25 AND FORM 28 SHALL REMAIN PERPETUALLY VALID UPTO 02/03/2029 AS THE LICENSEE HAS DEPOSITED A LICENCE RETENTION FEE VIDE CHALLAN NO. 261 DATED 19/03/2024 AS PER THE DRUGS & COSMETICS RULES, 1945.
2. NAMES OF DRUGS: AS PER LIST ATTACHED.
3. NAMES OF APPROVED COMPETENT TECHNICAL STAFF: AS PER LIST ATTACHED.
4. FIRM SHALL COMPLY TO THE DRUGS & COSMETICS ACT, 1940 & RULES 1945 THEREUNDER.

DATED: 16 APR 2024

(S. ASKER ALI) IAS

ASSISTANT DRUGS CONTROLLER &

LICENSING AUTHORITY,

UT OF DADRA & NAGAR HAVELI AND DAMAN & DIU

DAMAN

**NOTE:**

1. IN FORM 25 FOR PARAGRAPH 3 THE FOLLOWING PARAGRAPH SHALL RESPECTIVELY BE SUBSTITUTED, THE LICENCE UNLESS SOONER SUSPEENDED OR CANCELLED SHALL REMAIN VALID PERPETUALLLY, HOWEVER THE COMPLIANCE WITHT THE CONDITIONS OF LICENCE AND DRUGS AND COSMETICS ACT, 1940 (23 OF 1940) AND DRUGS AND COSMETICS RULES, 1945 SHALL BE ASSESSED NOT LESS THAN ONCE IN THREE YEARS OR AS NEEDED AS PER RISK BASED APPROACH.”
2. IN FORM 28 FOR PARAGRAPH 4, THE FOLLOWING PARAGRAPH SHALL RESPECTIVELY BE SUBSTITUTED, “THE LICENCE UNLESS SOONER SUSPEENDED OR CANCELLED SHALL REMAIN VALID PERPETUALLLY, HOWEVER THE COMPLIANCE WITHT THE CONDITIONS OF LICENCE AND THE PROVISIONS OF THE DRUGS & COSMETICS ACT, 1940N (23 OF 1940), AND THE DRUGS AND COSMETICS RULES, 1945 SHALL BE ASSESSED NOT LESS THAN ONCE IN THREE YEARS OR AS NEEDED AS PER RISK BASED APPROACH.”

**Annexure P-11**

**Softech Pharma Pvt. Ltd.** Plot Nol 708/6, Behind Somnath Temple

Somnath Road, Dabhel, Nani Daman-396215, INDIA

Phone:(02080)2242705/2242806Fax:(0260) 2242011

Email: [info@softechpharma.com](mailto:info@softechpharma.com) Website: wwwsoftechpharma.com

Date: 23.09.2013

DRUGS CONTROLLER GENERAL (INDIA)

Directorate General of Health Services,

F.D.A Bhawan, Kotla Road,

New Delhi-110 002.

Sub: Approval for Marketing & Manufacturing Combination of Gamma Linolenic Acid 120MG (FROM BORAGE OIL) + Methylcobalamin 500MCG CAPSULE ALREADY BEING MANUFACTURED AND MARKETED IN INDIA UNDER SLA

Dear Sirs,

In reference to the subject cited above, we would like to inform you that the said Combination of Gamma Linolenic Acid 120mg (from Borage Oil) + Methylcobalamin 500mcg Capsule is being manufacture & marketed by us in India since Feb. 2006.

We are enclosing the following documents:

1. True copy of TR6 Challan for Rs. 15,000/-
2. Form 44
3. Copy of State License
4. Copy of Manufacturing License
5. Raw Material Detail
6. Detail of formulation & Manufacturing Procedure
7. Finished Product specification
8. Method of Analysis
9. Certificate of Analysis
10. Stability Study
11. Draft Label
12. Package Insert
13. Rational Literature

TRUE COPY

**Softech Pharma Pvt. Ltd.** Plot Nol 708/6, Behind Somnath Temple

Somnath Road, Dabhel, Nani Daman-396215, INDIA

Phone:(02080)2242705/2242806Fax:(0260) 2242011

Email: [info@softechpharma.com](mailto:info@softechpharma.com) Website: wwwsoftechpharma.com

**We will submit rest of the pending documents as soon as possible.**

As there is no SAE reported upto today, it proves that this product is safe & effective.

We request your good self to grant us the approval to continue Manufacturing & marketing for Gamma Linolenic Acid 120mg (from Borage Oil) + Methylcobalamin 500mcg Capsule.

Your kind co-operation will be highly obliged.

Thanking you,

Yours truthfully,

FOR SOFTECH PHARMA PVT. LTD.

Nitin M. Khakker

Managing Director

**Annexure P – 12**

**NOTIFICATION**

New Delhi, the 10th March, 2016

**S.O. 708(E)**---- Whereas, the Central Government is satisfied that the use of the drug fixed dose combination of Nimesulide + Tazanidine is likely to involve risk to human beings whereas safer alternatives to the said drug are available.

And Whereas, the matter has been examined by an Expert Committee appointed by the Central Government and the said Expert Committee recommended to the Central Government that the said drug is found to have no therapeutic justification.

And Whereas on the basis of the recommendations of the said Expert Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition of manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, on the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of the said drug fixed dose combination of Nimesulide + Tazanidine with immediate effect.

(F.No.X-11035/53/2014-DFQC)

K.L. SHARMA, Jt.Secy.

**NOTIFICATION**

**New Delhi, the 10th March, 2016**

**S.O. 764(E)**---- Whereas, the Central Government is satisfied that the use of the drug fixed dose combination of Amoxycillin + Tinidazole is likely to involve risk to human beings whereas safer alternatives to the said drug are available.

And Whereas, the matter has been examined by an Expert Committee appointed by the Central Government and the said Expert Committee recommended to the Central Government that the said drug is found to have no therapeutic justification.

And Whereas on the basis of the recommendations of the said Expert Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition of manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, on the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of the said drug fixed dose combination of Amoxycillin + Tinidazole with immediate effect.

(F.No.X-11035/53/2014-DFQC)

K.L. SHARMA, Jt.Secy.

**NOTIFICATION**

**New Delhi, the 10th March, 2016**

S.O. 815 (E)---- Whereas, the Central Government is satisfied that the use of the drug fixed dose combination of Glimepiride + Pioglitazone + Metformin is likely to involve risk to human beings whereas safer alternatives to the said drug are available.

And Whereas, the matter has been examined by an Expert Committee appointed by the Central Government and the said Expert Committee recommended to the Central Government that the said drug is found to have no therapeutic justification.

And Whereas on the basis of the recommendations of the said Expert Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition of manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, on the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of the said drug fixed dose combination of Glimepiride + Pioglitazone + Metformin with immediate effect.

(F.No.X-11035/53/2014-DFQC)

K.L. SHARMA, Jt.Secy.

**NOTIFICATION**

**New Delhi, the 10th March, 2016**

**S.O. 909(E)**---- Whereas, the Central Government is satisfied that the use of the drug fixed dose combination of Chlorpheniramine Maleate + Codeine Syrup is likely to involve risk to human beings whereas safer alternatives to the said drug are available.

And Whereas, the matter has been examined by an Expert Committee appointed by the Central Government and the said Expert Committee recommended to the Central Government that the said drug is found to have no therapeutic justification.

And Whereas on the basis of the recommendations of the said Expert Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition of manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, on the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of the said drug fixed dose combination of Chlorpheniramine Maleate + Codeine Syrup with immediate effect.

(F.No.X-11035/53/2014-DFQC)

K.L. SHARMA, Jt.Secy.

**Annexure P - 15 (Colly)**

**Reminder**

F. No. 4-732/2016-DC (PSC-Softech)

Directorate General of Health Services

Office of Drugs Controller General (India)

(FDC Division)

FDA Bhawan, Kotla Road,

New Delhi-110002

Dated: 21 APR 2017

To,

M/s. Softech Pharma Pvt. Ltd.,

Plot No. 708/6, Behind Somnath Temple,

Somnath Road, Dadhel Nani Daman-396215.

Subject: FDC of Gamma Linolenic Acid 120mg (from Borage Oils) +   
 Methylcobalamin IP 500mcg soft gelatine capsule-regarding.

Sir,

Please refer to this Directorate letter no. 4-732/2016-DC (PSC-Softech) dated 13.10.2016 whereby you were requested to show cause as to why manufacturing license in respect of above FDC may not deemed to have been cancelled as the said FDC has been found to be irrational.

In this regard, your reply is not yet received by this office and therefore considered as NIL. If you have anything to say in this regard, you may communicate to this office immediately.

Yours faithfully,

(Dr. G. N. Singh)

Drugs Controller General (India)

Copy to:-

Drugs Licensing Authority, Directorate of Medical Health Services, Daman-396220.

**Softech Pharma Pvt. Ltd.** Plot Nol 708/6, Behind Somnath Temple

Somnath Road, Dabhel, Nani Daman-396215, INDIA

Phone:(02080)2242705/2242806Fax:(0260) 2242011

Email: [info@softechpharma.com](mailto:info@softechpharma.com) Website: wwwsoftechpharma.com

8th June 2017

To,

The Drugs Controller General of India

Directorate General of Health Services

Ministry of Health and Family Welfare

FDA Bhavan, ITO, Kotla Road,

New Delhi -110002

Subject: FDC of Gamma Linolenic acid 120 mg (from Borage oil) + Methylcobalamin JP 500 mcg soft gelatin capsule.

Respected sir,

This is in reference to the letter no. 4-732/2016 – DC (PSC – Softech) dated 24th April 2017 please find enclosed therapeutic rationale of GLA M capsule.

Thanking you,

Yours truthfully,

For Softech Pharma Pvt. Ltd.

Nitin Thakker

Managing Director

**Rationale**

The World Health Organization estimates that the global prevalence of diabetes is currently approaching 5%; thus, this disease can be called an epidemic of the 21st century. Diabetes is considered a major cause of mortality and morbidity, and statistically, diabetic neuropathy is the second most common cause of polyneuropathic nerve damage. Therefore, clinical reality suggests the need for the effective treatment of neuropathic pain accompanying diabetes. There are three main types of diabetes: insulin-dependent diabetes mellitus (type 1), non-insulin-dependent diabetes mellitus (type 2) and gestational diabetes.

Diabetes is one of the leading causes of neuropathy worldwide. Diabetic neuropathy is not always painful, however, 12% of all diabetic patients are affected with symptomatic painful diabetic neuropathy, the most common chronic and earliest occurring complication. Diabetic neuropathy affects all peripheral nerves including pain fibres, motor neurons and the autonomic nervous system.

There are no pathophysiological or morphological differences between patients with type 1 and type 2 diabetes nor between diabetic patients with and without painful neuropathy.

The most common type of diabetic neuropathy is peripheral neuropathy, which causes pain or loss of feeling in the toes, feet, legs, hands, and arms. Diabetic neuropathic pain treatment is difficult because no specific relief medication is available.

Gamma linolenic acid (G.LA.), Also known as evening primrose oil, G.LA is an omega-6 fatty acid that is an important constituent of neuronal cell membranes—and believed to decrease neuropathic pain by having some anti-inflammatory effects. This suggests that therapy with GLA has the potential to improve neuropathic pholipidic structure and neurocirculation.

The first step in the metabolism of essential fatty acids (EFA), linolenic acid (i.e. delta-6 desaturation of linoleic acid to gamma linolenic acid) is impaired in diabetes, and this defect can be bypassed by the administration of GLA. This may be a rate limiting step for the synthesis of many biologically important eicosanoids like PGE1, PGE2 and prostacyclins. Several studies have confirmed clinical and electrophysiological improvement in peripheral nerve function when GLA is administered to neuropathic patients.

Methylcobalamine is a vitamin B12 co-enzyme that occurs in the blood and the cerebrospinal fluid; it is taken up by the nerve tissues more actively and extensively than other homologues of vitamin B12. Biochemically, methylcobalamine accelerates the metabolic pathways of nucleic acids, proteins and lipids through its involvement in the transmethylation reaction; thus, it exerts a repairing effect on injured nerve tissues. People who have good blood sugar control may find GLA and methylcobalamine more effective than those with poor blood sugar control.

Rationale of Combination:

This combination works synergistically. Gamma linolenic acid is an important constituent of the neuronal membrane and has shown to preserve nerve blood flow. Methylcobalamine is a vitamin B12 co-enzyme that occurs in the blood and the cerebrospinal fluid; it is taken up by nerve tissues more actively and extensively than other homologues of vitamin B12. Biochemically, methylcobalamine accelerates the metabolic pathways of nucleic acids, proteins and lipids through its involvement in the transmethylation reaction; thus, it exerts a repairing effect on injured nerve tissues. Clinically, methylcobalamine and gamma linolenic acid individually shown to be effective and useful for the treatment of numbness, pain and paralysis due to peripheral neuropathies.

Approval Status international

**Gamma linolenic acid:**

**USFDA**: - Gamma linolenic acid (GLA) is approved as an ingredient in dietary supplements on 23 Dec 2009.

**South Africa**: - Gamma linolenic acid (GLA) is approved as a dietary supplement. Evening Primrose Oil with Vitamins and minerals.

**EU** - Gamma linolenic acid (GLA) is approved as an ingredient in food & dietary supplements on 14 Dec 2009.

**Methylcobalamine**:

**UK**: - Cyanocobalmin (B12) 50micrograms Tablets approved in UK on 16th November 1993.

**Health Canada**: - Vitamin B12 (cyanocobalamin) approved as Oral OTC Various form like Capsules 100 mcg; Tablets 100 μg, 250 mcg, 1000 mcg; Sustained release tablet 1200 mcg; Sublingual tablet 1000 mcg. Approved in April 2012.

**USDA**: Vitamin B12 (cyanocobalamin) is approved as Generally Recognized As Safe (GRAS) food substance in the year 1978.

Methylcobalamine has been applied mainly in the treatment of hyperhomocysteinaemia and peripheral neuropathy. The clinical effective dosage of methylcobalamine is 0.5 - 6 mg/day. Although both monotherapy and combined therapy are beneficial in lowering plasma serum Hey levels and improve the neuropathic symptoms, combined therapy with other B vitamins seems to be more effective, in addition to definitive inferiority of methylcobalamine to the other agents used as monotherapy has been found.

The gamma-linolenic acid supplementation brings some hopeful effects in treatment of diabetic neuropathy, eczema, cyclic mastalagia, rheumatoid arthritis, osteoporosis and ADHD. Many double blind trials have been performed for defective assessment of GLA efficiency. The gamma-linolenic acid is completely safe, non-toxic, and non-carcinogenic substance. It can be an interesting alternative for supporting treatment.

Diabetic hyperglycemia damages peripheral nerves by triggering ischemia, oxidative stress, and inflammation. Gamma linolenic acid (GLA) and methylcobalamin (MC) are known to improve signs of diabetic peripheral neuropathy (DPN), possibly by producing highly significant clinical and neurophysiological improvements. Two studies conducted in patients with diabetic neuropathy showed that the administration of gamma-linolenic acid significantly improved a variety of symptoms, such as neuropathy symptom scores, median nerve motor conduction velocity and compound muscle action potential amplitude, median and sural sensory nerve action potential amplitude and ankle heat and cold threshold values. Patients with diabetic neuropathy, treatment with both gamma linolenic acid and pure methylcobalamin appeared to improve the symptoms rather than electrophysiological results.

In conclusion, both gamma linolenic acid and methylcobalamine approved generally Recognized As Safe (GRAS) food substances and marketed and sold as dietary and food supplement for more than three decades. Efficacy and safety in patients with diabetic neuropathy significantly improved the symptoms and possibly by producing highly significant clinical and neurophysiological improvements.

**References**

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Annexure P – 18 (Colly)

File No. 4-01/2013-DC (Misc. 13 PSC Part III)

Directorate General of Health Services

Office of Drugs Controller General (India)

(FDC Division)

FDA Bhawan, Kotla Road

New Delhi-110002

Dated: 9 MAY 2019

**NOTICE**

Subject:  **Evaluation of Fixed Dose Combinations (FDCs) by DTAB Sub-committee which were earlier considered as irrational in the assessment report of the Prof. Kokate committee – regarding.**

The 82nd meeting of the Drugs Technical Advisory Board (DTAB) was held on 2nd April 2019 under the Chairmanship of the Director General of Health Services. It deliberated on the report of Prof. Kokate Committee with respect to Fixed Dose Combinations (FDCs) considered as irrational in the assessment report of the committee.

Accordingly, a Sub-committee has been constituted under the Chairmanship

of Dr Nilima Kshirsagar, the Chair in Clinical Pharmacology, (ICMR, Mumbai) to

examine these FDCs declared as irrational in the assessment report of the

committee (Copy enclosed).

In this regard, a meeting of the Sub-committee of DTAB took place did in

order to give an opportunity to the manufacturers of said FDCs and the concerned

stakeholders for presenting the precise data with respect to these FDCs. The Sub-

committee has desired that the manufacturers and other stakeholders submit the

information in the prescribed format as per Annexure P-18 (along with supporting

documents) which is enclosed herewith for further action.

Accordingly, all the manufacturers of said FDCs and the concerned stakeholders are hereby requested to submit the information in the prescribed format

and the relevant supporting documents in hard copy as well as soft copy (i.e. in CD

Form) to this office latest by 30th June 2019 till 5:00 PM.

**(Sanjeev Kumar)**

**Convener**

**Sub-Committee of DTAB**

Copy to:

1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB
2. Indian Drug/Pharmaceuticals Association (IPA)
3. Website of CDSCO for information and necessary action by manufacturers of said FDCs and concerned stakeholders

**Annexure A – May 2019**

**FDC**

**Identification**

**Number as on**

**The website:**

Version 1 dated 17.05.2019

**Format for submission of information on FDC to DTAB Sub-Committee**

(Submit all the information including full text of references

as hard copy as well as soft copy)

|  |  |  |  |
| --- | --- | --- | --- |
| S. No. | Item | Response | |
| 1a. | (a) Composition of product (FDC)  (Details of all ingredients, strengths/dosage forms) |  | |
|  | (b) Brand name/s if any: |  | |
|  | (c) Name and Address of the Applicant  Whether the applicant is   1. Manufacturer: 2. Marketer: 3. Anu other (please specify): 4. -- |  | |
| 1b. | Licensing authority with year of license and information, if any submitted to Licensing Authority while obtaining the License. | Name and Designation of the licensing Authority | Date & Year of Product License |
|  |  |
|  |  |
|  |  |
|  |  |
| 1c. | Whether the FDC is approved by DCGI, if so details/evidence thereof. |  | |
| 1d. | Whether the FDC is Pre 1988, if so details / evidence thereof. |  | |

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Items** | **Response** |
| 2. | Particulars of the drug: Dosage form, composition of the formulation (including all active ingredients) |  |
| 3. | Indication(s) |  |
| 4. | Provide a copy of the approved Package insert that is currently provided. |  |
| 5. | State the category under which FDC approval is claimed as per Drugs and Cosmetics Rules. |  |
| 6. | Pharmacological classification |  |
| 7. | a) Therapeutic justification / rationale for each ingredient and quantity contained in the FDC |  |
|  | b) Therapeutic value claimed or purported to be claimed of the FDC (Postulated advantage/ Therapeutic value of FDC/Tick (√) appropriate option(s) |  |
|  | i. Increased efficacy |  |
|  | ii. Reduced incidence of adverse effects |  |
|  | iii. Dose reduction |  |
|  | iv. Reduced cost |  |
|  | v. Booster for another drug |  |
|  | vi. Improved patient adherence/ Convenience |  |
|  | vii. Minimization of abuse of other actives |  |
|  | viii. Reduced development of microbial resistance |  |
|  | ix. Any other (please specify) |  |
|  | c) Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five relevant full text articles in peer-reviewed journals/ relevant information from textbooks. |  |
| 8. | Pharmacokinetic/pharmacodynamics rationality with half-life details of individual ingredients, dosage schedule of individual drugs and dosage schedule of FDC.  (submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five most relevant full text articles in peer-reviewed journals/relevant information from textbooks) |  |
| 9. | Published data regarding safety and efficacy of FDC (Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five most relevant full text articles in peer-reviewed journals/ relevant information from textbooks) |  |
| 10. | Safety & Efficacy data if any, regarding the FDC, generated by the applicant.  (Submit a one-page summary. Also submit the article based on these data, if published or evidence ahead of case study if unpublished with CTRI number if available) |  |
| 11. | Please specify the guidelines National/ International/ Professional Association/ Chapters/bodies) if any, that have recommended the use of the above FDC or use of the ingredients thereof concurrently |  |
| 12. | a) marketed in EU, UK, Canada, Australia, Japan and the USA? |  |
|  | b) If yes, which country/countries? |  |
|  | c) Specify country-wise product brand name, ingredients, dosage form, its strength, amount of usual ingredients per dosage form, indications and dosage regimen. |  |
| 13. | Regulatory status of the FDC in other countries |  |
| 13.1 | (a) Marketed |  |
|  | (b) Approved |  |
|  | (c) Approved as IND |  |
|  | (d) withdrawn, if any, with reasons |  |
| 13.2 | Restrictions on use, if any, in countries where marketed/approved |  |
| 14. | Specimen of labels and cartons |  |
| 15. | Ay other relevant information |  |
| 16. | Submit one page summary of grounds and reasons in support of FDC with not more than 5 relevant references |  |
| 17. | Submit PPT of presentation in hard copy (Maximum 7 slides) which the company will present to the committee |  |

(Note: Individual Form shall be submitted for each FDC and all above information shall be provided for each strength/dosage in the same Form of FDC)

Signature of the Authorized representative \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| For Office Use: | |
| Identification No. |  |

**F. No. 04-01/2013-DC (Misc. 13-PSC Part III)**

**Government of India**

**Directorate General of Health Services**

**Central Drugs Standard Control Organization**

**(FDC Division)**

FDA Bhawan, Kotla Road,

New Delhi

**NOTICE**

Subject:- **Evaluation of Fixed Dose Combinations (FDCs) by DTAB Sub-Committee which were earlier considered as irrational in the assessment report of the Prof. Kokate Committee reg.**

Sir,

This is in continuation to this office notice 4-01/2013-DC (Misc. 13-Part III) dated 29.05.2019 on the subject cited above whereby all the manufacturers/ stakeholders were requested to submit the information in the prescribed format as per Annexure 'A' by 30th June 2019 till 5.00 P.M. for further action.

In this regard, various representations have been received requesting for further extending the timeline for submission of the information. The issue was considered and it has been decided that manufacturers/stakeholders may be permitted to submit the information in the prescribed format by 16.08.2019.

In view of the above, all the manufacturers/stakeholders may note that the date for submission of information in the prescribed format is extended upto 16.08.2019 till 5.00 p.m.

(Sanjeev Kumar)

Encl: As above Convener

Sub-Committee of DTAB

To:

1. Indian Drug/Pharmaceuticals Association Forum
2. Website of CDSCO for information and necessary action by manufacturers of said FDCs and concerned stakeholders.

Copy to:

1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB
2. Drugs Controller General (I), Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi-110002

Copy for information to:

Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.

Date: 10.08.2019

To,

The Directorate General of Health Services

CDSCO (FDC Division)

Date: 10.08.2019

Subject: Submission of information for Evaluation of Fixed Dose Combinations (FDCs) by DTAB which were earlier considered as irrational in the assessment report of the Prof. Kokate Committee.

Respected Sir,

This is in reference to the notice F.No.04-01/2013-DC (Misc.13-PSC Part III) dated 01st July 2019 wherein we are directed to comply with the notice received from CDSCO (FDC Division) File No.4-01/2013-DC(Misc.13 PSC Part III) dated 29th May 2019.

Please find enclosed information in the prescribed format as per Annexure 'A' along with supporting documents for the FDC Identification No.5404 (Gamma Linolenic Acid 300mg Soft Gelatin Capsules).

Request you to please review our submission and provide us with the NOC for said FDC.

For Softech Pharma Pvt. Ltd.

Authorised Signatory

Nitin Thakker

Managing Director

**Annexure P-19**

**Ministry of Health and Family Welfare**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 2nd June, 2023

S.O. 2394(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Nimesulide+ Paracetamol dispersible tablets vide notification number S.O.712 (E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter alia, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988, Central Government may, if it so chooses, de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940),

the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 712 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Nimesulide + Paracetamol dispersible tablets with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

New Delhi, the 2nd June, 2023

S.O. 2395(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Amoxicillin+ Bromhexine vide notification number S.O. 777 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter alia, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under Section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended”.

And whereas on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 777 (E) dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Amoxicillin+ Bromhexine** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

S.O. 2396(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Pholcodine+ Promethazine vide notification number S.O. 789 (E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter ali, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.789 (E) dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Pholcodine + Promethazine with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

S.O. 2397(E).—Whereas, the Central Government in exercise of the powers conferred by Section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Chlorpheniramine maleate + Dextromethorphan + Guaiphenesin + Ammonium Chloride + Menthol vide notification number S.O. 869 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter alia, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 869 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Chlorpheniramine maleate + Dextromethorphan + Guaiphenesin + Ammonium Chloride + Menthol with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt.Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

S.O. 2398(E).— Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Chlopheniramine Maleate + Codeine Syrup vide notification number S.O. 909 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter alia, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act ,1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee.

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”.

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 909 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Chlopheniramine Maleate + Codeine Syrup with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

S.O. 2399(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Ammomium Chloride + Bromhexine + Dextromethorphan vide notification number S.O 922 (E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter alia, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee.

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under Section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended”;

And whereas on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 922(E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Ammomium Chloride + Bromhexine + Dextromethorphan with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

S.O. 2400(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol vide notification number S.O. 926(E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter alia, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 926 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

S.O. 2401(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Dextromethorphan + Chlorpheniramine + Guaiphenesin + Ammonium Chloride vide notification number S.O. 930 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter alia, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee.

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 930 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Dextromethorphan + Chlorpheniramine + Guaiphenesin + Ammonium Chloride with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

S.O. 2401(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Dextromethorphan + Chlorpheniramine + Guaiphenesin + Ammonium Chloride vide notification number S.O. 930 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, inter alia, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee.

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 930 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Dextromethorphan + Chlorpheniramine + Guaiphenesin + Ammonium Chloride with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

**S.O. 2402(E).—**Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Paracetamol + Bromhexine + Phenylephrine + Chlorpheniramine +** **Guaiphenesin** vide notification number S.O. 977(E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia,* mentioning that in respect of 15 FDCs claimed to be approved prior to 1988, Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O 977 (E) dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Paracetamol +** **Bromhexine+ Phenylephrine + Chlorpheniramine + Guaiphenesin** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

**S.O. 2403(E).—**Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Salbutamol + Bromhexine** vide notification number S.O. 978 (E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia,* mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 978 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Salbutamol +** **Bromhexine** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

New Delhi, the 2nd June, 2023

**S.O. 2404(E).—**Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Chlorpheniramine + Codeine Phosphate + Menthol Syrup** vide notification number S.O 983 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 983 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Chlorpheniramine + Codeine Phosphate + Menthol Syrup** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

New Delhi, the 2nd June, 2023

**S.O. 2405(E).—**Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Phenytoin + Phenobarbitone sodium** vide notification number S.O. 1028 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988 , Central Government may, if it so chooses , de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”.

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 1028 (E), dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Phenytoin +** **Phenobarbitone sodium** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

**S.O. 2406(E).—**Whereas, the Central Government in exercise of the powers conferred by Section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol (100mg + 40mg + 2.5mg + 0.9mg) , (125mg + 55mg + 4mg + 1mg) , (110mg + 46mg + 3mg + 0.9mg) & (130mg + 55mg + 3mg + 0.5mg) per 5ml syrup** vide notification number S.O. 4411(E) published in the Gazette ofIndia, Extraordinary, Part II, Section 3(ii),dated the 07th September 2018;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its order dated 14.02.2019 in the Miscellaneous application No. 600 of 2018 in Civil Appeal No.s 23405-23472 of 2017, the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for this FDC in the above mentioned strengths and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC in the above mentioned strengths under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 4411(E) dated the 07th September 2018; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Ammonium** **Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol (100mg + 40mg + 2.5mg + 0.9mg) , (125mg** **+ 55mg + 4mg + 1mg) , (110mg + 46mg + 3mg + 0.9mg) & (130mg + 55mg + 3mg + 0.5mg) per 5ml syrup** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

**NOTIFICATION**

**New Delhi, the 2nd June, 2023**

**S.O. 2407(E).—**Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of **Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine** vide notification number S.O. 4687(E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 07th September 2018;

And whereas, in light of the directions given by the Hon’ble Supreme Court of India in its order dated 14.02.2019 in the Miscellaneous application No.600 of 2018 in Civil Appeal No.s 23405-23472 of 2017, the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that “there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended”;

And whereas, on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide S.O. number 4687(E), dated the 07th September 2018; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Salbutamol +** **Hydroxyethyltheophylline (Etofylline) + Bromhexine** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.