

**Recommendations of the SEC (Dermatology & Allergy) made in its 06<sup>th</sup>/24 meeting held on 11.06.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	E-1402 and E-11952 Ustekinumab	M/s. Reliance Life Sciences	<p>The firm presented the final CSR of the product- Ustekinumab (45mg PFS presentation) of Phase III clinical study vide protocol No. RLS/DRM/208/04version 2.0 along with package insert.</p> <p>After detailed deliberation, the committee noted the results of clinical study presented by the firm. Further, the committee recommended to revise the package insert by including the clinical trial information from the final CSR and other clinical updates like TEAEs, AEs etc. (example- Hepatitis and other infections).</p> <p>Accordingly, the firm should submit the revised package insert to CDSCO for further evaluation.</p>
<b>Medical Device Division</b>			
2.	IMP/MD/2023/104766 Oxygen Delivery System (ODS) (Model No. : NA055-30), Oxygen Delivery System (ODS) (Model No. :NA055-01)	M/s.GR Health Aids Private Limited	The firm did not turn up for presentation.
3.	IMP/MD/2023/104740 NATROX® Oxygen Generator Kit (OG) (Model No.:NA040)	M/s. GR Health Aids Private Limited	The firm did not turn up for presentation.
<b>SND Division</b>			
4.	SND/MA/24/000018 Epinephrine Tartarate Injection 0.15mg/ml & 0.3mg/ml	M/s. Mylan Laboratories Limited	The firm did not turn up for presentation.