Recommendations of the SEC (Radio-Diagnostic) made in its 11th meeting held on 09.11.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000014 Kit for the Preparation of Technetium (99mTc) Sestamibi Injection 1 mg	M/s. IBA Molecular Imaging	The firm did not turn up for presentation.
2.	ND/Form44/FF/ 12019/15422 Gadoteridol Injection	M/s. Imaging Pvt. Ltd.	In light of earlier SEC recommendation dated 15.11.2019, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee considered the results of Phase IV clinical trial as presented by the firm.
3.	ND/MA/22/000117 Insoluble Prusian Blue Capsules 340mg	M/s. Scott Edil Pharmacia Ltd.	The firm presented their proposal for manufacture and market of Insoluble Prussian Blue Capsule 340 mg along with justification for waiver of Phase III clinical trial and BE study before the committee. The committee noted that the drug is already approved in other countries like USA on 2003 and the drug is designated as an orphan drug & indicated for rare and life threatening condition and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug for the proposed indication subject to condition that the drug should be sold by retail under the prescription of the designated medical specialist only. However, the committee opined that the opinion from Nuclear Radio Diagnostic expert is also required.
4.	ND/MA/22/000121 FDC of Insoluble Prussian Blue and magnesium Hydroxide 340mg/500mg Capsule	M/s. Scott Edil Pharmacia Ltd.	The firm presented their proposal for manufacture and market of Insoluble Prussian Blue 340mg and Magnesium Hydroxide 500mg capsules along with justification for waiver of Phase III clinical trial and BE study before the committee. The committee noted that the drug is already approved in other countries like USA on 2003 and drug is designated as an orphan

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			drug & indicated for rare and life threatening condition and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug for the proposed indication subject to the condition that the drug should be sold by retail under the prescription of the designated medical specialist only. However, the committee opined that the opinion from Nuclear Radio Diagnostic expert is also required.