Nil

File No. 4-113/2014-DC
Government of India
Directorate General of Health Services
Central Drug Standard Control Organizatio
(FDC Division)

Tele. No. : 011-23236965
Fax No. : 011-23236973

FDA Bhawan, KotlaRoad
New Delhi-110002

Dated:
06 JUL 2026

To,
M/s. Suncare Formulation Pvt. Ltd.,
E-20, UPSIDC, Industrial Area, Selaqui,
Dehradun-248194, Uttarakhand.

Subject: FDC of Liquor Bismuth Ammonium Citrate B.P.C 2.5ml (Eq. to Bi203 140mg) (Clear solution of Bismuth Citrate USP & Ammonia Solution Dilute)+ Belladonna dry extract IP 9mg +Menthol IP0.2mg + Thymol IP 0.15gm per 5ml oral liquid-regarding.

Reference: Your application dated Nil in Form 44.

Sir,

All the State Drug Controllers vide this office letter no. 4-01/2013-DC (Misc. 13-PSC) dated 15.01.2013 were requested to ask the concerned manufactures to prove safety and efficacy of such FDCs before DCG (I), the Licensing Authority under Rule 21(b) of the Drugs and Cosmetics Rules, 1945 as amended from time to time within 18 months, in case these are being manufactured without such approval on the basis of licenses granted by State Licensing Authority.

Accordingly, FDC of **Liquor Bismuth Ammonium Citrate B.P.C 2.5ml (Eq. to Bi203 140mg)(Clear solution of Bismuth Citrate USP & Ammonia Solution Dilute) + Belladonna dryextract IP 9mg + Menthol IP 0.2mg + Thymol IP 0.15gm per 5ml oral liquid**was examined and considered for granting approval for manufacturing and marketing with condition to conduct Active Post Marketing Surveillance.

In this regard, your Active Post Marketing Surveillance report was examined by the committee and considered for continued manufacturing and marketing. However, the firm should not use this information/data for promotional purpose.

Accordingly, this Directorate has no objection for continued manufacturing and marketing of FDC of **Liquor Bismuth Ammonium Citrate B.P.C 2.5ml (Eq. to Bi203 140mg)(Clear solution of Bismuth Citrate USP & Ammonia Solution Dilute) + Belladonna dryextract IP 9mg + Menthol IP 0.2mg + Thymol IP 0.15gm per 5ml oral liquid.**

This approval is issued with the following conditions:-

1. **The said FDC is indicated of Symptomatic treatment of acid peptic disease.**
2. The formulation shall conform to the standards and requirements of Drugs and Cosmetics Act and Rules thereunder.
3. The proper name of the drug shall be printed or written in indelible ink and shall appear in a more conspicuous manner than the trade name, if any, which shall be

shown immediately after or under the proper name on the label of the innermost container of the drug or every other cover which the container is packed.

4. The label of the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

   "WARNING: To be sold by retail on the prescription of R.M.P. only".

5. As Post marketing surveillance, the applicant shall submit Periodic Safety Update Reports every six months for the first two years. For subsequent two years, the Periodic Safety Update Reports shall be submitted annually.
6. All reported adverse reactions related to the drug shall be intimated to the DCG(I) and Licensing Authority; and regulatory action resulting from their review should be complied with.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to:-

State Drugs Controller,**Uttarakhand**-with a request to issue permission of subject FDC, if other conditions of License under Drugs and Cosmetics Rules, which needs to be verified by you, are found to have been fulfilled. You are requested to verify the quality of subject drug applied by **M/s. Suncare Formulation Pvt. Ltd.,E-20, UPSIDC, Industrial Area, Selaqui, Dehradun-248194, Uttarakhand,** as per Drugs and Cosmetics Rules, 1945 before grant of license.